

STRENGTHENING ORGANIC ENFORCEMENT

Summary of Proposed Rule and OTA's Positions

The USDA National Organic Program published the Strengthening Organic Enforcement Proposed Rule to support continued growth of the organic market and improve oversight at critical links in the supply chain. The proposed rule aims to build consistent certification practices to deter and detect organic fraud, improve transparency and traceability of organic products throughout the supply chain, and protect organic integrity. USDA accept comments on the proposed rule until October 5, 2020. Below is an at-a-glance summary of each topic in the proposed rule and the Organic Trade Association's positions on each topic. Please refer to our full comments on each topic for complete, comprehensive and authoritative information on OTA's positions and recommendations.

RESOURCES

- [Full text of OTA Comments](#)
- [Full text of Proposed Rule](#)
- [OTA's webpage with additional background and resources](#)

LIST OF TOPICS

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Exemptions from Certification – Proposed Rule Section #1

SUMMARY OF PROPOSED RULE

- **Revise the definition of *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.** (Intended to include brokers, traders, importers, exporters.)
- Any operation that conducts activities described in the definition of *Handle* must be certified, unless they meet a specific exemption.
- **Retail operations are exempt if they sell but do not process, or that only process on-site at the point of sale to the final customer.** The definition of *Retailer* is revised to include on-line or virtual retailers.
- **An operation that only stores, receives and/or loads agricultural products, but does not process or alter such products is exempt.** (Intended to exempt storage facilities, transporters, distributors, and warehouses that are not combining, splitting, containerizing, packing, repacking, treating, sorting, opening, enclosing, or labeling/relabeling.)
- Exemptions retained in the proposed rule include operations with less than \$5000 or less in annual income, and operations that handle products with less than 70 percent organic ingredients or only identify organic ingredients in the ingredient statement.
- All exempt operations must prevent commingling and contamination; additional recordkeeping and labeling requirements for some exemptions.
- NOP considered an amendment but did not include this in the proposed rule regarding identification of brand owners on products produced under private label arrangements.

OTA supports:

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

OTA does not support:

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

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

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

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

- Revise the definition of ‘handle’ to better capture the activities in the organic supply chain that must be certified unless specifically exempt

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

OTA further recommends:

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

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

SUMMARY OF PROPOSED RULE

- **Each shipment of organic products imported into the U.S. must be associated with an NOP Import Certificate, regardless of country of origin.** Not intended to slow trade. Organic imports that pass through U.S. Ports of Entry need to be associated with –but not accompanied by– an NOP Import Certificate. Product can be exported and landed in U.S. in advance of NOP Import Certificate being issued, meaning that a shipments may enter the U.S. stream of commerce without an import certificate at the time of entry.
- **Certifier must review each exporter’s request for an NOP Import Certificate and issue valid certificate for compliant products within 30 days.**
- **Data from the NOP Import Certificate must be uploaded to US Customs and Border Protection’s Automated Commercial Environment (CBP-ACE) system.** Should occur within 10 days after the shipment physically entering the US.
- **The importer must verify compliance of the physical shipment:** that the physical shipment aligns with NOP Import Certificate and has not been in contact with prohibited substances since export.
- **Equivalent data sources may substitute for NOP Import Certificate**
- **The exporter and importer are both intended to be certified under proposed rule for exemptions from certification.**

- OTA supports the expanded use of electronic import certificates to support supply chain traceability and import data transparency.
- OTA recommends that AMS aggregates and reports data from the CBP-ACE system to meet the need for reliable comprehensive data on organic imports that is not currently provided by HTS codes.
- OTA supports the allowance of equivalent data systems to be used as a substitute for NOP Import Certificates provided that the same data is able to be collected and is able to (and required to) be uploaded to the CBP-ACE system.
- OTA recommends that NOP clarify which party is responsible for uploading the Import Certificate (or equivalent) into the CBP-ACE system.
- OTA recommends revisions to the proposed definitions of *organic exporter* to ensure clarity and alignment of the exporter’s activities under the definition of *Handle* as proposed in Section #1 of the Proposed Rule.
- OTA does not support the 30-day timeframe for certifiers to issue certificates as written in the proposed rule because it is not tethered to the CBP’s deadline for uploading data into the ACE system, nor the importer’s responsibilities upon receiving the shipment.
- OTA recommends that certifiers issue valid NOP Import Certificates for compliant shipments as soon as possible, ideally upon arrival of the physical shipment at the U.S. Port of Entry. However, the procedures and deadlines for requesting and issuing NOP Import Certificates need to accommodate various modes of transportation and frequencies of shipments (particularly perishable, high frequency and/or short-notice shipments arriving by ground transportation from Mexico and Canada), balanced with certifier’s

operational capacity, without impeding legitimate trade flow or compromising organic integrity and enforcement capabilities. We recommend that NOP issue guidance to explain the procedures and ideal deadlines for requesting and issuing NOP Import Certificates.

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

Labeling of Nonretail Containers – Proposed Rule Section #3

SUMMARY OF PROPOSED RULE

- **Nonretail container** is currently defined in the NOP Regulations as “Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.”
- **Organic Identification** is a new mandatory label element: Must use the term, “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable.)
- **Certifier Statement** is a new mandatory label element: Must identify the certifier of the “producer of the product, or, if processed, the certifying agent that certified the last handler that processed the product”
- **Name of certified operation remains optional.**
- **Traceability Information (e.g. lot numbers) remains mandatory on label**
- Preamble allows for some exceptions for on-container displays of mandatory information when impractical, e.g. for large containers that are associated with a mode of transportation or storage (trucks, barges, etc.), as long as the mandatory information is evident in documentation associated with and traceable to the container

- OTA supports mandatory organic identification on nonretail containers, and recommends the regulations allow flexibility for operators to use alternative abbreviations or indicators of a product’s organic status.
- OTA does not support the proposed rule that designates the name of the certified operation as optional. OTA recommends mandatory identification of the certified operation and the certifier on nonretail containers.
- OTA recommends a regulatory revision to improve consistency in identifying which operation and certifier should be displayed on nonretail containers.
- OTA supports the ongoing requirement to display traceability information such as lot numbers on nonretail containers.
- OTA recommends that implementation of these requirements provides flexibility for organic operations in displaying mandatory information on nonretail containers in a manner that is adaptable to the wide variety of nonretail containers while still ensuring that the information is immediately accessible.

- OTA recommends that NOP develop additional guidance to support common understanding and consistent implementation of the requirement that nonretail containers “*must display*” the mandatory information listed in §205.307.
- OTA recommends the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within two years after publication of the final rule.

On-site and Unannounced Inspections – Proposed Rule Section #4

SUMMARY OF PROPOSED RULE

- **Requires certifiers to conduct mass-balance audits during inspection**
 - Verify that sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold or transported
 - Must involve risk-based selection of products to audit
- **Requires certifiers to conduct trace-back audits during inspection**
 - Verify that organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source
 - Must involve risk-based selection of products to audit
- **Requires certifiers to conduct unannounced inspections on at least 5% of operations they certify.**
 - May select operations for any reason (random, risk-based, investigation)
 - Certifiers must not accept applications from operations in locations where they are unable to conduct unannounced inspections

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

- OTA recommends adding as a new term and defining 'supply chain traceability' in the organic regulations.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

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

SUMMARY OF PROPOSED RULE

- **Requires certifiers to generate organic certificates from the NOP Organic Integrity Database.**
 - Mandatory data elements on certificate is not specified in the rule text
 - Certifier may issue optional certificate addendums with additional info
 - Intend to include new requirements for expiration date on certificate to help assesses whether an organic certificate is current although it would not impact the certification status of the operation, even if expired
- **Add new term INTEGRITY to define the NOP Organic Integrity Database**
- **Requires certifiers to maintain current and accurate data in the NOP Database for each operation that it certifies.**
 - Certification status must be update within 3 days of surrender, suspension, or revocation
 - Intended to include list of certified products and acreage data among other data fields (data fields and frequency of updates is not specified)
- **Removes several reporting requirements for certifiers in lieu of new requirement to report to eh NOP Database.**
 - No need to send copies of notices of approval or denial of certification to the Administrator following the issuance of NCs to an applicant
 - No need for certifiers to submit annual list of certified operations master list to Administrator submit by Jan. 2nd

Certificates of Organic Operation

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

- OTA recommends a *two-year* implementation period after the publication of the final rule for the proposals in this section.

Paperwork Submissions to the Administrator

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

Continuation of Certification – Proposed Rule Section #6

SUMMARY OF PROPOSED RULE

- **Clarifies that certified operations do not need to submit a full OSP every year and only need to submit sections of the OSP that have changed.**
- **Removes the requirement for certified operations to include an update of on the correction of minor non-compliances with the annual OSP update.**
- **Clarifies that certifiers must conduct on-site inspections of certified operation at least once per calendar year** (instead of once every 18 months on an on-going basis which could mean two inspections over a 3-year period).
- NOP considered an amendment but did not include this in the proposed rule regarding expiration of certification.

- OTA supports revisions to the rule that will eliminate unnecessary paperwork without compromising oversight of organic operations.
- OTA supports the clarification that operations are only required to submit sections of the Organic System Plan that have changed during the annual certification year rather than submitting a full plan every year.
- OTA supports a rule that provides certifying agents with the flexibility needed to adjust the timing of an inspection in circumstances when it is impossible to conduct an on-site inspection.

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

Personnel Training and Qualifications – Proposed Rule Section #8

SUMMARY OF PROPOSED RULE

- **Expands requirements for certifiers to continuously use a sufficient number of qualified and trained personnel for conducting inspections and certification review activities.**
- **Personnel must have the required knowledge, skills, and experience required for the scope and scale of operations as assigned**
- **Personnel must have evidence of formal education, training, or professional experience in the fields of agriculture, science, or organic production and handling that directly relates to assigned duties**
- **Minimum requirements for inspectors**
 - Must have adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, auditing practices and skills in written and oral communications, sample collection, investigation techniques, and preparation of technically accurate inspection documents
 - Must have minimum of 1 year of field-based experience related to both the scope and scale of operations they will inspect
- **Minimum requirements for certification reviewers**
 - Must have adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, and practices applicable to the type, volume, and range of review activities assigned
- **Mandatory annual requirement for 20-hours of training for inspectors and certification reviewers**
- **Certifiers must conduct on-site evaluation of inspectors per 3 years or more if warranted.**

- OTA supports strengthening certification personnel and inspector training and qualifications requirements.
- OTA recommends an expanded list of required knowledge and skills for inspectors that includes specific references to mass balance and traceability auditing skills.

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

Oversight of Certification Activities – Proposed Rule Section #9

SUMMARY OF PROPOSED RULE

- **Clarifies that NOP’s oversight extends to any person conducting any *Certification Activities* on behalf of the certifying agent.** Includes subcontractors, subcontractor organizations, and activities performed in any certification office.
- **Requires certifiers to notify NOP within 90 calendar days after opening a new certification office where certification activities will be conducted.** Notification should include location and nature of activities and qualification of personnel at the location.
- Includes an unexplained revision to 205.640 regarding fees and other charges: Eliminates “accreditation services” from the list of costs of the accreditation services rendered under the regulations.

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

Accepting Foreign Conformity Assessments – Proposed Rule Section #10

SUMMARY OF PROPOSED RULE

- **Congress provides authority to USDA to allow imported agricultural products to be represented as organic in the U.S. if it determines that such products have been produced and handled under an organic certification program that is at least equivalent to the USDA Organic Regulations.**
 - Equivalency arrangements (Canada, EU, Japan, South Korea, Switzerland, Taiwan)
 - Recognition agreements (India, Israel, New Zealand)
- **The proposed rule codifies USDA’s existing authority procedures to initiate, evaluate, accept, and terminate foreign conformity assessment systems through an equivalence determination process.** Intent is to codify existing practices, without establishing any new requirements, that will provide basis for developing additional details that describe the process and requirements for equivalence determinations.
 - Adds new definitions for *conformity assessment system* and *technical requirements* and identifies both as equally important aspects of equivalence determinations
 - Authorizes USDA to describe the scope of each determination based on its assessment of the foreign country’s organic program
 - Specifies the re-review audit cycle to determine continued eligibility
 - Specifies the conditions under which a equivalency determination may be terminated

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

Noncompliance, Mediation and Appeals – Proposed Rule Section #11-15

SUMMARY OF PROPOSED RULE

- **Clarifies that NOP’s investigation and enforcement authorities extend to all operations that violate the Act, including uncertified operations and any “responsibly connected” persons a certified operation**
 - Adds new term for *Adverse Action* that covers all types of actions that adversely affect certification or accreditation or a person subject to the Act (e.g. proposed suspension or revocation, civil penalties, etc.).
 - **Requires certifier to update operator’s status in NOP Organic Integrity Database within 3 days of issuing a notification of suspension or revocation, or the effective date of an operation’s surrender**
 - **Mediation (alternative option for dispute resolution)**
 - Adds requirement for certifiers to develop and maintain decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions
 - Defines 30 day window for operation to request mediation after receipt of the adverse action
 - **Appeals (request that adverse action is reexamined by higher authority)**
 - AMS “may” (instead of “will”) initiate formal administrative proceeding (hearing). Intended to reflect current practice that AMS may pursue the resolution of appeals through expedited, alternative means, such as settlement agreements, before initiating a formal administrative proceeding.
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- OTA supports the authority of NOP to investigate and enforce against violators of OFPA including uncertified operations.
 - OTA supports consistent clarification that enforcement actions extend to all accountable parties per the existing definition of “responsibly connected.” OTA recommends guidance be developed to clarify procedures for certifier to report responsibly connected parties for operations that they certify, and for responsibly connected persons to submit a request for eligibility to be certified per §205.662(f)(1).
 - OTA supports timely updates in the NOP Organic Integrity Database regarding the certification status of surrendered, suspended or revoked operations.
 - OTA supports clear explanations of the mediation process and procedures as proposed in §205.663. OTA recommends guidance be developed to clarify the criteria that should be included in a certifier’s internal policies and procedures for acceptance or denial of mediation requests, and to clarify that a third-party mediator is not required per §205.663(c).
 - OTA does not support the revision as proposed in §205.681 regarding administrative proceedings, and recommends revisions to clarify and maintain the appellant’s right to an administrative hearing when requested and/or when not settled through other means, and to include a timeframe within which the appellant can request the hearing.
 - OTA supports the clarifications proposed for the general appeals section of the regulations at §205.680 and recommends that NOP staff itself appropriately so that it can respond to appeals in a timely manner.
 - OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

Grower Group Operations – Proposed Rule Section #16

SUMMARY OF PROPOSED RULE

- **Established new standards for grower group certification eligibility criteria, including Internal Control System (ICS) requirements, and certifier inspection requirements.**
- **No limits on size or scale of groups or group members**
- **Scope is limited only to crop and wild crop production**
- **ICS must have policies and procedures to ensure all production and handling is compliant with the USDA organic regulations and the Act**
 - Conduct internal inspections at least annually of every member
 - Implement system of sanctions to address noncompliant members
 - Identify high-risk members
 - Define geographical proximity criteria for grower group members and production units
 - Ensure a complete audit trail from each grower group member and grower group production unit to sale and distribution
- **Certifier must conduct external onsite inspection to assess ICS**
 - Witness audit of ICS inspectors
 - Inspection of 1.4 times square foot of total members, including all high risk members, all handling facilities, and at least one per production unit

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

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

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

Calculating Percent Organic Ingredients – Proposed Rule Section #17

SUMMARY OF PROPOSED RULE

- **Essentially a technical correction to the regulation that addresses the process of dividing organic ingredients by the total combined ingredients (organic and non-organic) to determine the organic percentage of a NOP certified product.**
- **Replaces “finished product” with “all ingredients at formulation” to clarify that the calculation of organic content is to be made at the time of formulation, regardless of whether further processing occurs after formulation.**

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

Supply Chain Traceability and Fraud Prevention – Proposed Rule Section #18

SUMMARY OF PROPOSED RULE

- **Requires certified operations to maintain audit trail documentation for products that they produce, receive, and or/handle**
 - Must provide supply chain traceability within their operation, back to their suppliers, and forward to their customers
 - Requires organic identification on all records
- **Requires that certified operations have monitoring practices and procedures to verify organic status of suppliers and prevent/detect organic fraud**
 - Elements may include: identify critical control points; conduct vulnerability assessment; implement mitigation measures to correct vulnerabilities and minimize supplier risk
 - Scope/complexity verifies by operation, e.g. producers who do not handle products produced by another operation don’t need supplier verification practices but may need to verify other purchased inputs
 - OTA’s Organic Fraud Prevention Solutions is cited as example
- **Adds new definition for *Organic Fraud*:** Intentional deception for illicit economic gain, where nonorganic products are represented as organic
- Requires that certifiers have procedures for identifying high-risk operations and to annually conduct risk-based supply chain audits
- Requires certifiers to have procedures for reporting credible evidence of fraud to the USDA
- Requires certifiers to share information with other certifying agents to help verify supply chains and conduct investigations

- OTA supports adding the new term ‘*organic fraud*’ to the organic regulations to clarify the actions this proposed rule is intended to reduce and to support global communication and overall strategic direction of organic fraud prevention.
- OTA supports the proposed definition of ‘*organic fraud*’ whereas the action taking place is ‘intentional deception’ and the motivation is economic gain. However, OTA recommends that the term ‘illicit’ be removed from and the definition is revised to more clearly encompass the types of fraudulent activities that occur in the organic supply chain.

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

Technical Corrections – Proposed Rule Section #19

SUMMARY OF PROPOSED RULE

- **Change “produced” to “processed” in §205.301(f)(2) and vice versa in §205.301(f)(3) to better describe the application methods of ionizing radiation and sewage sludge, respectively**
- **Change “205.200” to “205.201” in §205.400(b) and §205.401(a) to correct the reference to the OSP section of the regulations.**

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

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

SUMMARY OF AMENDMENTS CONSIDERED

- **Packaged Product Labeling** – Considers an amendment to the labeling requirements for packaged products (205.303–304) to clarify which certified operation and certifying agent must be listed on the label of a private-label organic product.
- **Expiration of Certification** – Considers an amendment in which an operation’s certification would expire on an annual basis if the operation did not submit fees and update its certificate of organic operation.
- **Fees to AMS and Oversight of Certifying Agents’ Fee** – Asks for public comments on how fees from certifying agents to NOP could strengthen testing and enforcement across all stakeholders to ensure that NOP keeps pace with the rapid growth and better serves the industry.

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

Implementation Timeframe

SUMMARY OF AMENDMENTS CONSIDERED

- **Operations must be in full compliance within 1 year after publication of the final rule**

Topic	OTA’s Recommended Implementation Timeframe (from publication of the final rule)
Exemptions from Certification	2 Years for handling operations that must get certified as a result of this proposed rule
Imports to the United States (Import Certificates)	2 Years for shipments by ground transportation from Mexico and Canada; 1 year from publication of final rule for all other imports
Labeling of Nonretail Containers	2 Years for all nonretail containers
On-site and Unannounced Inspections	1 Year
Organic Certificates & Data Reporting	2 Years for mandatory use of Organic Integrity Database for generating certificates

Continuation of Certification	1 Year
Personnel Training and Qualifications	1 Year
Oversight of Certification Activities	1 Year
Accepting Foreign Conformity Assessments	1 Year
Noncompliance, Mediation and Appeals	1 Year
Grower Group Operations	1 Year
Calculating Percent Organic Ingredients	1 Year
Supply Chain Traceability & Fraud Prevention	1 Year
Technical Corrections	Immediately upon final rule becoming effective