

Every certified handling operation in the United States is required to comply with the USDA organic regulations. These rules ensure the integrity of the organic supply chain and marketplace, but studying legal terminology and language can induce a headache in even the most savvy reader. In this guide, we will take a plain language tour of the USDA organic regulations, focusing-in on the sections that are most pertinent to organic handling operations.



A Newcomer's Guide to Organic Regulations for Handlers

A plain language overview of the organic regulations, how they are organized, and what sections are pertinent to organic handling

Every handling operation pursuing organic certification must understand the regulations that govern the program. The organic regulations are legally binding to operations who handle organic agricultural products. Your operation will be inspected under these regulations. Having a thorough understanding of the regulations will help you to design compliant systems at your operation and to effectively communicate with your certifier. Knowing the regulations allows you to know your rights and obligations as a certified organic operation.

What are the regulations?

The regulations are a set of rules that govern the USDA National Organic Program. The full text of the regulations are published in Title 7 Part 205 of the Code of Federal Regulations <https://www.ecfr.gov/current/title-7/subtitle-B/chapter-I/subchapter-M/part-205>

Tips for navigating the Code of Federal Regulations

Use the table of contents to find sections that you need to know.

Search for specific words or phrases with the keyboard shortcut "ctrl+f" or "command+f".

Familiarize yourself with the terminology of organic certification. Check out the resource "Glossary of Organic Certification Terms for Handlers".

The screenshot shows the Code of Federal Regulations website. At the top, there is a header with the National Archives logo and the text "Code of Federal Regulations" and "A point in time eCFR system". Below this, there is a blue bar with "Title 7". A search bar is present with the text "Enter a search term or CFR reference (eg. fishing or 1 CFR 1.1)". Below the search bar, there is a breadcrumb trail: "Title 7 / Subtitle B / Chapter I / Subchapter M / Part 205". To the right of the breadcrumb trail are links for "Previous", "Next", and "Top". On the left side, there is a sidebar with a "Table of Contents" link and other options like "Details", "Print/PDF", "Display Options", "Subscribe", "Timeline", "Go to Date", "Compare Dates", "Published Edition", and "Developer Tools". The main content area shows the "ENHANCED CONTENT" section for "PART 205—NATIONAL ORGANIC PROGRAM". It includes the "Authority" (7 U.S.C. 6501-6524), the "Source" (65 FR 80637, Dec. 21, 2000, unless otherwise noted), and the "Subpart A—Definitions" section. Under "Subpart A—Definitions", there are two sections: "§ 205.1 Meaning of words." and "§ 205.2 Terms defined." The "§ 205.2 Terms defined." section includes definitions for "Accreditation", "Act", and "Action level".



Individual rules are referred to by their *citation*.

The elements of the citation describe the organizational segments of the code (from largest to smallest): part > subpart > section > subsection. Let's look at the example "§ 205.103(b)(4)". Each element points to an ever more specific portion of the code until you get down to a single line, or rule. To read this citation aloud, you would say "section two-oh-five one-oh-three, subsection b-four". The symbol "§" signifies the word "section".

Part	Subpart	Section	Subsection
205	B	103	(b)(4)

Go to the eCFR website and find what § 205.103(b)(4) says.

Answer on the last page

The titles of the regulations' subparts are useful for navigating the table of contents quickly, though they are not regularly referred to in common conversation or used in the formatting of citations.

Subpart A — Definitions contains a glossary of terms that are used throughout the regulations. These are legal definitions and should be read carefully because they can and will be applied to your certified organic operation during its certification and inspection process.

Subpart B — Applicability describes who is required to get certified, and what is and is not allowed in organic handling (e.g., allowed and prohibited substances and methods).

Subpart C — Organic Production and Handling Requirements contains the specific practices that are required in organic crop and livestock production, as well as organic handling and processing. Also contains the regulations that pertain to the import of organic agricultural products into the United States.

Subpart D — Labels, Labeling, and Market Information explains how organic products must be labeled, the claims that may be placed on the product label, when and how the term "organic" may be used, and when and how the USDA organic seal may be used.

Subpart E — Certification outlines what is required to become certified and maintain certification, inspection requirements, and the process for granting or denial of certification.

Subpart F — Accreditation of Certifying Agents contains the requirements that organic certifiers must meet in order to become accredited. This section does not contain information that is applicable to organic handling operations.

Subpart G — Administrative contains the list of allowed and prohibited substances, requirements for testing organic products, enforcement actions, and the appeals process.

A tour of the regulations

Let's take a tour of the regulations from top to bottom. The regulations will be summarized here in plain language, with citations to the relevant sections of the code. This summary is not exhaustive. You may have unique or special circumstances that are covered by less commonly referenced regulations that are not summarized here. Use this tour as a way to gain a foundational understanding of the regulations as a springboard into deeper study.

§ 205.2 Who is a “handler”

A “handler” is any operation that **sells, processes, or packages agricultural products**, except for final retailers that do not process agricultural products.

“**Handling**” activities include, but are not limited to: “**Processing**” activities include, but are not limited to:

- Trading, and facilitating sale or trade;
- Importing and exporting;
- Combining, aggregating;
- Conditioning and treating;
- Packaging, containerizing, repackaging;
- Labeling;
- Storing, receiving, and loading.
- Milling, freezing, chilling, dehydrating, drying, pickling, canning, preservation;
- Fermenting, churning, pasteurizing;
- Mixing, separating, combining ingredients to create new product;
- Cooking, baking, curing, heating;
- Pressing, extracting, distilling;
- Slaughtering, grinding, eviscerating;
- Packaging or repackaging.

§ 205.100 What has to be certified

Each operation that handles agricultural products that are represented as “100 percent organic,” “organic” or “made with organic (specified ingredients)” must be certified, unless they meet one of the exemptions.

The regulations detail the composition and labeling requirements for livestock feed separately from products intended for human consumption. The regulations for livestock feed can be found in § 205.301(e) Product composition, Livestock feed, and § 205.306 Labeling of livestock feed.

“Agricultural products” are any raw or processed agricultural commodity or product, including those derived from livestock, that is marketed for consumption by a human or livestock in the United States.



§ 205.101 Exemptions from certification

An operation is exempt from getting certified if they fall into any of the following categories:

- Have gross organic sales of \$5,000 or less per year;
- Are a retail establishment that does not process organic agricultural products;
- Are a retail establishment that processes organic agricultural products only at the point of sale;
- Handles only products that contain less than 70% organic ingredients;
- Only receives or stores products that are in sealed, tamper-evident packages or containers prior to being received, and remain in the same packaging while in the control of the operation;
- Only arranges for the shipping, storing, or transportation of organic agricultural products;
- Are a licensed customs broker.

Operations that are exempt from going through the formal certification process are still allowed to handle organic agricultural products. Though they do not have to apply for certification and undergo organic inspections, they must follow all of the handling requirements to ensure the integrity of the organic supply chain.

§ 205.103 Recordkeeping by certified operations

Certified handling operations must keep records of all activities and transactions related to the handling and processing of organic agricultural products. The records must be sufficient to demonstrate that all handling activities for organic products were done in compliance with the regulations. The records must be structured in a way that provides an audit trail that is traceable back to the last certified operation.

Nonorganic ingredients may only be used in a product labeled as “organic” when the ingredient is listed in § 205.606 and is not commercially available in organic form.

§ 205.105 Allowed and prohibited substances, methods, and ingredients

Organic agricultural products must be handled and processed without the use of any prohibited substances, methods, or ingredients. These prohibitions include:

- Synthetic substances, unless they are included in the National List (§ 205.601 and § 205.603);
- Some specific natural substances, itemized in the National List (§ 205.602 and § 205.604);
- Substances that are not products of agriculture, except for those itemized in the National List (§ 205.605);
- Nonorganic agricultural substances;
- Substances produced with genetic engineering;
- Ionizing radiation;
- Sewage sludge;
- Volatile synthetic solvents or other synthetic processing aid (see § 205.270)

A list of exceptions to these rules is referred to as “The National List” and can be found in § 205.605 and § 205.606.

§ 205.201 The organic system plan

Handling operations must develop a comprehensive plan that describes all of the aspects of the operation's practices and procedures that ensure compliance with the regulations. The plan must be in writing and approved by their certifier. The plan is referred to as an "organic system plan" or "OSP", and includes but is not limited to substances, inputs, ingredients, pest control and sanitation procedures, packaging and labeling, transport, sales, purchases, management practices to prevent commingling and contamination, monitoring practices, and a description of the operation's record keeping system. The OSP is frequently made up of the application forms supplied to the operation by their certifier.

§ 205.400 - § 205.406 Requirements for certification

Operations that meet all of the requirements of organic certification (as described throughout this document) may apply for organic certification. The certifier will then review the application and conduct an on-site inspection to determine whether the operation meets the requirements for certification. The inspection must cover each production unit, facility, and site that produces or handles organic production, as well as a thorough review of the records of the operation. The inspection may include sampling and testing of products and substances to ensure compliance with the regulations. Within a reasonable time after completion of the initial inspection, the certifier must review the inspection report and make the certification determination.

Once the operation is certified, they must submit an annual update of the OSP to the certifier and undergo annual on-site inspections. The annual inspection is typically conducted with notice and scheduled ahead of time. The certifier may conduct unscheduled/unannounced inspections, as well as additional inspections in a year, if necessary to ensure compliance with the regulations.

Check out the companion resource "Certification Process Overview for Handlers" for a more detailed overview of the certification process.

Sections 205.405 and 205.662 describe the process for how issues of noncompliance are to be handled, including the process for submitting a rebuttal to the certifier. Sections 205.680 and 205.681 detail the process for appealing the decision of the certifier.

§ 205.271 Facility pest management

Pests in and around the organic handling facility must be controlled using a tiered approach.

- 1) Preventive Practices** - Pest issues must be prevented through management methods such as removal of habitat, food sources, and breeding areas; preventing their access to the handling facility; and environmental factors such as temperature, light, humidity, etc.
- 2) Mechanical/Physical Barriers** - Pests may be controlled through mechanical/physical controls such as traps, light, or sound, and lures/repellents using nonsynthetic substances.
- 3) Approved Input Materials** - If the above methods are not effective, then pest control may be achieved with use of synthetic substances consistent with the National List.
- 4) Synthetic Inputs** - If all else fails, then a synthetic substance not on the National List may be used, so long as the certifier has agreed to the substance, its method of application, and measures must be taken to prevent contact with the organically produced products and ingredients.

All pest control substances must be pre-approved by the certifier and included in the operation's OSP.

§ 205.272 Preventing commingling and contact with prohibited substances

All handling operations must prevent any **commingling** of organic and nonorganic agricultural products. Standard operating procedures for the prevention of commingling must be documented in the operation's OSP. Examples of commingling prevention include effective labeling of organic and nonorganic products, storing organic and nonorganic substances in separate areas, and the training of staff on the SOPs.

Handling operations must also prevent the **contamination** of an organic product by a prohibited substance. This includes contamination from cleaners and sanitizers used on equipment and materials used in packaging. If a prohibited substance is used in a facility, then measures must be taken to prevent contact with organic products.

“Commingling” is the physical contact between unpackaged organic products and nonorganic products at any time other than during the manufacture of a multiingredient product containing both types of ingredients.

Organic agricultural products cannot use any **packaging or storage materials** that contain a synthetic fungicide, preservative, or fumigant.

Operations are permitted to handle and process both organic and nonorganic agricultural products. These are referred to as “split operations”. Extra care must be taken by split operations to ensure that no commingling and contamination occurs. Effective segregation and equipment cleaning procedures must be in place in the handling facility.

§ 205.300 - § 205.311 Labeling and Marketing Information

Organic agricultural products must be appropriately labeled in accordance with the regulations. The regulations detail how organic claims can be communicated in various places on the product label including the principal display panel, information panel, any other panel of the package, and any marketing information concerning the product.

Organic product composition is divided into 4 categories:

- **100% organic**, where all of the ingredients are organically produced and any processing aids must be organic;
- **Organic**, where at minimum 95% of the ingredients are organically produced, any remaining ingredients are allowable substances;
- **Made with organic (specified ingredients or food group(s))**, where at least 70% of the ingredients are organically produced and handled, and no ingredients may be produced using prohibited substances or methods;
- **Less than 70 percent organically produced ingredients**, may contain any percentage of organic content and may contain over 30% of nonorganically produced agricultural ingredients and/or other substances.

For “100% organic”, “organic”, and “made with organic...”, the product must not be produced using GMOs, ionizing radiation, sewage sludge, processing aids not approved in the National List, nonorganic ingredients when organic ingredients are available, or include organic and nonorganic forms of the same ingredient. They must also not contain sulfites, nitrites, or nitrates added during the handling process, except for wine containing added sulfites.

Note - Product composition percentages are calculated by weight or fluid volume, excluding water and salt.

The product composition category to which the product belongs determines the requirements of the product label, including the use and placement of:

- the term “100 percent organic” or “organic” to modify the name of the product (e.g. Organic Flaxseed);
- claims about the percentage of organic ingredients in the product;
- the term “organic” to identify the organic ingredients in a multiingredient product (e.g. Ingredients: Organic oats, organic cranberries, peanuts);
- the USDA organic seal;
- the seal, logo, or identifying mark of the certifier.

Nonretail containers used to ship or store certified organic products must display a marking identifying the product as organic, and include a unique identifier such as a lot number or shipping identification number.

Products handled and processed in the United States that are intended for export to another country may be labelled in accordance with the requirements of the destination country.

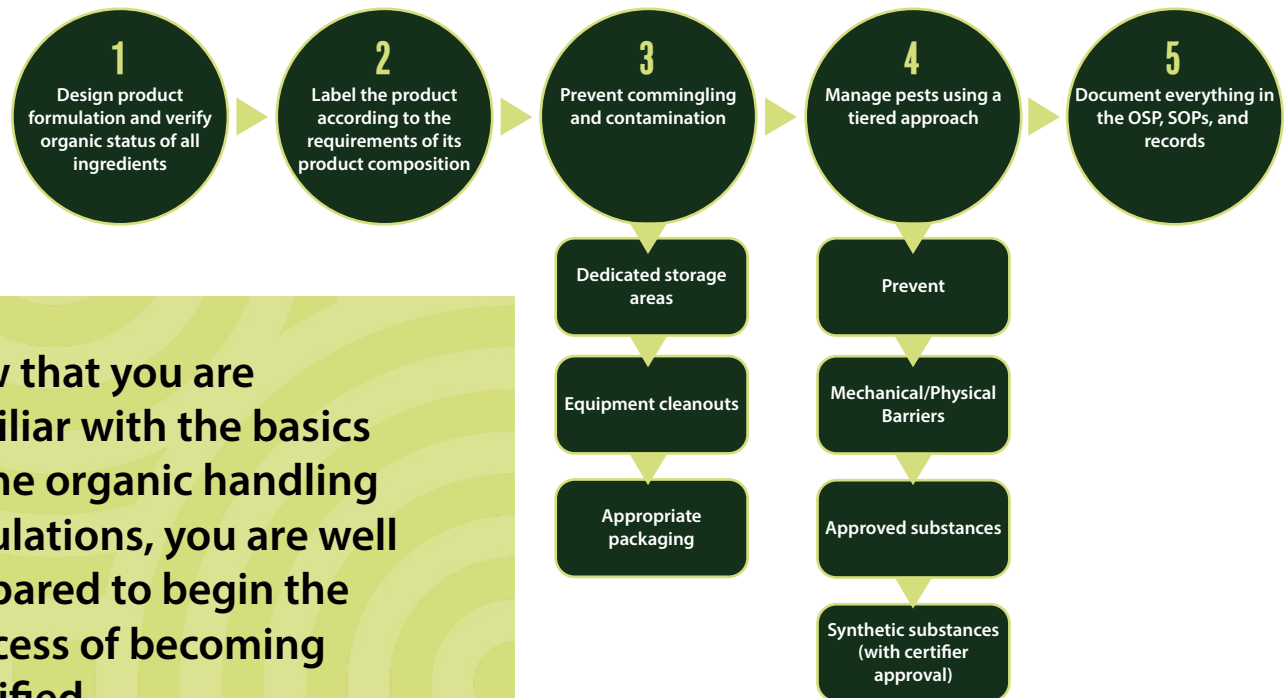
§ 205.273 Imports to the United States

All imports of organic products into the United States must be certified and labeled to the USDA organic standards. Imports must be declared as organic to U.S. Customs and Border Protection and be associated with a valid NOP Import Certificate. The NOP Import Certificate must be issued by a certifier prior to the product leaving its origin country. Imported organic products must be clearly marked and identified as organic on all packaging and documentation. Upon receiving possession of the imported product, the importer must verify that the product had no contact with prohibited substances or exposure to ionizing radiation since its export from the origin country.



Putting it all together

In summary, the regulations detail all of the requirements for certification of organic handlers and processors. While there are many details to become familiar with, compliance for handlers boils down to five essential buckets.



Now that you are familiar with the basics of the organic handling regulations, you are well prepared to begin the process of becoming certified.



Sources Cited

CFR Part 205 National Organic Program

<https://www.ecfr.gov/current/title-7/subtitle-B/chapter-I/subchapter-M/part-205>

Dig Deeper Resources

Organic Integrity Learning Center Course: "Keep It Organic When Handling and Processing"

<https://www.ams.usda.gov/services/organic-certification/training>

Organic Labeling and Composition Guide by Oregon Tilth

https://cms.organictransition.org/wp-content/uploads/2024/01/OrganicLabellingGuide_180220.pdf

Answer: Certified operations must maintain records for five years



United States Department of Agriculture
Agricultural Marketing Service
National Organic Program

