



# Organic Standards for All Organic Operations

## Highlights of the USDA's National Organic Program Regulations

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By Ann H. Baier  
NCAT Agriculture  
Specialist  
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This collection of excerpts from the USDA's National Organic Program provides the reader with key standards relevant to all certified organic operations. This publication should be used as needed with excerpts for crop production, livestock production or handling.

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Highlights of the USDA's National Organic Program Regulations include key standards for:

- 1) All certified organic operations
- 2) Crop production
- 3) Livestock production
- 4) Handling (including processing)

Use this publication for all certified organic operations, in combination with one or more of publications two, three or four as relevant to organic crop production, livestock production or handling.

## Introduction

This publication provides easy reference to the standards relevant to all organic operations. These excerpts from the USDA's National Organic Program Final Rule contain the general requirements for an organic system plan, recordkeeping, product labeling and preventing commingling and contamination.

This is *not* a complete collection of organic standards. It must be used in conjunction with standards for crops production, livestock production or handling of agricultural products, as applicable.

This set of excerpts is not a substitute for reading the entire set of standards, which can be found online at [www.ams.usda.gov/NOP](http://www.ams.usda.gov/NOP). This set of excerpts should also not be used for verifying points of compliance for organic production and handling activities with an accredited organic certifier. For a list of these, go to the List of Accredited Certifying Agents on the National Organic Program Web site, [www.ams.usda.gov](http://www.ams.usda.gov).

### Using this guide:

This is a collection of verbatim excerpts from key parts of the National Organic Program's Final Rule. Organic regulations are

found under the USDA's Agricultural Marketing Service 7 CFR Part 205. CFR stands for Code of Federal Regulations.

Part 205 of the regulations, found under Title 7: Agriculture, is the National Organic Program.

The Organic Foods Production Act was enacted under the 1990 Farm Bill. The Act, as it is referred to in the text, authorized creation of the USDA National Organic Program to set national standards for the production, handling and processing of organically grown agricultural products. The National Organic Program oversees mandatory certification of organic production. Producers who meet National Organic Program standards may label their products as "USDA Certified Organic." The subparts reference organizational levels in each excerpt.

The following sections of the National Organic Program are excerpted:

- Recordkeeping and organic system plan
  - o § 205.103 Recordkeeping by certified operations
  - o § 205.201 Organic production and handling system plan
- The National List of Allowed and Prohibited Substances

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- o § 205.600 Evaluation criteria for allowed and prohibited substances, methods and ingredients
- Labels, labeling and market information
  - o § 205.300 Use of the term “organic”
  - o § 205.301 Product composition
- § 205.2 Selected defined terms

For complete information about labeling requirements, see sections 205.302-3.11 included in *ATTRA’s Organic Handling Standards Highlights*.

## Excerpts

### ***Recordkeeping and organizing systems***

#### 1) § 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 groups).”
  - i) Such records must:
    - 1) Adapt to the particular business that the certified operation is conducting;
    - 2) Fully disclose all activities and transactions of the certified operation in sufficient detail that is readily understood and audited;
    - 3) Be maintained for at least 5 years beyond their creation; and
    - 4) Demonstrate compliance with the Act and the regulations in this part.
  - ii) A certified operation must make records available for inspection and copying by authorized representatives of the secretary, the

applicable state program’s governing official and the certifying agent during normal business hours.

#### 2) § 205.201 Organic production and handling system plan

- a) A producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label or represent agricultural products as “100 percent organic,” “organic” or “made with organic (specified ingredients or food groups)” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling.”
  - i) An organic production or handling system plan must include:
    - 1) A description of practices and procedures to be performed and maintained, and the frequency with which they will be performed;
    - 2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used and documentation of commercial availability, as applicable;
    - 3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
    - 4) A description of the record-keeping system implemented to comply with the requirements established in § 205.103;
    - 5) A description of the management practices and physical

barriers established to prevent commingling of organic and non-organic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and

6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

b) A producer may substitute a plan prepared to meet the requirements of another federal, state or local government regulatory program for the organic system plan, provided that the submitted plan meets all the requirements of this subpart.

## ***The National List of Allowed and Prohibited Substances***

### **1) § 205.600 Evaluation criteria for allowed and prohibited substances, methods and ingredients**

a) The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

i) Synthetic and non-synthetic substances considered for inclusion in or deletion from the National List will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

ii) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

1) The substance cannot be produced from a natural source and there are no organic substitutes;

2) The substance's manufacture, use and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

3) The nutritional quality of the food is maintained when the substance is used and the substance itself or its breakdown products do not have an adverse effect on human health as defined by applicable federal regulations;

4) The substance's primary use is not as a preservative or to re-create or improve flavors, colors, textures or nutritive value lost during processing, except where the replacement of nutrients is required by law;

5) The substance is listed as generally recognized as safe by the Food and Drug Administration (FDA) when used in accordance with the FDA's good manufacturing practices and contains no residues of heavy metals or other contaminants in excess of tolerances set by the FDA; and

6) The substance is essential for the handling of organically produced agricultural products.

iii) Non-synthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

**Editor's note:** The National List of Allowed and Prohibited Substances is subject to change as a result of legal actions, petitions to add or remove materials or technical corrections. Please check the Web site [www.ams.usda.gov/nop/NOP/standards/FullRegTextOnly.html](http://www.ams.usda.gov/nop/NOP/standards/FullRegTextOnly.html) for the most current update of § 205.601-606 for lists of materials allowed and prohibited for crop and livestock production or handling.

## **Labels, labeling and market information**

### **1) § 205.300 Use of the term “organic”**

- a) The term “organic” may only be used on labels and in labeling of raw or processed agricultural products and ingredients that have been produced and handled in accordance with the regulations in this part. The term “organic” may not be used in a product name to modify a non-organic ingredient in the product.
- b) Products for export or produced and certified to foreign organic standards or foreign contract buyer requirements may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer if the shipping containers and shipping documents meet the labeling requirements specified in § 205.307(c).
- c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.
- d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

### **2) § 205.301 Product composition**

- a) Products sold, labeled or represented as “100 percent organic”
  - i) A raw or processed agricultural product sold, labeled or represented as “100 percent organic” must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

- b) Products sold, labeled or represented as “organic”
  - i) A raw or processed agricultural product sold, labeled or represented as “organic” must contain (by weight or fluid volume, excluding water and salt) at least 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced unless not commercially available in organic form or must be nonagricultural substances or non-organically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.
- c) Products sold, labeled or represented as “made with organic (specified ingredients or food groups)”
  - i) Multi-ingredient agricultural product sold, labeled or represented as “made with organic (specified ingredients or food groups)” must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients that are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs one through three of § 205.301(f). Non-organic ingredients may be produced without regard to paragraphs four through seven of § 205.301(f). If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.
- d) Products with less than 70 percent organically produced ingredients

- i) The organic ingredients in multi-ingredient agricultural product containing less than 70 percent organically produced ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The non-organic ingredients may be produced and handled without regard to the requirements of this part. Multi-ingredient agricultural product containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.
- e) Livestock feed
  - i) A raw or processed livestock feed product sold, labeled or represented as “100 percent organic” must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.
  - ii) A raw or processed livestock feed product sold, labeled or represented as “organic” must be produced in conformance with § 205.237.
  - iii) All products labeled as “100 percent organic” or “organic” and all ingredients identified as “organic” in the ingredient statement of any product must not:
    - 1) Be produced using excluded methods, pursuant to § 201.105(e);
    - 2) Be produced using sewage sludge, pursuant to § 201.105(f);
    - 3) Be processed using ionizing radiation, pursuant to § 201.105(g);
- 4) Be processed using processing aids not approved on the National List in subpart G of this part, however products labeled as “100 percent organic,” if processed, must be processed using organically produced processing aids;
- 5) Contain sulfites, nitrates or nitrites added during the production or handling process. However, wine containing added sulfites may be labeled “made with organic grapes”;
- 6) Be produced using non-organic ingredients when organic ingredients are available; or
- 7) Include organic and non-organic forms of the same ingredient.

For complete information about labeling requirements, see sections 205.302-3.11 included in *ATTRA’s Organic Handling Standards Highlights*.

### ***Selected defined terms***

- 1) Audit trail
  - a) Documentation that is sufficient to determine the source, transfer of ownership and transportation of any agricultural product labeled as “100 percent organic,” the organic ingredients of any agricultural product labeled as “organic” or “made with organic (specified ingredients or food groups)” or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as “organic” in an ingredients statement.
- 2) Certified operation
  - a) A crop or livestock production, wild-crop harvesting or handling operation or portion of such operations, that is certified by an accredited certifying agent as utilizing a

system of organic production or handling as described by the Act and the regulations in this part.

- 3) Certifying agent
    - a) Any entity accredited by the secretary as a certifying agent for the purpose of certifying a production or handling operation.
  - 4) Claims
    - a) Oral, written, implied or symbolic representations, statements, advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the terms “100 percent organic,” “organic” or “made with organic (specified ingredients or food groups),” or, in the case of agricultural products containing less than 70 percent organic ingredients, the term “organic” on the ingredients panel.
  - 5) Excluded methods
    - a) A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization or tissue culture.
  - 6) Inspector
    - a) Any person retained or used by a certifying agent to conduct inspections of certification
- applicants or certified production or handling operations.
- 7) Inspection
    - a) The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.
  - 8) Label
    - a) A display of written, printed or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container holding an agricultural product, except for package liners or a display of written, printed or graphic material which contains only information about the weight of the product.
  - 9) Labeling
    - a) All written, printed or graphic material accompanying an agricultural product at any time or written, printed or graphic material about the agricultural product displayed at retail stores.
  - 10) Market information
    - a) Any written, printed, audiovisual or graphic information, including advertising, pamphlets, flyers, catalogues, posters and signs, that are distributed, broadcast or made available outside of retail outlets and used to assist in the sale or promotion of a product.
  - 11) National List of Allowed and Prohibited Substances (National List)
    - a) A list of allowed and prohibited substances as provided for in the Act.
  - 12) National Organic Program
    - a) The program authorized by the Act for the purpose of implementing its provisions.

13) National Organic Standards Board

- a) A board established by the secretary under 7 U.S.C. 6518 to assist in the development of standards for substances to be used in organic production and to advise the secretary on any other aspects of the implementation of the National Organic Program.

14) Non-synthetic.

- a) A substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, non-synthetic is used as a synonym for natural as the term is used in the Act.

15) Organic production

- a) A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological and mechanical practices that foster the cycling of resources, promote ecological balance and conserve biodiversity.

16) Organic system plan

- a) A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

17) Person

- a) An individual, partnership, corporation, association, cooperative or other entity.

18) Practice standard

- a) The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials and conditions to establish a minimum performance level for planning, conducting and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

19) Prohibited substance

- a) A substance that is prohibited or not provided for in the Act or the regulations of this part for use in any aspect of organic production or handling.

20) Records

- a) Any information in written, visual or electronic form that documents the activities of a producer, handler or certifying agent to comply with the Act and regulations in this part.

21) Split operation

- a) An operation that produces or handles both organic and non-organic agricultural products.

22) Synthetic

- a) A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources. The term shall not apply to substances created by naturally occurring biological processes.

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By Ann H. Baier  
NCAT Agriculture Specialist  
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Holly Michels, Editor  
Amy Smith, Production

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