



# Organic Standards for Handling

## Excerpts of USDA's National Organic Program Regulations

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Complete USDA Organic Regulations for organic crop production, livestock production, or handling of agricultural products, as well as requirements for the inspection process and management of certifying agents, can be found on USDA's National Organic Program (NOP) website under Organic Regulations. USDA Organic Regulations are subject to revision or amendment. Check the NOP website at [www.ams.usda.gov/nop](http://www.ams.usda.gov/nop) for the most current version.

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### Introduction

This publication contains verbatim excerpts of selected USDA Organic Regulations that are relevant to operations that handle organic agricultural products. Two similar publications are available from ATTRA: *Organic Standards for Crop Production—Excerpts of USDA's National Organic Program Regulations*; and *Organic Standards for Livestock Production—Excerpts of USDA's National Organic Program Regulations*.

While this publication contains most of the key regulations that directly address handling, it is not a complete collection of all the regulations with which organic handlers must comply. The area of handling includes many types of activities, products and product compositions, labeling, and marketing issues. Review the USDA Organic Regulations in their entirety and check with an accredited organic certifying agent (certifier) to be sure that you are aware of and familiar with all the regulations that apply to your type of operation.

To achieve organic certification to USDA Organic Regulations, you can choose any USDA-accredited organic certifying agent. A list of certifying agents can be found on the NOP website at [www.ams.usda.gov/nop](http://www.ams.usda.gov/nop). You'll then need to complete the necessary application and organic system plan forms. You can clarify any points of compliance for organic production and handling activities with your certifier. Details of this process are described

in the ATTRA publication *Organic Certification Process*.

The Organic Foods Production Act (OFPA) was enacted under the 1990 Farm Bill. The Act authorized creation of USDA's NOP for the production, handling, and processing of organically grown agricultural products. Organic regulations are set forth under Title 7, Part 205 of the Code of Federal Regulations. The Subparts (for example, Subpart A: Definitions; Subpart B: Applicability) are simply part of the outline that organizes these regulations.

The NOP oversees mandatory certification of production and handling of all products to be marketed or represented as organic within the United States. Producers who meet USDA Organic Regulations may label their products as "USDA Certified Organic."

The following sections of Part 205—National Organic Program are excerpted in the order listed below:

#### Subpart B—Applicability

- § 205.100 What has to be certified
- § 205.101 Exemptions and exclusions from certification
- § 205.102 Use of the term "organic"
- § 205.103 Recordkeeping by certified operations
- § 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling

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**Related ATTRA Publications**  
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Organic Certification Process

Organic Standards for Crop Production: Excerpts of USDA's National Organic Program Regulations

Organic Standards for Livestock Production: Excerpts of USDA's National Organic Program Regulations

Subpart C—Organic Production and Handling Requirements

- § 205.200 General
- § 205.201 Organic production and handling system plan
- § 205.270 Organic handling requirements
- § 205.271 Facility pest management practice standard
- § 205.272 Commingling and contact with prohibited substance prevention practice standard

Subpart D—Labels, Labeling, and Market Information

- § 205.300 Use of the term, “organic”
- § 205.301 Product composition
- § 205.302 Calculating the percentage of organically produced ingredients
- § 205.303 Packaged products labeled “100 percent organic” or “organic”
- § 205.304 Packaged products labeled “made with organic (specified ingredients or food group(s))”
- § 205.305 Multi-ingredient packaged products with less than 70 percent organically produced ingredients
- § 205.306 Labeling of livestock feed
- § 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))”
- § 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “100 percent organic” or “organic”
- § 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients or food group(s))”
- § 205.310 Agricultural products produced on an exempt or excluded operation
- § 205.311 USDA Seal

Subpart E—Certification

- § 205.400 General requirements for certification

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

- § 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients
- § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))”
- § 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic”

Subpart A—Definitions

- § 205.2 Terms defined (selected terms relevant to handling)

## Subpart B—Applicability

### **§ 205.100 What has to be certified**

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

(b) Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation’s next anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from February 20, 2001.

(c) Any operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than 3.91(b)(1)(xxxvii) of this title per violation.

(2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

[65 FR 80637, Dec. 21, 2000, as amended at 70 FR 29579, May 24, 2005]

## **§ 205.101 Exemptions and exclusions from certification**

(a) Exemptions.

(1) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.

(3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(b) Exclusions.

(1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and

(ii) The labeling provisions of § 205.310.

(c) Records to be maintained by exempt operations. (1) Any handling operation exempt from

certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

(i) Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

### **§ 205.102 Use of the term "organic"**

Any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be:

(a) Produced in accordance with the requirements specified in § 205.101 or §§ 205.202 through 205.207 or §§ 205.236 through 205.240 and all other applicable requirements of part 205; and

(b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7193, Feb. 17, 2010]

### **§ 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.

### **§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling**

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;

(b) Nonsynthetic substances prohibited in § 205.602 or § 205.604;

(c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;

(d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;

(e) Excluded methods, except for vaccines: Provided, That, the vaccines are approved in accordance with § 205.600(a);

(f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and

(g) Sewage sludge.

## **Subpart C—Organic Production and Handling Requirements**

### **§ 205.200 General**

The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic

(specified ingredients or food group(s))” must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

### **§ 205.201 Organic production and handling system plan**

(a) The 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 group(s))” 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. An organic production or handling system plan must include:

- (1) A description of practices and procedures to be performed and maintained, including 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 recordkeeping 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 nonorganic 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.

### **§ 205.270 Organic handling requirements**

(a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

(b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:

(1) In or on a processed agricultural product intended to be sold, labeled, or represented as “organic,” pursuant to § 205.301(b), if not commercially available in organic form.

(2) In or on a processed agricultural product intended to be sold, labeled, or represented as “made with organic (specified ingredients or food group(s)),” pursuant to § 205.301(c).

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e) and (f) of § 205.105.

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605: Except, That, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement.

### **§ 205.271 Facility pest management practice standard**

(a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:

- (1) Removal of pest habitat, food sources, and breeding areas;
- (2) Prevention of access to handling facilities; and
- (3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.

(b) Pests may be controlled through:

- (1) Mechanical or physical controls including but not limited to traps, light, or sound; or
- (2) Lures and repellents using nonsynthetic or synthetic substances consistent with the National List.

(c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.

(d) If the practices provided for in paragraphs (a), (b), and (c) of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied: Provided, That, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.

(e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.

(f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations: Provided, That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

### **§ 205.272 Commingling and contact with prohibited substance prevention practice standard**

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and non-organic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

- (1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;
- (2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

## **Subpart D—Labels, Labeling, and Market Information**

### **§ 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, including 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 nonorganic ingredient in the product.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: Provided, That, 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.

### **§ 205.301 Product composition**

(a) Products sold, labeled, or represented as “100 percent organic.” 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.” A raw or processed agricultural product sold, labeled, or represented as “organic” must contain (by weight or fluid volume, excluding water and salt) not less than 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 nonorganically 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 group(s)).” Multiingredient agricultural product sold, labeled, or represented as “made with organic (specified ingredients or food group(s))” must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of § 205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of § 205.301. 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. The organic ingredients in multiingredient 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 nonorganic ingredients may

be produced and handled without regard to the requirements of this part. Multiingredient 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. (1) 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.

(2) A raw or processed livestock feed product sold, labeled, or represented as “organic” must be produced in conformance with § 205.237.

(f) 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) of this chapter;

(2) Be produced using sewage sludge, pursuant to § 201.105(f) of this chapter;

(3) Be processed using ionizing radiation, pursuant to § 201.105(g) of this chapter;

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, 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, Except, that, wine containing added sulfites may be labeled “made with organic grapes”;

(6) Be produced using nonorganic ingredients when organic ingredients are available; or

(7) Include organic and nonorganic forms of the same ingredient.

### **§ 205.302 Calculating the percentage of organically produced ingredients**

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified

ingredients or food group(s),” or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

### **§ 205.303 Packaged products labeled “100 percent organic” or “organic”**

(a) Agricultural products in packages described in § 205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:

(1) The term, “100 percent organic” or “organic,” as applicable, to modify the name of the product;

(2) For products labeled “organic,” the percentage of organic ingredients in the product; (The size of the percentage statement must not exceed one-half the size of the largest type size on the

panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

(3) The term, “organic,” to identify the organic ingredients in multi-ingredient products labeled “100 percent organic”;

(4) The USDA seal; and/or

(5) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: Provided, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: Provided further, That, such seals or marks are not individually displayed more prominently than the USDA seal.

(b) Agricultural products in packages described in § 205.301(a) and (b) must:

(1) For products labeled “organic,” identify each organic ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by \* \* \*,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

### **§ 205.304 Packaged products labeled “made with organic (specified ingredients or food group(s))”**

(a) Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other

panel and on any labeling or market information concerning the product:

(1) The statement:

(i) “Made with organic (specified ingredients)”: Provided, That, the statement does not list more than three organically produced ingredients; or

(ii) “Made with organic (specified food groups)”: Provided, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, Provided further, That, all ingredients of each listed food group in the product must be organically produced; and

(iii) Which appears in letters that do not exceed one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.

(2) The percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.

(3) The seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product.

(b) Agricultural products in packages described in § 205.301(c) must:

(1) In the ingredient statement, identify each organic ingredient with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by \* \* \*,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: Except, That, the business address, Internet address, or telephone number of the certifying agent may be included in such label.

(c) Agricultural products in packages described in § 205.301(c) must not display the USDA seal.

### **§ 205.305 Multi-ingredient packaged products with less than 70 percent organically produced ingredients**

(a) An agricultural product with less than 70 percent organically produced ingredients may only identify the organic content of the product by:

(1) Identifying each organically produced ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced, and

(2) If the organically produced ingredients are identified in the ingredient statement, displaying the product’s percentage of organic contents on the information panel.

(b) Agricultural products with less than 70 percent organically produced ingredients must not display:

(1) The USDA seal; and

(2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

### **§ 205.306 Labeling of livestock feed**

(a) Livestock feed products described in § 205.301(e)(1) and (e)(2) may display on any package panel the following terms:

(1) The statement, “100 percent organic” or “organic,” as applicable, to modify the name of the feed product;

(2) The USDA seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, Provided, That, such seals or marks are not displayed more prominently than the USDA seal;

(4) The word, “organic,” or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

(b) Livestock feed products described in § 205.301(e)(1) and (e)(2) must:

(1) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by \* \* \*,” or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

(2) Comply with other Federal agency or State feed labeling requirements as applicable.

**§ 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))”**

(a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

- (1) The name and contact information of the certifying agent which certified the handler which assembled the final product;
- (2) Identification of the product as organic;
- (3) Special handling instructions needed to maintain the organic integrity of the product;
- (4) The USDA seal;
- (5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

(b) Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of des-

tinuation or the container labeling specifications of a foreign contract buyer: Provided, That, the shipping containers and shipping documents accompanying such organic products are clearly marked “For Export Only” and: Provided further, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under § 205.101.

**§ 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “100 percent organic” or “organic”**

(a) Agricultural products in other than packaged form may use the term, “100 percent organic” or “organic,” as applicable, to modify the name of the product in retail display, labeling, and display containers: Provided, That, the term, “organic,” is used to identify the organic ingredients listed in the ingredient statement.

(b) If the product is prepared in a certified facility, the retail display, labeling, and display containers may use:

- (1) The USDA seal; and
- (2) The seal, logo, or other identifying mark of the certifying agent that certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: Provided, That, such seals or marks are not individually displayed more prominently than the USDA seal.

**§ 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients or food group(s))”**

(a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, “made with organic (specified ingre-

dients or food group(s)),” to modify the name of the product in retail display, labeling, and display containers.

(1) Such statement must not list more than three organic ingredients or food groups, and

(2) In any such display of the product’s ingredient statement, the organic ingredients are identified as “organic.”

(b) If prepared in a certified facility, such agricultural products labeled as “made with organic (specified ingredients or food group(s))” in retail displays, display containers, and market information may display the certifying agent’s seal, logo, or other identifying mark.

### **§ 205.310 Agricultural products produced on an exempt or excluded operation**

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA seal or any certifying agent’s seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as “organic” in a product processed by others.

(c) Such product is subject to requirements specified in paragraph (a) of § 205.300, and paragraphs (f)(1) through (f)(7) of § 205.301.

### **§ 205.311 USDA Seal**



(a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for raw or processed agricultural products described

in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.

(b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white background with a brown outer circle and with the term, “USDA,” in green overlaying a white upper semicircle and with the term, “organic,” in white overlaying the green lower half circle; or

(2) On a white or transparent background with black outer circle and black “USDA” on a white or transparent upper half of the circle with a contrasting white or transparent “organic” on the black lower half circle.

(3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.

## **Subpart E—Certification**

### **§ 205.400 General requirements for certification**

A person seeking to receive or maintain organic certification under the regulations in this part must:

(a) Comply with the Act and applicable organic production and handling regulations of this part;

(b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;

(c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in § 205.403;

(d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic program’s governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;

(e) Submit the applicable fees charged by the certifying agent; and

(f) Immediately notify the certifying agent concerning any:

(1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and

(2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

## Subpart G—Administrative

### The National List of Allowed and Prohibited Substances

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

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

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(b) 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 recreate or improve flavors, colors, textures, or nutritive value lost during process-

ing, except where the replacement of nutrients is required by law;

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

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

(c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

#### ***§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."***

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

(a) Nonsynthetics allowed:

Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic)

Agar-agar

Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin)

Bentonite

Calcium carbonate

Calcium chloride

Calcium sulfate—mined

Carrageenan

Dairy cultures

Diatomaceous earth—food filtering aid only

Egg white lysozyme (CAS # 9001-63-2)

Enzymes—must be derived from edible, non-toxic plants, nonpathogenic fungi, or nonpathogenic bacteria

Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative

Gellan gum (CAS # 71010-52-1)—high-acyl form only

Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited

Kaolin

L-Malic acid (CAS # 97-67-6)

Magnesium sulfate, nonsynthetic sources only

Microorganisms—any food grade bacteria, fungi, and other microorganism

Nitrogen—oil-free grades

Oxygen—oil-free grades

Perlite—for use only as a filter aid in food processing

Potassium chloride

Potassium iodide

Sodium bicarbonate

Sodium carbonate

Tartaric acid—made from grape wine

Waxes—nonsynthetic (Carnauba wax; and Wood resin)

Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked—nonsynthetic smoke flavoring process must be documented)

(b) Synthetics allowed:

Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only

Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid

Alginates

Ammonium bicarbonate—for use only as a leavening agent

Ammonium carbonate—for use only as a leavening agent

Ascorbic acid

Calcium citrate

Calcium hydroxide

Calcium phosphates (monobasic, dibasic, and tribasic)

Carbon dioxide

Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid

Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite)

Cyclohexylamine (CAS # 108-91-8)—for use only as a boiler water additive for packaging sterilization

Diethylaminoethanol (CAS # 100-37-8)—for use only as a boiler water additive for packaging sterilization

Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus

Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization)

Glycerides (mono and di)—for use only in drum drying of food

Glycerin—produced by hydrolysis of fats and oils

Hydrogen peroxide

Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))” prohibited in agricultural products labeled “organic”

Magnesium chloride—derived from sea water

Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))” prohibited in agricultural products labeled “organic”

Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods

Octadecylamine (CAS # 124-30-1)—for use only as a boiler water additive for packaging sterilization

Ozone

Pectin (low-methoxy)

Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces

Phosphoric acid—cleaning of food-contact surfaces and equipment only

Potassium acid tartrate

Potassium carbonate

Potassium citrate

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process

Potassium iodide—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Potassium phosphate—for use only in agricultural products labeled “made with organic (specific ingredients or food group(s)),” prohibited in agricultural products labeled “organic”

Silicon dioxide

Sodium acid pyrophosphate (CAS # 7758–16–9)—for use only as a leavening agent

Sodium citrate

Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables

Sodium phosphates—for use only in dairy foods

Sulfur dioxide—for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm

Tartaric acid—made from malic acid

Tetrasodium pyrophosphate (CAS # 7722–88–5)—for use only in meat analog products

Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative

Xanthan gum

(c)–(z) [Reserved]

[68 FR 61993, Oct. 31, 2003, as amended as 68 FR 62217, Nov. 3, 2003; 71 FR 53302, Sept.

11, 2006; 72 FR 58473, Oct. 16, 2007; 73 FR 59481, Oct. 9, 2008; 75 FR 77524, Dec. 13, 2010; 77 FR 8092, Feb. 14, 2012]

**§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic”**

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form

- (a) Casings, from processed intestines
- (b) Celery powder
- (c) Chia (*Salvia hispanica* L.)
- (d) Colors derived from agricultural products
  - (1) Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble
  - (2) Beet juice extract color (pigment CAS # 7659–95–2)
  - (3) Beta-carotene extract color, derived from carrots (CAS # 1393–63–1)
  - (4) Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3)
  - (5) Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3)
  - (6) Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3)
  - (7) Carrot juice color (pigment CAS # 1393–63–1)
  - (8) Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3)
  - (9) Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3)
  - (10) Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3)

- (11) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (12) Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (13) Paprika color (CAS # 68917-78-2)—dried, and oil extracted
- (14) Pumpkin juice color (pigment CAS # 127-40-2)
- (15) Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (16) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (17) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (18) Saffron extract color (pigment CAS # 1393-63-1)
- (19) Turmeric extract color (CAS # 458-37-7)
- (e) Dillweed oil (CAS # 8006-75-5)
- (f) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606
- (g) Fortified cooking wines
- (1) Marsala
- (2) Sherry
- (h) Fructooligosaccharides (CAS # 308066-66-2)
- (i) Galangal, frozen
- (j) Gelatin (CAS # 9000-70-8)
- (k) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean)
- (l) Hops ( *Humulus lupulus* )
- (m) Inulin-oligofructose enriched (CAS # 9005-80-5)
- (n) Kelp—for use only as a thickener and dietary supplement
- (o) Konjac flour (CAS # 37220-17-0)

- (p) Lecithin—unbleached
- (q) Lemongrass—frozen
- (r) Orange shellac-unbleached (CAS # 9000-59-3)
- (s) Pectin (high-methoxy)
- (t) Peppers (Chipotle chile)
- (u) Starches
- (1) Cornstarch (native)
- (2) Rice starch, unmodified (CAS # 977000-08-0)—for use in organic handling until June 21, 2009
- (3) Sweet potato starch—for bean thread production only
- (v) Tragacanth gum (CAS #-9000-65-1)
- (w) Turkish bay leaves
- (x) Wakame seaweed (*Undaria pinnatifida* )
- (y) Whey protein concentrate

[72 FR 35140, June 27, 2007, as amended at 75 FR 77524, Dec. 13, 2010]

## Subpart A—Definitions

### § 205.2 *Terms defined (selected terms relevant to handling)*

**Agricultural product.** Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

**Allowed synthetic.** A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

**AMDUCA.** The Animal Medicinal Drug Use Clarification Act of 1994 (Pub. L. 103-396).

**Audit trail.** 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 the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement.

**Biodegradable.** Subject to biological decomposition into simpler biochemical or chemical components.

**Bulk.** The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.

**Certification or certified.** A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

**Certified operation.** A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation 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.

**Certifying agent.** Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.

**Certifying agent's operation.** All sites, facilities, personnel, and records used by a certifying agent to conduct certification activities under the Act and the regulations in this part.

**Claims.** Oral, written, implied, or symbolic representations, statements, or advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the term, "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or, in the case of agricultural products containing less than 70 percent organic ingredients, the term, "organic," on the ingredients panel.

**Commercially available.** The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

**Commingling.** Physical contact between unpackaged organically produced and nonorganically produced agricultural products during production, processing, transportation, storage or handling, other than during the manufacture of a multiingredient product containing both types of ingredients.

**Excipients.** Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

**Excluded methods.** 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.

**Feed.** Edible materials which are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage, fodder). The term, "feed," encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

**Feed additive.** A substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals.

**Feed supplement.** A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be: (1) Diluted with other feeds when fed to livestock; (2) Offered free choice with other parts of the ration if separately available; or (3) Further diluted and mixed to produce a complete feed.

**Handle.** To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

**Handler.** Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their

own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

**Handling operation.** Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

**Information panel.** That part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one usable surface).

**Ingredient.** Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

**Ingredients statement.** The list of ingredients contained in a product shown in their common and usual names in the descending order of predominance.

**Inspection.** 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.

**Inspector.** Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations.

**Label.** 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 containing 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.

**Labeling.** 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 about the product.

**Lot.** Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing

house and which are available for inspection at the same time.

**Market information.** Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcast, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.

**National Organic Program (NOP).** The program authorized by the Act for the purpose of implementing its provisions.

**Natural resources of the operation.** The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

**Nonagricultural substance.** A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

**Nonsynthetic (natural).** 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, nonsynthetic is used as a synonym for natural as the term is used in the Act.

**Nonretail container.** Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

**Nontoxic.** Not known to cause any adverse physiological effects in animals, plants, humans, or the environment.

**Organic.** A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.

**Organic production.** 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 cycling of

resources, promote ecological balance, and conserve biodiversity.

**Organic system plan.** 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 that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

**Principal display panel.** That part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.

**Private entity.** Any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services.

**Processing.** Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

**Processing aid.** (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form; (2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and (3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

**Producer.** A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products.

**Production lot number/identifier.** Identification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.

**Prohibited substance.** A substance the use of which in any aspect of organic production or

handling is prohibited or not provided for in the Act or the regulations of this part.

**Records.** Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part.

**Responsibly connected.** Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.

**Retail food establishment.** A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat food.

**Sewage sludge.** A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

**Split operation.** An operation that produces or handles both organic and nonorganic agricultural products.

**Synthetic.** 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, except that such term shall not apply to substances created by naturally occurring biological processes.

**Wild crop.** Any plant or portion of a plant that is collected or harvested from a site that is not maintained under cultivation or other agricultural management.

# Notes

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**Organic Standards for Handling**

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