

Guidance on Handler Packer Compliance with 205.103 Recordkeeping Requirements

Section 205.103 of the USDA National Organic Program regulations describes the general requirements for recordkeeping under the USDA National Organic Program Regulations:

§205.103 Recordkeeping by certified operations.

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(b) Such records must:

(1) Be adapted to the particular business that the certified operation is conducting;

(2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;

(3) Be maintained for not less than 5 years beyond their creation; and

(4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program’s governing State official, and the certifying agent.

These requirements are broad. Because of the breadth of these requirements, operations may need more guidance on how to effectively implement these requirements and what the certifying agent is looking for.

Given the variations between operations and different types of production and handler systems it is impossible to give a specific, detailed explanation of how each operation can demonstrate compliance with the regulation. In reviewing records, and thinking about recordkeeping systems, the certifying agent and the certified operation must remember that function controls over form. This means that a recordkeeping system which fully documents all transactions and activities in sufficient detail as to be readily understood and audited by the certifying agent and which demonstrates compliance with the other requirements of the regulation will meet the requirements of section 205.103, even if they don’t meet the specific requirements laid out in this guidance document. Assuming the recordkeeping system meets all 205.103 requirements and provides for traceability and mass balance exercises described in section B below, it will be considered compliant.

That being said, there is a common set of core records that every operation should implement and which the certifying agent will expect to be maintained in most cases. This guidance document explains the common set of core records that each handler-packer operation should consider implementing to meet section 205.103 requirements.

A. 205.103(b) (1): Guidance on Required Records and Packer Documentation

Generally, a packer operation should have a plan to obtain, create, and maintain records and documents which record all transactions and activities and which demonstrate compliance. Generally, that would normally include the following documentation:

- Supplier Documentation (Current organic certificates for each supplier, documentation as required by any equivalency agreement)

- Receiving Records (Farm Generated Trip Tickets, Bills of Lading, Receipts, Invoices, Date of Receipt, Amount Received, Identity, Source and Composition, Supplier Assigned Lot #, Packer Assigned Lot #, Organic Status)
- Periodic Physical Inventories (Actual Physical Counts of Unpacked Ingredients/Crops and Finished/Packed Product)
- Packing Records (Per Event Records of the Amount Packed, the Source of the Product Packed, Lot Numbers of Ingredients Packed, Date Packed).
- Other Removals from Inventory (Records must be Maintained of Product, Crops or Ingredients Removed from Inventory Due to Wastage, Sampling, Employee Gifts, R&D, and Diversion to Non-Organic Sales or Production)
- Shipping Records (Date, Product Shipped, Lot Number, Organic Status, Amount Shipped, To Whom Shipped)
- Sales Records (Date, Product Sold, Organic Status, Amount Sold, Identification of Buyer, Lot #)
- Other Miscellaneous Documentation (Necessary to Document Compliance with the NOP regulations, such as equipment cleaning records, appropriate documentation for allowed non-organic (section 205.205/section 205.606) processing aids and substances, etc.

A more detailed description of these records is as follows:

Supplier Documentation: For each supplier of organic products or ingredients, the operation must have a plan, policy and a practice of obtaining and maintaining current organic certificates for each supplier. For product which is obtained under (or will be exported and marketed under) a foreign equivalency arrangement (e.g. US-Canada Equivalency Arrangement), the documentation obtained must include verification that the supplier is approved under that equivalency arrangement.

For Example: For organic product that is imported into the US under the US-Canada Equivalency Agreement (or which will be exported to Canada under that agreement) the packer must have a plan, policy and practice of obtaining documentation from the supplier that they are certified under the US-Canada Equivalency Arrangement and must maintain this documentation and make it available for review by the certifying agent upon request.

Another Example: For organic product imported into the US under the US-EU Equivalency Agreement or the India-US Equivalency Agreement, the packer must have a plan, policy, and practice of obtaining (in addition to the organic certificate for the supplier) a copy of the NOP Import Authorization issued for each shipment of product received (issued by the supplier's certifying agent) and must maintain this documentation and make it available for review by the certifying agent upon request.

Receiving Records:

The packer must have a plan, policy and practice of documenting the receipt of organic ingredients or products which includes certain required information. Generally, two key receiving records are required: a shipping/transport/delivery document and a receiving log.

A shipping/transport/delivery document must be obtained and maintained for each shipment of crop, product or ingredient received. Such a document may include a bill of lading, a delivery receipt, or a

farm generated trip ticket, if it contains the following information: The identity of the material received, its organic status, the date received, the amount received, from whom it is received. If the product received is a processed product (rather than raw unprocessed crop) it must also have a lot number or other traceability code assigned to it by the source which is listed in the shipping/transport/delivery document. It is the packer's responsibility to ensure that any shipment received is accompanied by such a document which contains all the necessary information. If the document lacks the required information, it is the packer's responsibility to proactively reach out to the supplier and obtain this shipment specific information and to maintain such documentation. All documentation must be maintained and made available for review by the certifying agent upon request.

A receiving log must be maintained that records each shipment of crops, ingredients, or products received from any supplier. This log must be maintained in a contemporaneous manner (e.g. entries are made on or about the time the shipment is received) and must record the following information: the crop or product received, its organic status, its source, the amount received, the date received, and traceability information as assigned by the supplier. It is also usually necessary for the packer to assign its own internal lot number for each shipment and record this in the receiving log if the product received is of the type that a supplier assigned lot number is likely to be repeated in separate shipments. This log may be a paper log, electronic, or take any other form, so long as it records the information described above. All documentation must be maintained and made available for review by the certifying agent upon request.

Periodic Physical Inventories: Unless the packer is a seasonal operation that begins each season with zero inventory on hand and completes its packing season in less than a year (at which point it has zero inventory on hand as a matter of practice) a packer operation is required to conduct actual periodic physical inventories. An actual periodic physical inventory means that at least once per year, the operation goes in and actually observes and records the amount of ingredients, raw materials, or unpacked product, in process product, and actual packed finished goods which are on hand. The actual physical inventory means a count of what is actually there; it is not a generated report of what "should" be on hand; it is an actual count of what is on hand. Periodic means this inventory must be conducted at least once per year for most operations. The inventory must be accurate and it must be recorded. The record should include: the date the inventory was conducted, the products inventoried (listed by unit sizes and product identification/sku, presentations, brand names, etc) and the amount of each on hand. A packer operation must have a plan, policy, and practice which addresses these requirements. All documentation must be maintained and made available for review by the certifying agent upon request.

Packing/Processing Records: All packing events must be documented. This means that a record is generated at or around the time of the packing event which records the amount of product packed, the ingredients or crops used in the packing event, the internal packer assigned lot number for the ingredients or crops used in the packing event (from the receiving log), the date packed, and the identity and status of the final packed product. For instance, if a load of blueberries from Grower A is packed by a blueberry packing operation, a packing record would be generated which records (for example) that on a specific recorded date 1,000 lbs of organic blueberries were packed into Brand X 6 oz clamshells, yielding 2660 (6 oz) clamshells and the blueberries came from internal lot number xxxxx which were received from Grower A.

Other Removals from Inventory: Frequently crops, products, and ingredients are removed from inventory for reasons other than packing events. Such reasons may include gifts and samples, wastage, culling, employee use, internal use, R&D, sampling for testing, and diversion to non-organic sales or packing. Such removals must be recorded so that all organic product and crops can be accounted for. Standard shrinkage due to moisture loss need not be specifically recorded and culls during packing need not be specifically recorded if they do not exceed a known and specified industry standard or common factor. All other removals from inventory must be recorded in a record. Such a record should include the date removed from inventory, the identity and organic status of the material removed from inventory and the amount removed. The record must be made at or around the time of removal. A packer operation must have a plan, policy, and practice which addresses these requirements. All documentation must be maintained and made available for review by the certifying agent upon request.

Shipping Records:

The packer must have a plan, policy and practice of documenting the shipping of organic product which leaves the possession of the packer. Such records must include certain required information.

A shipping/transport/delivery document must be generated and maintained for each shipment of crop, product or ingredient shipped or delivered. Such a document may include a bill of lading, transfer ticket, or a delivery receipt, if it contains the following information: The identity of the material shipped, its organic status, the amount and form of packaging, the date shipped, the amount shipped, the packer shipping it, to whom it is shipped, and a traceability number such as a lot number. Such records must be made at or around the time of shipping. All documentation must be maintained and made available for review by the certifying agent upon request. In some cases, such as internal transfers from one packer owned facility to another, this may take the form of a log.

Sales Records: A record must be made of each sale of organic product (or a service fee record for operations who charge a fee only for the handling/packing of organic product) for each shipment or lot sold (or serviced). This record must be made at or around the time of sale or service. Such a record must include what was sold (or serviced), its organic status, and the amount sold or serviced. The record must also identify to whom the product was sold (or charged for the service).

Facility Diagram: It is the packer's responsibility to create and maintain a facility diagram which illustrates the layout of the facility and which includes an identification of all areas where organic crops, products or ingredients are received, stored, handled, processed, and shipped from. The facility diagram must be accurate and updated as needed. This diagram must be submitted to the certifying agent and will be reviewed for accuracy during onsite inspections.

Process Flow Description: It is the packer's responsibility to create and maintain a process flow description which describes each event involved in the handling and packing of organic products. Typically this is a numbered series of events which record the order of events and what each event entails. For instance, a simplified packer process flow might include: 1) Receiving, 2) Cooling, 3) Washing, 4) Culling, Sizing, and Grading, 5) Packing, 6) Storage, 7) Shipping. The process flow would describe the event, where it takes place, any equipment used, any record generated, and any

substances used in contact with organic product, crops, or ingredients at that stage. A process flow diagram is similar in some ways to a facility diagram but is narrative in form and includes a greater amount of detail. The process flow description must be accurate and updated as needed. This process flow description must be submitted to the certifying agent and will be reviewed for accuracy during onsite inspections.

Other Miscellaneous Records: If an aspect of the regulation is documentary in nature or has a documentary component (persistent quat sanitizers require testing to confirm removal, non-organic ingredients or processing aids (listed in 205.605 or 205.606 for “organic label claims”) which have annotations or commercial availability search requirements, phytosanitary documents for unpacked raw crops imported, etc) then there should be a corresponding record which demonstrates compliance with that requirement. Some examples include:

- Pest control application records which record the date of the application, where the substance was applied, and why the substance was applied.
- Pest observation records to support the use of allowed synthetic pest control products (level 3 pest control products) or other synthetic pest control products (level 4 pest control products).
- Documentation that food contact surfaces are free of quat residues (through the record of a zero ppm test strip evaluation post quat removal) for operations which use quat products on food contact surfaces.
- Specific ingredient or food contact substance annotations as listed in section 205.605, 205.606 of the regulations.
- Commercial availability search supporting the use of certain non-organic ingredients as listed in section 205.605 or 205.606 (e.g. certain non-organic colors, flavors, yeast, etc).
- Non-GMO, Non-Irradiation, Non-Biosolids documentation for any non-organic agricultural ingredient listed in section 205.605 or 205.606.
- Phytosanitary documents showing that imported organic crops were not treated with prohibited substances in transit.
- If labels from another uncertified distributor are used, proof that the uncertified distributor has given permission to pack into their label.
- If labels from a certified organic distributor are used that carry another certifying agent’s “Certified Organic by” statement, the packer must provide documentary proof that the other certifying agent is aware of the copacking relationship and has approved the use of the labels.

B. 205.103(b) (2): Guidance on Maintaining Auditable Records for Handler-Packer Operations:

In general, an operation must be able to demonstrate compliance with section 205.103, including section 205.103(b) (2). In demonstrating compliance, functionality controls over form. This means that the recordkeeping system is sufficient if it:

- Can demonstrate that the operation has complied the requirements of the USDA National Organic Program regulations, and;
- Fully documents all transactions and activities in a manner which is readily understood and audited, and;

- Allows traceability of organic products, crops, and ingredients, and;
- Allows a mass balance of outputs or inputs to be conducted.

Traceability of inputs is defined as the ability to select a particular unit of packed product and to identify through records all the sources of organic crops, products, or ingredients which went into the packing, processing, or manufacture of the finished product, including the composition, identity, and source of the input. Generally this can be done using a combination of the sales, shipping, packing, inventory, receiving, and supplier records.

A mass balance of outputs or inputs is defined as the ability to select a particular packed crop or type of packed product and to verify through records that there is a reasonable relationship established in the records between the amount of crop, ingredients, or product received, packed, shipped, and sold. Generally this is conducted by reviewing the listed records, but it may also include bank records if necessary.

C. 205.103(b) (3): Guidance on the Requirement to Retain Records for 5 Years After Creation

Operations must have a plan and policy to maintain all records related to certification for 5 years after their creation. Once certified, applicant should be able to produce a requested record if it was created after their date of certification and within the past five years. This would include any record created during certified activities in the previous five years.

D. 205.103(b) (4): Guidance on Ensuring that Records Demonstrate Compliance

Records must be sufficient to demonstrate compliance. If an aspect of the regulation is documentary in nature or has a documentary component (persistent quat sanitizers require testing to confirm removal, non-organic ingredients or processing aids (listed in 205.605 or 205.606 for “organic label claims”) which have annotations or commercial availability search requirements, phytosanitary documents for unpacked raw crops imported, etc) then there should be a corresponding record which demonstrates compliance with that requirement. While it is impossible to provide a list of all the records or documents that would be needed to demonstrate compliance given the variety of operations which seek certification, a good starting point for documenting compliance through records is to follow the recordkeeping guidance described in policy in section A above.

E. 205.103(C): Guidance on Making All Records Available During Onsite Inspections

During the inspection you can expect that the inspector will ask to review all of the types of records described in this guidance. They will attempt to conduct one or more exercises such as a traceability exercise and mass balance exercise as described in section B above. They will also request to review other documentation as described as Other Miscellaneous Records in section A above.

It is a packer’s responsibility to make these records available for review, auditing and copying during the onsite inspection. Such records must be provided to the inspector within a reasonable time after the request, during the inspection, and at the site of the inspection. It is solely within the inspector’s discretion to determine when the operation has been given a reasonable amount of time to provide a document or record and to conclude that the record is not available or not easily auditable because it cannot be provided in reasonable time. Providing the records after the inspection has concluded is not

sufficient to demonstrate compliance. If records will not be at the primary site, and the auditor will need to visit another site to view any records, it is the packer's responsibility to explain this to the certifying agent and the inspector in the submitted application at the time of applying for organic certification so appropriate time and logistics management can be conducted to include the records location in the inspection process.