

Labeling -- Preamble

Subpart D - Labels, Labeling, and Market Information

The Act provides that a person may sell or label an agricultural product as organically produced only if the product has been produced and handled in accordance with provisions of the Act and these regulations. This subpart sets forth labeling requirements for organic agricultural products and products with organic ingredients based on their percentage of organic composition. For each labeling category, this subpart establishes what organic terms and references can and cannot be displayed on a product package's principal display panel (pdp), information panel, ingredient statement, and on other package panels. Labeling requirements also are established for organically produced livestock feed, for containers used in shipping and storing organic product, and for denoting organic bulk products in market information which is displayed or disseminated at the point of retail sale. Restrictions on labeling organic product produced by exempt operations are established. Finally, this subpart provides for a USDA seal and regulations for display of the USDA seal and the seals, logos, or other identifying marks of certifying agents.

The intent of these sections is to ensure that organically produced agricultural products and ingredients are consistently labeled to aid consumers in selection of organic products and to prevent labeling abuses. These provisions cover the labeling of a product as organic and are not intended to supersede other labeling requirements specified in other Federal labeling regulations. The Food and Drug Administration (FDA) regulates the placement of information on food product packages in 21 CFR parts 1 and 101. USDA's Food Safety and Inspection Service's (FSIS) Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act have implementing regulations in 9 CFR part 317 which must be followed in the labeling of meat, poultry, and egg products. The Federal Trade Commission (FTC) regulations under the Fair Packaging and Labeling Act (FLPA) in 16 CFR part 500 and the Alcohol Tobacco and Firearms (ATF) regulations under the Federal Alcohol Administration Act (FAA) in 27 CFR parts 4, 5, and 7, also must be followed, as applicable to the nature of the product. The labeling requirements specified in this subpart must be implemented in a manner so that they do not conflict with the labeling requirements of these and other Federal labeling requirements.

While this regulation does not require labeling of an organic product as organic, we assume that producers and handlers choose to label their organic products and display the USDA seal to the extent allowed in these regulations. They do this to improve the marketability of their organic product.

Under the National Organic Program (NOP), the assembly, packaging, and labeling of multiingredient organic products are considered handling activities. The certification of handling operations is covered in subpart C of this regulation. No claims, statements, or marks using the term, "organic," or display of certification seals, other than as provided in this regulation, may be used. Based on comments received, several important labeling changes from the proposed rule are made in this final rule. (1) The term, "organic," cannot be used in an agricultural product name if it modifies an ingredient that is not organically produced (e.g., "organic chocolate ice cream" when the chocolate flavoring is not organically produced). (2) The 5 percent or less of nonorganic ingredients in products labeled "organic" must be determined not "commercially available" in organic form. (3) Display of a product's organic percentage is changed from required to optional for "organic" and "made with ..." products. (4) The minimum organic content for "made with..." products is increased from 50 percent to 70 percent. (5) In addition to listing individual ingredients, the "made with..." label may identify a food group on the label ("made with organic fruit"). (6) A new section is added to provide labeling of livestock feed that is organically produced. (7) Finally, a revised design for the USDA seal is established. In addition to these changes, we have made a few changes in the regulatory text for clarity and consistency purposes. These do not change the intent of the regulation.

Once a handler makes a decision to market a product as organic or containing organic ingredients, the handler is required to follow the provisions in this subpart regarding use, display, and location of organic claims and certification seals. Handlers who produce and label organic ingredients and/or assemble multiingredient products composed of 70 percent or more organic ingredients must be certified as an organic handling operation. Handlers of products of less than 70 percent organic ingredients do not have to be certified unless the handler actually produces one or more of the organic ingredients used in the product. Repackers who purchase certified organic product from other entities for repackaging and labeling must be certified as an organic operation. Entities which simply relabel an organic product package are subject to recordkeeping requirements which show proof that the product purchased prior to relabeling was, indeed, organically produced and handled. Distributors which receive and transport labeled product to market are not subject to certification or any labeling requirements of this regulation.

Many commenters appealed for "transition" or "conversion" labeling. This issue is discussed under Applicability in subpart B. Transition labeling is not provided for in the Act or the proposed rule and is not provided for in this regulation.

Description of Regulations

General Requirements

The general labeling principle employed in this regulation is that labeling or identification of the organic nature of a product increases as the organic content of the product increases. In other words, the higher the organic content of a product, the more prominently its organic nature can be displayed. This is consistent with provisions of the Act which establish the three percentage categories for organic content and basic labeling requirements in those categories.

Section 205.300 specifies the general use of the term, "organic," on product labels and market information. Paragraph (a) establishes that the term, "organic," may be used only on labels and in market information as a modifier of agricultural products and ingredients that have been certified as produced and handled in accordance with these regulations. The term, "organic," cannot be used on a product label or in market information for any purpose other than to modify or identify the product or ingredient in the product that is organically produced and handled. Food products and ingredients that are not organically produced and handled cannot be modified, described, or identified with the term, "organic," on any package panel or in market information in any way that implies the product is organically produced.

Section 6519(b) of the Act provides the Secretary with the authority to review use of the term, "organic," in agricultural product names and the names of companies that produce agricultural products. While we believe that the term, "organic," in a brand name context does not inherently imply an organic production or handling claim and, thus, does not inherently constitute a false or misleading statement, we intend to monitor the use of the term in the context of the entire label. We will consult with the FTC and FDA regarding product and company names that may misrepresent the nature of the product and take action on a case-by-case basis.

Categories of Organic Content

Section 205.301 establishes the organic content requirements for different labeling provisions specified under this program. The type of labeling and market information that can be used and its placement on different panels of consumer packages and in market information is based on the percentage of organic ingredients in the product. The percentage must reflect the actual weight or fluid volume (excluding water and salt) of the organic ingredients in the product. Four categories of organic content are established: 100 percent organic; 95 percent or more organic; 70 to 95 percent organic; and less than 70 percent organic.

100 Percent Organic

For labeling and market information purposes, this regulation allows a "100 percent organic" label on: (1) agricultural products that are composed of a single ingredient such as raw, organically produced fruits and vegetables and (2) products composed of two or more organically produced ingredients, provided that the individual ingredients are, themselves, wholly organic and produced without any nonorganic ingredients or additives. Only processing aids which are, themselves, organically produced, may be used in the production of products labeled "100 percent organic." With the exception of the description phrase "100 percent" on the pdp, the labeling requirements for "100 percent organic" products are the same as requirements for 95 percent organic products specified in section 205.303.

Organic

Products labeled or represented as "organic" must contain, by weight (excluding water and salt), at least 95 percent organically produced raw or processed agricultural product. The organic ingredients must be produced using production and handling practices pursuant to subpart C. Up to 5 percent of the ingredients may be nonagricultural substances (consistent with the National List) and, if not commercially available in organic form pursuant to section 205.201, nonorganic agricultural products and ingredients in minor amounts (hereinafter referred to as minor ingredients) (spices, flavors, colorings, oils, vitamins, minerals, accessory nutrients, incidental food additives). The nonorganic ingredients must not be produced using excluded methods, sewage sludge, or ionizing radiation.

Made with Organic Ingredients

For labeling and market information purposes, the third category of agricultural products are multiingredient products containing by weight or fluid volume (excluding water and salt) between 70 and 95 percent organic agricultural ingredients. The organic ingredients must be produced in accordance with subpart C and subpart G. Such products may be labeled or represented as "made with organic (specified ingredients or food group(s))." By "specified," we mean the name of the agricultural product(s) or food group(s) forming the organic ingredient(s). Up to three organically produced ingredients or food groups may be named in the phrase.

If one or more food groups are specified in the phrase, all ingredients in the product which belong to the food group(s) identified on the label must be organically produced. For the purposes of this labeling, the following food groups may be identified as organically produced on a food package label: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables. In addition, processed milk products (butter, cheese, yogurt, milk, sour creams, etc.) also may be identified as a "milk products" food group. For instance, a vegetable soup made with 85 percent organically produced and handled potatoes, tomatoes, peppers, celery, and onions may be labeled "soup made with organic potatoes, tomatoes, and peppers" or, alternatively, "soup made with organic vegetables." In the latter example, the soup may not contain nonorganic vegetables. For the purposes of this labeling provision, tomatoes are classified, according to food use, as a vegetable.

To qualify for this organic labeling, the nonorganic agricultural ingredients must be produced and handled without use of the first three prohibited practices specified in paragraph (f) of section 205.301, but may be produced or handled using practices prohibited in paragraphs (f)(4) through (f)(7).

Because of the length of the labeling phrase "made with organic (specified ingredients or food group(s)), such products are referred to in this preamble as "made with..." products. The labeling requirements for "made with..." products are specified in section 205.304.

Product With Less Than 70 Percent Organic Ingredients

The final labeling category covers multiingredient products with less than 70 percent organic ingredients (by weight or fluid volume, excluding water and salt). The organic ingredients must be produced in accordance with subparts C and G. The remaining nonorganic ingredients may be produced, handled, and assembled without regard to these regulations (using prohibited substances and prohibited production and handling practices). Organic labeling of these products is limited to the information panel only as provided in section 205.305.

Products that fail to meet the requirements for one labeling category may be eligible for a lower labeling category. For example, if a product contains wholly organic ingredients but the product formulation requires a processing aid or less than 5 percent of a minor ingredient that does not exist in organic form, the product cannot be labeled "100 percent organic" and must be labeled as "organic." If a multiingredient product is 95 percent or more organic but contains a prohibited substance in the remaining 5 percent, the product cannot be labeled as "organic," because of the presence of the prohibited substance, but may be labeled as a "made with..." product. Further, a handler who produces a "100 percent organic" or "organic" product but chooses not to be certified under this program may only display the organic percentage on the information panel and label the ingredients as "organic" on the ingredient statement. The handler must comply with recordkeeping requirements in subpart E.

Livestock feed

All agricultural ingredients used in raw and processed livestock feed that is labeled as "100 percent organic" and "organic" must be organically produced and handled in accordance with the requirements of these regulations. The difference between the two labels is that feed labeled as "100 percent organic" must be composed only of organically produced agricultural ingredients and may not contain nonorganic feed additives or supplements. The agricultural portion of livestock feed labeled as "organic" must contain only organically produced raw and processed agricultural ingredients and may contain feed additives and supplements in conformance with the requirements of section 205.237. Additionally, labeling of livestock feed containers must follow State livestock feed labeling laws.

Prohibited Practices

The labeling of whole products or ingredients as organic is prohibited if those products or ingredients are produced using any of the following production or handling practices: (1) ingredients or processing aids produced using excluded methods; (2) ingredients that have been produced using applications of sewage sludge; (3) ingredients that have been processed with ionizing radiation; (4) synthetic substances not on the National List; (5) sulfites, nitrates, or nitrites added to or used in processing of an organic product in addition to those substances occurring naturally in a commodity (except the use of sulfites in the production of wine); (6) use of the phrase, "organic when available," or similar statement on labels or in market information when referring to products composed of nonorganic ingredients used in place of specified organic ingredients; and (7) labeling as "organic" any product containing both organic and nonorganic forms of an ingredient specified as "organic" on the label.

These seven prohibitions apply to the four labeling categories of products and are not individually repeated as prohibited practices in the following sections. Table 1, Prohibited Production and Handling Practices for Organic Labeling, shows how use of the seven prohibited practices affects the labeling of organically produced products and ingredients used in those products.

TABLE 1: PROHIBITED PRODUCTION AND HANDLING PRACTICES FOR LABELING CATEGORIES

Organic and use label	Use excluded methods	Use sewage sludge	Use ionizing radiation	Use substances not on National List	Contain added sulfites, nitrates, nitrites	Use nonorganic ingredients and label "when available"	Use both organic and nonorganic forms of same ingredient
"100 percent organic" Single/multiingredients completely organic	NO	NO	NO	NO	NO	NO	NO
"Organic"							
Organic ingredients (95% or more)	NO	NO	NO	NO	NO	NO	NO
Nonorganic ingredients (5% or less)	NO	NO	NO	NO	NO	NO	NO
"Made with organic ingredients"							
Organic ingredients (70-95%)	NO	NO	NO	NO	NO-except wine	NO	NO
Nonorganic ingredients (30% or less)	NO	NO	NO	OK	OK	NA*	NA*
Less-than 70% organic ingredients							
Organic Ingredients (30% or less)	NO	NO	NO	NO	NO-except wine	NO	NO
Nonorganic Ingredients (70% or more)	OK	OK	OK	OK	OK	NA*	NA*

* Not applicable, provided that the nonorganic ingredient is not labeled as "organic" on the ingredient statement and is not counted in the calculation of the product's organic percentage.

Calculating the Percentage of Organic Ingredients

Section 205.302 specifies procedures for calculating the percentage, by weight or fluid volume, of organically produced ingredients in an agricultural product labeled or represented as "organic." The calculation is made by the handler at the time the finished product is assembled.

The organic percentage of liquid products and liquid ingredients is determined based on the fluid volume of the product and ingredients (excluding water and salt). When a product is identified on the pdp or the information panel as being reconstituted with water from a concentrate, the organic content is calculated on the basis of a single-strength concentration.

For products that contain organically produced dry and liquid ingredients, the percentage of total organic ingredients is based on the combined weight of the dry organic ingredient(s) and the weight of the liquid organic ingredient(s) (excluding water and salt). For example, a product may be made using organically produced vegetable oils or grain oils or contain organic liquid flavoring extracts in addition to other organic and nonorganic ingredients. In such cases, the weight of the liquid organic oils or flavoring extracts, less any added water and salt, would be added to other solid organic ingredients in the product, and their combined weight would be the basis for calculating the percentage of organic ingredients.

At the discretion of the handler, the total percentage of all organic ingredients in a food product may be displayed on any package panel of the product with the phrase, "contains X percent organic ingredients," or a similar phrase. If the total percentage is a fraction, it must be rounded down to the nearest whole number. The percentage of each organic ingredient is not required to be displayed in the ingredient statement.

A certified operation that produces organic product may contract with another operation to repackage and/or relabel the product in consumer packages. In such cases, the repacker or relabeler may use information provided by the certified operation to determine the percentage of organic ingredients and properly label the organic product package consistent with the requirements of this subpart.

Labeling "100 Percent Organic" and "Organic" Products

Section 205.303 includes optional, required, and prohibited practices for labeling agricultural products that are "100 percent organic" or "organic." Products that are composed of wholly organic ingredients may be identified with the label statement, "100 percent organic," on any package panel. Products composed of between 95 and 100 percent organic ingredients may be identified with the label statement "organic" on any package panel, and the handler must identify each organic ingredient in the ingredient statement.

The handler may display the following information on the pdp, the information panel, and any other part of the package and in market information representing the product: (1) the term, "100 percent organic" or "organic," as applicable to the content of the product; and (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. It also must appear in its entirety in the same type size, style, and color without highlighting; (3) the USDA seal; and (4) the seal, logo, or other identifying mark of the certifying agent (hereafter referred to as "seal or logo") which certified the handler of the finished product. The seals or logos of other certifying agents which certified organic raw materials or organic ingredients used in the product also may be displayed, at the discretion of the finished product handler. If multiple organic ingredients are identified on the ingredient

statement, the handler of the finished product that combined the various organic ingredients must maintain documentation, pursuant to subpart B of this regulation.

While certifying agent identifications can appear on the package with the USDA seal, they may not appear larger than the USDA seal on the package. There is no restriction on the size of the USDA seal as it may appear on any panel of a packaged product, provided that display of the Seal conforms with the labeling requirements of FDA and FSIS.

If a product is labeled as "100 percent organic" the ingredients may be identified with the term, "organic," but will not have to be so labeled because it is assumed from the 100 percent label that all ingredients are organic. For 95 percent-plus products, each organically produced ingredient listed in the ingredient statement must be identified with the term, "organic," or an asterisk or other mark to indicate that the ingredient is organically produced. Water and salt cannot be identified as "organic" in the ingredient statement.

The handler of these products also must display on the information panel the name of the certifying agent which certified the handling operation that produced the finished product. The handler may include the business address, Internet address, or telephone number of the certifying agent. This information must be placed below or otherwise near the manufacturer or distributor's name.

Labeling Products "Made with Organic (specified ingredients or food group(s))"

With regard to agricultural products "made with..."--those products containing between 70 and 95 percent organic ingredients--this rule establishes, in section 205.304, the following optional, required, and prohibited labeling practices.

Under optional practices, the "made with..." statement is used to identify the organically produced ingredients in the product. The statement may be placed on the pdp and other panels of the package. The same statement can also be used in market information representing the product. However, the following restrictions are placed on the statement: (1) the statement may list up to three ingredients or food group commodities that are in the product; (2) the individually specified ingredients and all ingredients in a labeled food group must be organically produced and must be identified as "organic" in the ingredient statement on the package's information panel; (3) the statement cannot appear in print that is larger than one half (50 percent) of the size of the largest print or type appearing on the pdp; and (4) The statement and optional display of the product's organic percentage must appear in their entirety in the same type size, style, and color without highlighting.

The following food groups can be specified in the "made with" labeling statement: fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables. In addition, organically produced and processed butter, cheeses, yogurt, milk, sour cream, etc., may be identified as a "milk products" food group. For the purposes of this labeling, tomatoes are considered as vegetables, based on their use in a product. As noted immediately above, all of a product's ingredients that are in the specified food group(s) must be organically produced.

Display of the "made with..." statement on other panels must be similarly consistent with the size of print used on those panels. These restrictions are in accordance with FDA labeling requirements and similar to the recommendations of the National Organic Standards Board (NOSB). This provision helps assure that the "made with..." statement is not displayed in such a manner as to misrepresent the actual organic composition of the product.

The USDA seal may not be displayed on the pdp of products labeled "made with organic ingredients." However, at the handler's option and consistent with any contract agreement

between the organic producer or handler and the certifying agent, the certifying agent's seal or logo may be displayed on the pdp and other package panels.

Packages of "made with..." products may display on the pdp, information panel, or any package panel, the total percentage of organic ingredients in the product. Any organically produced ingredient, including any ingredient that is a member of a food group listed on the "made with..." statement, must be identified in the ingredient statement with the term, "organic." Alternatively, an asterisk or other mark may be placed beside each organically produced ingredient in the ingredients statement with an explanation that the mark indicates the ingredient is organically produced.

The name of the certifying agent which certified the handler of the finished product must be displayed below or otherwise near the manufacturer or distributor's name. The statement may include the phrase, "Certified organic by..." or "Ingredients certified as organically produced by...." to help distinguish the certifying agent from the manufacturer or distributor. The handler may include the business address, Internet address, or telephone number of the certifying agent which certified the handler of the finished product.

If the percentage of organic ingredients in the product is displayed, the handler who affixes the label to the product package is responsible for determining the percentage. The handler may use information provided by the certified operation in determining the percentage. As part of the certifying agent's annual certification of the handler, the certifier must verify the calculation and labeling of packages.

Labeling Products with Less Than 70 Percent Organic Ingredients

Section 205.305 covers the final labeling category of packaged multiingredient agricultural products containing less than 70 percent organic ingredients.

Handlers of "less than 70 percent" multiingredient products, who choose to declare the organic nature of their product, may do so only in the ingredient statement by identifying the organically produced ingredients with the term, "organic," or with an asterisk or other mark. If the handler identifies the ingredients that are organically produced, the handler also may declare the percentage of organic content in the product. The percentage may only be placed on the information panel so that it can be viewed in relation to the ingredient statement.

Processed products composed of less than 70 percent organic content cannot display the USDA seal or any certifying agent's organic certification seal or logo anywhere on the product package or in market information.

Handlers of such products are subject to this regulation in the following ways. Those handlers who only purchase organic and nonorganic ingredients and assemble a finished product of less than 70 percent organic content do not have to be certified as organic handlers. However, they are responsible for appropriate handling and storage of the organic ingredients (section 205.101(a)(3)) and for maintaining records verifying the organic certification of the ingredients used in the product (section 205.101(c)). To the extent that the packaging process includes affixing the label to finished product package, those handlers are responsible for meeting the labeling requirements of this subpart. The nonorganic ingredients may be produced, handled, and assembled without regard to the requirements of this part.

Table 2, Labeling Consumer Product Packages, provides a summary of the required and prohibited labeling practices for the four labeling categories.

TABLE 2: LABELING CONSUMER PRODUCT PACKAGES

Labeling category	Principle display panel	Information panel	Ingredient statement	Other package panels
"100 percent Organic" (Entirely organic; whole, raw or processed product)	"100 percent organic" (optional) USDA seal and certifying agent seal(s) (optional)	"100% organic" (optional) Certifying agent name (required); business/Internet address, tele. # (optional)	If multiingredient product, identify each ingredient as "organic" (optional)	"100 percent organic" (optional) USDA seal and certifying agent seal(s) (optional)
"Organic" (95% or more organic ingredients)	"Organic" (plus product name) (optional) "X% organic" (optional) USDA seal and certifying agent seal(s) (optional)	"X % organic" (optional) Certifying agent name (required); business/Internet address, tele. # (optional)	Identify organic ingredients as "organic" (required if other organic labeling is shown)	X% organic" (optional) USDA seal and certifying agent seal(s) (optional)
"Made with Organic Ingredients" (70 to 95% organic ingredients)	"made with organic (ingredients or food group(s))" (optional) "X % organic" (optional) Certifying agent seal of final product handler (optional) <u>Prohibited: USDA seal</u>	"X % organic ingredients" (optional) Certifying agent name (required); business/Internet address, tele. # (optional) <u>Prohibited: USDA seal</u>	Identify organic ingredients as "organic" (required if other organic labeling is shown)	"made with organic (ingredients or food group(s))" (optional) "X % organic" (optional) Certifying agent seal of final product handler (optional) <u>Prohibited: USDA seal</u>
Less-than 70% organic ingredients	<u>Prohibited: Any reference to organic content of product</u> <u>Prohibited: USDA seal & certifying agent seal</u>	"X % organic" (optional) <u>Prohibited: USDA seal & certifying agent seal</u>	Identify organic ingredients as "organic" (optional) (required if % organic is displayed)	<u>Prohibited: USDA seal & certifying agent seal</u>

Misrepresentation in Labeling of Organic Products. The labeling requirements of this final rule are

intended to assure that the term, "organic," and other similar terms or phrases are not used on a product package or in marketing information in a way that misleads consumers as to the contents of the package. Thus, we intend to monitor the use of the term, "organic," and other similar terms and phrases. If terms or phrases are used on product packages to represent "organic" when the products are not produced to the requirements of this regulation, we will proceed to restrict their use.

Handlers may not qualify or modify the term, "organic," using adjectives such as, "pure" or "healthy," e.g., "pure organic beef" or "healthy organic celery." The term, "organic," is used in labeling to indicate a certified system of agricultural production and handling. Terms such as "pure," "healthy," and other similar adjectives attribute hygienic, compositional, or nutritional characteristics to products. Use of such adjectives may misrepresent products produced under the organic system of agriculture as having special qualities as a result of being produced under the organic system. Furthermore, use of such adjectives would incorrectly imply that products labeled in this manner are different from other organic products that are not so labeled.

Moreover, "pure," "healthy," and other similar terms are regulated by FDA and FSIS. These terms may be used only in accordance with the labeling requirements of FDA and FSIS. The prohibition on use of these terms to modify "organic" does not otherwise preclude their use in other labeling statements as long as such statements are in accordance with other applicable regulations. Representations made in market information for organic products are also subject to the requirements and restrictions of other Federal statutes and applicable regulations, including the Federal Trade Commission Act, 15 U.S.C. 45 et seq.

Labeling Organically Produced Livestock Feed Products

New section 205.306 is added to provide for labeling of the two categories of livestock feed that are organically produced under this regulation. Feed labeled "100 percent organic" may contain only organically produced agricultural product. Such feed must not contain feed additives, supplements, or synthetic substances. Feed labeled "organic" must contain only organically produced agricultural products and may contain feed additives and supplements in accordance with section 205.237, Livestock Feed, and section 205.603 of the National List. This rule does not limit the percentage of such additives and supplements in organic feed products, which may be required under various State laws.

Livestock feed labeled "100 percent organic" and "organic" may, at the handler's option, display the USDA seal and the seal or logo of the certifying agent. The organic ingredients listed on the ingredient statement may be identified with the word, "organic," or other reference mark. The name of the certifying agent must be displayed on the information panel. The business address, Internet address, and other contact information for the certifying agent may be displayed. These are the only labeling options to indicate that livestock feed that is organically produced.

Labeling of Products Shipped in International Markets

Domestically produced organic products intended for export may be labeled to meet the requirements of the country of destination or any labeling requirements specified by a particular foreign buyer. For instance, a product label may require a statement that the product has been certified to, or meets, certain European Union (EU) organic standards. Such factual statements regarding the organic nature of the product are permitted. However, those packages must be exported and cannot be sold in the United States with such a statement on the label because the statement indicates certification to standards other than are required under this program. As a safeguard for this requirement, we require that shipping containers and bills of lading for such exported products display the statement, "for export only," in bold letters. Handlers also are expected to maintain records, such as bills of lading and U.S. Customs Service documentation,

showing export of the products. Only products which have been certified and labeled in accordance with the requirements of the NOP may be shipped to international markets without marking the shipping containers "for export only."

Organically produced products imported into the United States must be labeled in accordance with the requirements of this subpart. Labeling and market representation of the product cannot imply that the product is also certified to other organic standards or requirements that differ from this national program.

Labeling Nonretail Containers

Section 205.307 provides for labeling nonretail containers used to ship or store raw or processed organic agricultural products that are labeled "100 percent organic," "organic," and "made with organic..." Labeling nonretail containers as containing organically produced product should provide for easy identification of the product to help prevent commingling with nonorganic product or handling of the product which would destroy the organic nature of the product (fumigation, etc.). These labeling provisions are not intended for shipping or storage containers that also are used in displays at the point of retail sale. Retail containers must meet labeling provisions specified in section 205.307.

Containers used only for shipping and storage of any organic product labeled as containing 70 percent or more organic content may, at the handler's discretion, display the following information: (1) the name and contact information of the certifying agent which certified the handler of the finished product; (2) the term, "organic," modifying the product name; (3) any special handling instructions that must be followed to maintain the organic integrity of the product; and (4) the USDA seal and the appropriate certifying agent seal. This information is available to handlers if they believe display of the information helps ensure special handling or storage practices which are consistent with organic practices.

Containers used for shipping and storage of organic product must display a production lot number if such a number is used in the processing and handling of the product. Much of this information may overlap information that the handler normally affixes to shipping and storage containers or information that is required under other Federal labeling regulations. There are no restrictions on size or display of the term, "organic," or the certifying agent seal unless required by other Federal or State statutes.

Labeling Products at the Point of Retail Sale

Section 205.308 applies to organically produced "100 percent organic" and "organic" products that are not packaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased.

The terms, "100 percent organic" and "organic," as applicable, may be used to modify the name of the product in retail displays, labeling, and market information. The ingredient statement of a product labeled "organic" displayed at retail sale must identify the organic ingredients. If the product is prepared in a certified facility, the retail materials may also display the USDA seal and the seal or logo of the certifying agent. If shown, the certifying agent seal must not be larger than the USDA seal.

Section 205.309 addresses "made with..." products that are not packaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased. These products include, but are not limited to, multiingredient products containing between 70 and 95 percent organic ingredients. The "made with..." label may be used to modify the name of the product in retail displays, labeling, and market information. Up to three organic

ingredients or food groups may be identified in the statement. If such statement is declared in market information at the point of retail sale, the ingredient statement and market information must identify the organic ingredients. Retail display and market information of bulk products cannot display the USDA seal but may, if the product is prepared in a certified facility, display the seal or logo of the certifying agent which certified the finished product. The certifying agent's seal or logo may be displayed at the option of the retail food establishment.

Products containing less than 70 percent organic ingredients may not be identified as organic or containing organic ingredients at retail sale. The USDA seal and any certifying agent seal or logo may not be displayed for such products.

Labeling Products Produced in Exempt or Excluded Operations

Section 205.310 provides limited organic labeling provisions for organic product produced or handled on exempt and excluded operations. Such operations would include retail food establishments, certain manufacturing facilities, and production and handling operations with annual organic sales of less than \$5,000. These operations are discussed more thoroughly in subpart B, Applicability.

Any such operation that is exempt or excluded from certification or which chooses not to be certified may not label its organically produced products in a way which indicates that the operation has been certified as organic. Exempt producers may market whole, raw organic product directly to consumers, for example, at a farmers market or roadside stand as "organic apples" or "organic tomatoes." Exempt producers may market their products to retail food establishments for resale to consumers. However, no terms may be used which indicate that such products are "certified" as organic. Finally, exempt organic producers cannot sell their product to a handler for use as an ingredient or for processing into an ingredient that is labeled as organic on the information panel.

These provisions are truth in labeling provisions because display of a certification seal indicates that the product has been certified. We believe this requirement helps differentiate between certified and uncertified products and helps maintain the integrity of certified products while providing organic labeling opportunities for exempt and excluded operations.

USDA Organic Seal

This final rule establishes a USDA seal that can be placed on consumer packages, displayed at retail food establishments, and used in market information to show that certified organic products have been produced and handled in accordance with these regulations. The USDA seal can only be used to identify raw and processed products that are certified as organically produced. It cannot be used for products labeled as "made with organic ingredients" (70 to 95 percent organic ingredients) or on products with less than 70 percent organic ingredients.

The USDA seal is composed of an outer circle around two interior half circles with an overlay of the words "USDA Organic." When used, the USDA seal must be the same form and design as shown in figure 1 of section 205.311 of this regulation. The USDA seal must be printed legibly and conspicuously. On consumer packages, retail displays, and labeling and market information, the USDA seal should be printed on a white background in earth tones with a brown outer circle and separate interior half circles of white (upper) and green (lower). The term, "USDA," must appear in green on the white half circle. The term, "organic," must appear in white on the green half circle. The handler may print the USDA seal in black and white, using black in the place of green and brown. Size permitting, the green (or black) lower half circle may have four light lines running from left to right and disappearing at the right horizon, to resemble a cultivated field. The

choice between these two color schemes is left to the discretion of the producer, handler, or retail food establishment.

Labeling - Changes Based on Comments

The following changes are made based on comments received.

(1) Use of "Organic" in Product Names. The NOSB, State organic program (SOP) managers, certifying agents, and a large number of individual commenters strongly recommended that USDA prohibit use of the term, "organic," to modify an ingredient in a product name if the ingredient, itself, is not produced organically. The examples offered were "organic chocolate ice cream" and "organic cherry sweets" in which the ice cream and candy are at least 95 percent organic but the chocolate and cherry flavoring is not organically produced.

We agree with commenters that such product names can be misleading and would be a violation of section 205.300(a). In the examples, the word, "organic," precedes the words, "chocolate" and "cherry," and clearly implies that those ingredients are organically produced. The chocolate and cherry flavorings must be organically produced to be used in this way. If the product is at least 95 percent organically produced but the flavoring is nonorganic, the word sequence must be reversed or the word, "flavored," must be added to the name; e.g., "chocolate organic ice cream" or "chocolate flavored organic ice cream." A sentence has been added to section 205.300(a) to specify that the term, "organic," may not be used in a product name to identify an ingredient that is not organically produced.

A similar comment was received asking how a single product with two separately wrapped components can be labeled if one of the components is organically produced and the other is not. The commenter's example was a carrot and dip snack pack in which the carrots are organically produced and the dip is a conventional product. Another example is ready-to-eat tossed green salad in which the salad greens are organically produced but the separately pouched salad dressing is a nonorganic component of the product.

Such products also must be labeled in accordance with section 205.300(a). It would be misleading to label the snack pack "organic carrots and dip" or "organic green salad and ranch dressing," if the dip and ranch dressing are not produced with organic ingredients. The salad may be labeled "organic green salad with ranch dressing."

Section 6519(b) of the Act provides the Secretary with the authority to take action against misuse of the term, "organic." USDA will monitor use of the term, "organic," in product names and will restrict use of the term in names that are determined to be deliberately misleading to consumers. Such determinations must be made on a case-by-cases basis.

(2) Labeling Livestock Feed. In the definition of "agricultural product," the Act includes product marketed for "livestock consumption." This means that NOP regulations have applicability to livestock feed production. The Association of American Feed Control Officials (AAFCO) and a few States departments of agriculture commented that the proposed provisions conflict with widely followed standards for livestock feed labeling. AAFCO's "Model Bill and Regulation" standards are incorporated in many State feed laws. The commenters claimed that the requirement to identify organic ingredients in the ingredient statement conflicts with feed regulations which prohibit reference to an ingredient's "quality or grade." They also claimed that the percentage of organic content requirement is a quantitative claim that must be verified by independent sources (e.g., sources other than the certifying agent). The commenters suggested that a provision be added to address labeling of commercial livestock feed.

We have added new paragraph (e) of section 205.301 which provides for two kinds of feed that can be labeled as "organic." The first is feed that contains only organically produced agricultural ingredients and contains no added nutrients or supplements. The second organic feed category also must contain only organically produced agricultural ingredients but may contain feed additives and supplements that are needed to meet the nutritional and health needs of the livestock for which the feed is intended. Feed labeled as "organic" must conform with the requirements of section 205.237, Livestock feed. That section provides that feed additives and supplements produced in conformity with section 205.603 of the National List may be used. The NOP requires that livestock under organic management must only be fed organically produced agricultural ingredients.

We also have added new section 205.306 to address commenters' labeling concerns. The new section provides for optional display of a feed's organic percentage and optional identification of the feed ingredients that are organically produced. The labeling requirements are not intended to supersede the general feed labeling requirements established in the FFDCA and those found under various State laws. Handling processes, feed formulations and recordkeeping must be sufficient to meet the requirements of applicable State regulations.

We believe the provisions in new paragraph (e) of section 205.301 on feed content and new section 205.306 on labeling will allow livestock feed producers to produce and label organic livestock feed that is in accordance with these regulations and State requirements.

(3) Organic Processing Aids. Several industry leaders and SOP managers questioned whether the proposed rule intended to exclude the use of certified organic processing aids in the creation of "100 percent organic" products. Commenters pointed out that a handler should be able to use organically produced processing aids to create products that are labeled as "100 percent organic." The processing aid can be a by-product of an organic agricultural product; e.g., a filter made of rice hulls from organically produced rice. AMS concurs. Accordingly, a change is made in paragraph (f)(4) of section 205.301 to provide for use of organically produced processing aids in products labeled "100 percent organic."

To help clarify this and correct an incomplete reference in the proposed rule preamble, we have changed the column heading of the fourth prohibited practice in the preamble table 1.

(4) Content of "100 Percent Organic Products." Certifying agents and several industry commenters called attention to the regulatory text of section 205.301(a) describing 100 percent organic products. They argued that the proposed rule would allow products with one or more 95 percent-plus "organic" ingredients to be combined as components and have the resulting product be labeled as "100 percent organic."

We did not intend to allow any ingredient that is less than 100 percent organic to be used in a product labeled "100 percent organic." To leave no doubt as to the nature of any product labeled "100 percent organic," we have changed the wording of paragraph (a) of section 205.301 to clarify that a multiingredient "100 percent organic" product must be comprised entirely of 100 percent organic ingredients.

(5) Labeling of Organic Percentage. We received many comments requesting clearer display of a product's percentage of organic content. Most suggested that any product containing less than 100 percent organic ingredients should be required to display the organic percentage on the pdp. They argued that display of the organic percentage on the front of the package would enable consumers to more easily determine organic content, compare competing products, and make better purchase decisions. The NOSB did not recommend display of organic percentage on the pdp for all products containing organic ingredients.

We also received several comments from handlers concerned that the required display of a product's organic percentage can be a burden on handlers. They stated that, to save packaging and printing costs, handlers order bulk quantities of printed packages, labels, and other printed marketing materials. When printed in advance of a growing season and harvest, the handler may not be able to assemble a product that is exactly consistent with the preprinted labeling information, particularly the percentage of organic content. One commenter representing a commodity association opposed the required percentage labeling because the association believes consumers will not understand any organic claim if a percentage of less than 100 percent is displayed.

We believe that display of the percentage of organic content is important product information that can be very helpful to consumers in their purchase decisions. We also believe that the opportunity to display the percentage content of organically produced ingredients can be a positive factor in encouraging handlers to use more organic ingredients in their multiingredient products. At the same time, we understand the financial commitment involved in preprinting bulk quantities of packages and labels well in advance of harvests, which determine availability of needed ingredients.

This final rule implements changes in sections 205.303 and 205.304 for products labeled "organic" and "made with organic ingredients." The requirement to display the percentage of organic content on the information panel is removed. That requirement is replaced with optional labeling of the product's organic percentage on the pdp or any other package panels. This will allow those handlers to display the percentage of their product's organically produced contents on the pdp where it will be most immediately visible to consumers. Handlers who cannot, with certainty, display their product's organic percentage or who choose not to display the percentage, are not required to do so.

This revised labeling provision also removes the requirement in section 205.305 that products with less than 70 percent organic content display the product's organic percentage on the information panel. Under this final rule, that percentage labeling is optional but is still restricted to the information panel. The percentage of a less than 70 percent organic product may not be displayed on the pdp and may not be displayed if the organic ingredients are not identified in the ingredient statement.

(6) Designation of Organically Produced Ingredients. A certifying agent suggested that identification of organic ingredients in ingredient statements should be allowed to be made with an asterisk or similar mark, with the asterisk defined on the information panel. The commenter stated that the repetitive use of the word, "organic," may cause space problems on some small packages and that use of a mark is a common industry practice. We agree with the comment and have changed sections 205.303(b)(1), 205.304(b)(1), and 205.305(a)(i) of the regulatory text accordingly. Thus, organic ingredients may be identified in the ingredient statement with either the term, "organic," or an asterisk or other mark, provided that the asterisk or other mark is defined on the information panel adjacent to the ingredient statement.

(7) Minimum Organic Percentage for Labeling. In the proposed rule's preamble, we asked for public comment on whether the 50 percent minimum organic content for pdp labeling should be increased. The 50 percent minimum content was established in section 6505(c) of the Act. However, the Act also provides the Secretary with the authority to require such other terms and conditions as are necessary to implement the program. Thus, the minimum organic content level for pdp labeling could be changed if the change would further the purposes of the Act.

Comments to the first (1997) proposal and to the revised proposed rule suggested that the minimum organic content for labeling purposes should be increased. All comments received, including comments from certifying agents, a leading organic association, the EU and other international commenters recommended that the minimum organic content to qualify for pdp

labeling should be raised to 70 percent, which is the EU's minimum. All comments stated that the increase is necessary to make the NOP standards consistent with international organic standards. Commenters also pointed to advances in organic production and processing technologies and to increases in the availability of organically produced products and processed ingredients. These factors should make it easier for handlers to assemble food products with higher organic content.

We concur with the comments. We view this as a tightening of labeling requirements in that pdp labeling now requires a higher percentage of organic ingredients and makes the U.S. standard consistent with international norms.

In the proposed rule's preamble, we also asked for specific public comment on whether a minimum percentage of total product content should be required for any single organic ingredient that is included in the pdp statement "made with organic (specified ingredients)." No commenters responded to this question. Therefore, no required minimum percentage for a single organic ingredient in "made with..." products is established.

(8) "Made With Organic (Specified Food Groups)." Several industry organizations suggested that, as an alternative to listing up to three organic ingredients in the "made with..." label, the rule should also allow for identification of food "groups" or "classes" of food in the "made with" label. Commenters suggested, for instance, that a soup (with 70 percent or more organic ingredients, less water and salt) containing organically produced potatoes, carrots, and onions may be labeled as "soup made with organic potatoes, carrots, and onions" or, alternatively, "soup made with organic vegetables."

We agree that this label option offers handlers of such multiingredient products with more flexibility in their labeling. All ingredients in the identified food group must be organically produced and must be identified in the ingredient statement as "organic." In the above example, if soup also contains conventionally produced cauliflower, only "soup made with organic potatoes, carrots, and onions" can be displayed.

We also believe that some parameters must be established as to what are considered as food groups or classes of food. For the purposes of this regulation, products from the following food groups may be labeled as "organic" in a "made with..." label: beans, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, and vegetables. In addition, organically produced and processed butter, cheeses, yogurt, milk, sour cream, etc. may be combined in a product and identified as "organic milk products." Organically produced and processed sugar cane, sugar beets, corn syrup, maple syrup, etc. may be used in a product and identified as "organic sweeteners."

Finally, to be consistent with the "made with..." labeling for individual ingredients, up to three food groups can be identified in the "made with..." statement. Section 205.304 is changed accordingly.

(9) Labeling Products from Exempt and Excluded Operations. A change is made in redesignated section 205.310 which provides for labeling of organic products produced by exempt and excluded operations. SOP managers and an organic handler pointed out that the preamble suggested restrictions on labeling that would prevent exempt and excluded operations from identifying their products as "organic." After review of the proposed rule, we have revised redesignated section 205.310 to more clearly specify labeling opportunities for exempt operations. The regulatory text more clearly states that such operations may not label or represent their organic products as being "certified" as organic and that such exempt and excluded operations must comply with applicable production and handling provisions of subpart C. Labeling must be consistent with the four labeling categories based on the product's organic content.

A State organic advisory board recommended that proposed section 205.309 be revised to apply to exempt and excluded operations which choose to be certified under this program. We do not believe it is necessary to provide separate regulatory text for exempt and excluded operations that are certified. An exempt operation is not precluded from organic certification, if qualified.

(10) Redesigned USDA Seal. Leading industry members, certifying agents, SOP managers, and many individual commenters opposed the proposed wording and design of the USDA seal. Comments generally stated the following points: (1) the proposed Seal wording indicates that USDA is the certifying agent rather than accredited certifiers; (2) international Organization for Standardization (ISO) Guide 61 prohibits government bodies from acting or appearing as certifying agents; and (3) The shield or badge design indicates a certification of product "quality" and assurance of safety which is inconsistent with the NOP's claim to be a certification of "process" only. Commenters suggested several alternative seal statements, including: "Certified Organic - USDA Accredited," "Certified Organic - USDA Approved," "USDA Certified Organic Production," "Meets USDA Organic Production Requirements."

Based on comments received, we are implementing a revised USDA seal which is shown in the regulatory text under section 301.311. It is a circular design with the words, "USDA Organic." The color scheme is a white background, brown outer circle, white and green inner semicircles, and green and white words. A black and white color scheme also may be used if preferred by the handler.

Some commenters suggested changing the shape of the USDA seal to a circle or triangle which, they state, is more in keeping with recognized recycling and sustainability logos. We did not choose a triangle design because processors have commented that triangle designs may cause tears in shrink wrap coverings at the points of the triangle.

Labeling - Changes Requested But Not Made

(1) "Organic" in Company Names. Many commenters stated that the term, "organic," must not be used as part of a company name if the company does not market organically produced foods. They are concerned that the term in a company name would incorrectly imply that the product, itself, is organically produced.

While we understand commenter concerns, we do not know the extent of the problem. We do not believe those concerns require such a prohibition in the regulations at this time. These regulations may not be the best mechanism to address the issue. Section 6519(b) of the Act provides the Secretary with the authority to take action against misuse of the term, "organic." USDA will monitor use of the term, "organic," in company names and will work with the FTC to take action against such misuse of the term. These determinations must be made on a case-by-case basis. The proposed rule did not specifically address this issue. We have added a sentence to paragraph (a) of section 205.300 to this effect.

(2) The "100 Percent Organic" Label. A large number of commenters opposed the "100 percent organic" label for different reasons. A few claimed that the label is not authorized under the Act. Several commenters suggested that consumers will not understand the difference between multiingredient products labeled "100 percent organic" and "organic." Others raised the concern that the "100 percent organic" phrase to modify raw, fresh fruits and vegetables in produce sections and farmers markets may be confusing to consumers.

Regarding the first comment, the term is not specifically provided for in the Act. However, the Secretary has the authority under section 6506(a)(11) to require other terms and conditions as may be necessary to develop a national organic program. When a product is wholly organic, pursuant to the production and handling requirements of the NOP, we believe the handler should

have the option to differentiate it from products which, by necessity, are less than 100 percent organic. We believe the label meets the purposes of the Act.

Regarding consumer confusion, we believe consumers will understand the difference between the two kinds of organic products and will make their organic purchases accordingly.

Regarding the labeling of raw, fresh product as "100 percent organic," organically produced products can be labeled to a lower labeling category. Raw, fresh fruits and vegetables which qualify for a "100 percent organic" label may be labeled simply as "organic," if the producer or retail operator believes that label is best for marketing purposes.

(3) Explain Why Product Is Not 100 Percent Organic. A large number of commenters also suggested any "product that is less than 100 percent organic should carry that information on the main display panel..." By "that information," we assume the commenters are referring to the reasons why a product cannot be certified as "100 percent organic."

AMS believes such a labeling requirement is impractical. Products may fail to qualify for a "100 percent organic" label for very technical, or little understood, reasons. Contemporary food processing often uses ingredients, processing technologies, and product formulations that are complicated, technical, and probably not of interest to the general organic consumer. Such information is not required on nonorganically produced products for the simple reason that it is not considered useful to consumers. Explanations of the different processing technologies used in food products would be cumbersome and would interfere with other product labeling.

We believe the optional display of the organic percentage and required identification of organic ingredients on the information panel provides sufficient information for consumers to make purchase decisions. Other descriptive information regarding processing substances and procedures may, of course, be provided at the handler's option and placed in accordance with other Federal labeling requirements.

(4) Check the Appropriate Organic Category. One commenter suggested that packages of organically produced product display a small box listing the four organic label categories and a check mark beside the category which fits the product.

We understand the simplicity and comparative nature of such a standardized organic label that allows easy comparison of similar products. However, we believe that the optional display of the product's organic percentage and required identification of organic ingredients will be more helpful to consumers and makes the grid box redundant.

(5) Nonorganic Ingredients in Organic Products. A large number of comments were received on the composition and use of nonorganic ingredients in products labeled "made with..." and on conventional products with less than 50 (now 70) percent organic ingredients. Several industry commenters suggested that nonorganic ingredients in "made with..." products must be "natural" (nonsynthetic agricultural substances) and not be artificially produced. Commenters argued that all ingredients in "made with..." and less than 70 percent products should be produced in accordance with the prohibited practices under sections 205.105 and 205.301(f). A significant number of commenters opposed identification of organic ingredients in what they called "natural food" products.

First, we do not agree that the nonorganic ingredients in "made with..." products must be restricted to only "natural" products. Such restrictions on the composition of nonorganic ingredients would significantly reduce handlers' options in producing those products and, thus, reduce consumers' options in purchasing products with organic ingredients.

Regarding prohibited practices, this rule implements the strong industry and consumer demand that the prohibited practices found under section 205.105 (excluded methods, irradiation, and sewage sludge) not be used in nonorganic ingredients in "made with..." products. However, we do not believe that restrictions on use of the other prohibited practices, found in section 205.301(f), would further the purposes of the Act. Application of all prohibited practices on the nonorganic ingredients in the "made with..." and less-than 70 percent organic products would essentially require that those products be organically produced. The Act allows for products that are not wholly organic. We believe the "made with..." label and the labeling restrictions on the less-than 70 percent organic products clearly states to consumers that only some of the ingredients in those products are organically produced.

If accepted, these comments would unnecessarily restrict a handler's ability to truthfully represent and market a conventionally produced agricultural product with some organic ingredients. A handler should not be prohibited from making a truthful claim about some ingredients in a less than 70 percent organic product.

(6) Alternative "Made With..." Labels. A few SOP managers commented that the phrase, "made with...", is confusing. They stated that many processed foods contain at least 50 percent organic ingredients but do not make an organic claim on the pdp. They believe the label would be less confusing if it stated a minimum organic percentage rather than identifying the organic ingredients. They suggest the labeling category be changed to "contains at least 50 percent organic ingredients (or, as revised in this rule, "contains at least 70 percent organic ingredients").

We disagree. Identification of up to three organically produced ingredients or food groups on the pdp gives consumers useful, specific information about the product's organic ingredients. This label, combined with the optional display of the percentage content on the pdp and required identification of organic ingredients, should provide enough information for consumers to make good decisions.

A few commenters contended that the statement "made with organic (specified ingredients)" is unclear and "open ended" and that consumers may assume the entire product is organically produced. The "made with..." labeling claim refers only to the organic ingredients and not to the whole product. We do not believe that consumers will be confused by the label. (7) Use of Other Terms as Synonymous for "Organic". A few commenters representing international organic standards suggested that use of the terms, "biologic" and "ecologic," which are synonymous with "organic" in other countries, should be allowed under the NOP. Commenters claimed these terms are approved by Codex and their inclusion in this regulation would facilitate international trade and equivalency agreements.

These terms were addressed in the proposed rule and are not accepted. Under the NOP, these terms may be used as eco-labels on a product package but may not be used in place of the term, "organic." Although such terms may be considered synonymous with "organic" in other countries, they are not widely used or understood in this country. We believe their use as synonymous for "organic" would only lend to consumer confusion. Regarding the Codex labeling standard, we point out that Codex also provides that terms commonly used in a country may be used in place of "biologic" and "ecologic." Thus, the use of "organic" in the United States is consistent with Codex standards.

With regard to the commenters' claim that the alternate labels would facilitate international trade, this regulation allows alternative labeling of products which are being shipped to international markets. Thus, a certified organic operation in the United States may produce a product to meet contracted organic requirements of a foreign buyer, label the product as "biologic" or "ecologic" on the pdp consistent with the market preferences of the receiving country, and ship the product to the foreign buyer.

Other terms were suggested by commenters as alternatives to the term, "organic," including "grown by age-old, natural methods," "grown without chemical input," and "residue Free." These phrases may be consumer friendly but clearly do not convey the extensive and complex nature of contemporary organic agriculture. These phrases may be used as additional, eco-labels, provided they are truthful labeling statements. They are not permitted as replacements for the term, "organic."

(8) Reconstituted Organic Concentrates. A certifying agent objected to paragraph (a)(2) of section 205.302, which allows labeling of an organically produced concentrate ingredient which is reconstituted with water during assembly of the processed product. The commenter claimed that this provision gives consumers the message that reconstituted juice is equivalent to fresh juice when, the commenter claims, it is not the same.

AMS disagrees. This labeling is consistent with current industry practices. The Act does not prohibit such labeling of concentrates. We believe it is in the interest of the program to allow labeling of organically produced concentrates, provided that the process to produce the concentrate and the reconstitution process is consistent with organic principles and the National List.

(9) Calculating Reconstituted Versus Dehydrated Weight. Several comments were received regarding specific problems encountered in the calculation of the percentage of organic content as provided under section 295.302. A handler claimed the reconstituted weight of an organically produced spice should be counted in the percentage calculation rather than the dehydrated weight of the spice used in the formulation. A similar comment was received from a food cooperative suggesting that, if an organically produced concentrate (in powdered form) is added to the same organically produced ingredient in its organic liquid form (not from concentrate), then the product's organic percentage should be calculated based on the concentrate's single-strength reconstituted weight plus the weight of the natural organic liquid.

AMS disagrees with these comments. This regulation provides for an ingredient's weight to be calculated, excluding added water and salt. If an organically produced spice is added to a product in its natural form, the weight of the spice is calculated. If the spice ingredient is in dehydrated, powdered form when added in the product formulation, the dehydrated weight of the spice must be the basis for its percentage of content calculation. If an organically produced dehydrated spice is reconstituted with water prior to product assembly, the spice must still be calculated at its dehydrated weight because percentage calculations are based on the ingredient weight, excluding water and salt. It would be misleading to calculate the weight of the concentrate ingredient in its reconstituted form.

Likewise, if a powdered ingredient is added to the same organically produced ingredient in its natural, liquid form, the weight of the powdered ingredient must be used. Using the reconstituted weight of the powdered ingredient would increase the percentage of the ingredient above the actual weight of the ingredient in the product. We believe that if the comment were accepted, the handler would be able to use less natural organic liquid than the organic percentage and ingredient statement indicates.

(10) Calculate Organic Percentage in Tenths of a Percent. A trade organization suggested that the organic percentage be rounded to tenths of one percent to accommodate products that may contain a minor ingredient or additive that comprises less than 1 percent of the product. The example provided was Vitamin D in milk. The comment suggested that it is misleading to consumers to suggest that 1 percent of a milk product is nonorganic when the Vitamin D additive may be comprise only a few tenths of one percent of the product.

AMS disagrees. Rounding down the percentage to a whole number is sufficient for consumer information and does not misrepresent the product's organic content. A handler may add a qualifying statement regarding the minor ingredient's weight in relation to the whole product weight.

(11) Verifying Calculations. A State department of agriculture comment suggested that the paragraph (c) of section 205.302 be revised slightly to provide that percentage calculations must be verified "to the satisfaction" of the certifying agent. The commenter believes that the suggested language allows the handler the flexibility to determine the number calculations that need to be checked in order to verify that the organic percentage calculation is correct.

We do not believe the suggested change is necessary. We assume that any use of a certifying agent's seal on a product means that the certifying agent has checked and approves of the method of calculating the product's organic percentage. If the calculations are not to the certifying agent's satisfaction, the agent would not certify the handling process.

While we appreciate the point made by the commenter, we do not believe the suggested change means what the commenter intends. Paragraph (c) of section 205.302 does not specify the number and methods of calculations that need to be carried out by a certifying agent because that will depend on the handling process being certified and the ingredients in the product. We leave that to the discretion of the certifying agent. Also, the basis for a product's organic percentage calculation should be clarified in the organic plan. It is assumed that the certifying agent will either be satisfied that the methodology for calculating organic percentage is correct or the methodology will be changed.

(12) Labeling Nonretail Shipping Containers. A few State departments of agriculture commented that shipping and storage containers with organic products should be required to be labeled as containing organic product. Other commenters recommended that shipping containers be required to display the name of the grower and the certifying agent. They cite these requirements as current industry practice.

This regulation does not require organic labeling on shipping and storage containers because those containers are not used in the marketplace. The only information required by the NOP is the production lot number of the product, if a lot number exists for the particular product. Product content and shipper information may be displayed, as required by other Federal or State regulations or at the discretion of the handler. Proper identification of the organic nature of a product with special instructions for shipment or storage could prevent exposure to prohibited substances that would lead to subsequent loss of the shipment as an organic product.

(13) Disclaimers on Organic Products. Several commenters complained that consumers are misled by the organic labeling and the NOP. They claimed that when science-based technologies (genetic engineering, irradiation, chlorination, etc.) are not used on products, the food is less safe than conventionally produced foods. Some of the commenters suggested that a disclaimer regarding food safety and nutritional value be required on packages with organic labeling.

AMS disagrees. The USDA seal indicates only that the product has been certified to a certain production and/or handling "process" or "system." The seal does not convey a message of food safety or more nutritional value. The NOP prohibitions on use of excluded methods, ionizing radiation, sewage sludge, and some substances and materials are not intended to imply that conventionally produced products made by those methods or containing those prohibited substances are less safe or nutritious than organically produced products. We do not believe that organic food packages or labeling should carry disclaimers of what the USDA seal or a certifying agent's seal does not represent. Other Federal and State seals and marketing claims are placed on consumer products, including food products, without disclaimers regarding those seals and

claims. A disclaimer displayed in relation to USDA seal or a certifying agent's seal would confuse consumers. Finally, disclaimer statements also would present space problems on small product packages.

Labeling - Clarifications

Clarification is given on the following issues raised by commenters:

(1) Certification Is to an Organic Process, Not Organic Product. Several commenters suggested that the final rule more clearly state that the NOP provides for certification of an organic process or system of agriculture and not certification of products, themselves, as "organic." They stated that the phrase "...contain or be created using..." in paragraphs (a), (b), and (c) of section 205.301 implies certification of the product's content and not to the processed-based, organic system of agriculture.

We agree and have revised the wording in those paragraphs to clarify that such products must be organically produced in accordance with organic production and handling requirement of this regulation.

(2) Phasing Out Use of Old Labels and Packages. Citing FDA regulations, the NOSB, certifying agents, and some State agencies suggested a minimum 18-month period for handlers to use up their current supplies of packages and labels before complying with the new labeling requirements.

This rule provides for an interim period of 18 months between publication of the final rule and the implementation date of the program. Publication of this final rule serves notice to certified producers and handlers that they should begin planning for phasing out use of labels that are not in accordance with these requirements.

The implementation process is discussed in Applicability, subpart B. An organic operation will automatically be certified under this program when its certifying agent is accredited by AMS. At that time, the operation may begin following these labeling requirements but may not display the new USDA seal until the implementation date. AMS assumes that certifying agents and their client certified operations will maintain frequent contact as to the status of the agent's application for accreditation so that the certified operation may schedule the phasing out of old labels and purchase of new labels and packages. AMS expects to accredit all currently operating certifying agents by the implementation date of this regulation. Stick-on labels to comply with the new requirements are acceptable.

Newly established organic operations certified for the first time must immediately begin using labels in accordance with this program.

(3) Labeling of Products With Minor Ingredients. Several commenters questioned how the minor ingredients (spices, flavors, colorings, preservatives, oils, vitamins, minerals, accessory nutrients, processing aids, and incidental food additives) needed for formulation or processing of many multiingredient products will be treated under the "100 percent organic" and "organic" labeling categories. Because minor ingredients may not exist or are difficult to obtain in organic form, their use in a product can affect the labeling of the product, even though the percentage of the ingredient is extremely small compared to the rest of the product's ingredients.

Minor ingredients and processing aids must be treated as any other ingredient or substance which is used as an ingredient in or in the processing of an organically produced product. To be added as an ingredient or used in the processing of a product labeled "100 percent organic," a minor ingredient must be extracted from a certified organic source without the use of chemicals or

solvents. To be added as an ingredient or used in the processing of a product labeled "organic," a minor ingredient must be from an organic agricultural source, if commercially available. If not commercially available, the ingredient must be an agricultural product or a substance consistent with the National List.

(4) Reusing Containers. A commenter complained that small producers should not be subjected to costly packaging and labeling requirements when their products are sold directly to the public at farmers markets and roadside stands. The commenter requested that small producers be able to reuse retail boxes and labels. The commenter did not specify which labeling provisions presented burdensome costs on small entities.

We agree that costs for exempt operations, indeed all organic operations, should be kept to a minimum. NOP does not prohibit reuse of containers provided their labeling does not misrepresent product and does not allow organic product to come into contact with prohibited substances from the container's previous contents.

(5) Clarifying Prohibited Labeling Practices. Commenters identified a few inconsistencies between the preamble and regulatory text regarding the seven prohibited production and processing practices now specified in section 205.301(f). We have made the following changes to clarify the intent of the regulation.

A commenter correctly pointed out that the regulatory text of paragraph (f) incorrectly refers only to ingredients that cannot be produced using the seven prohibited production and handling practices listed in the paragraph. That text is not consistent with the preamble, which correctly states that whole products, as well as ingredients, labeled as "organic" cannot be produced or processed using the seven prohibited practices. The term, "whole products," is added to the introductory sentence of new section 205.301(f).

A few commenters pointed out that all seven practices are prohibited in the production of nonorganic ingredients used in products labeled as "organic." The second sentence of proposed paragraph (b) of section 205.301 (products labeled "organic") incorrectly listed only the first three prohibited practices. A phrase is added to the introductory sentence of new paragraph (f) to specify that the 5 percent or less of nonorganic ingredients in products labeled as "organic" may not be produced or handled using any of the seven prohibited practices.

Finally, with the addition of the commercial availability requirement in section 205.201, a conforming change is needed in section 205.301(f)(6) regarding use of nonorganic ingredients when organically produced ingredients are available.

(6) Consistency with State Labeling Requirements. One State organic association commented that the State's law requires identification of the certifying agent if the term, "certified organic," appears on the label. The comment was not clear about where on the package the certifier must be identified; e.g., with the "certified organic" term on the pdp or anywhere on the package. The commenter did not specifically suggest changing the labeling provisions to include the certifying agent on the pdp.

This regulation allows a handler the option of displaying the certifying agent's seal or logo on the pdp for products with 70 percent or more organically produced ingredients. This regulation also requires identification of the certifying agent on the information panel of all products containing 70 percent or more organically produced ingredients. The identification must include an address or contact information and be placed adjacent to identification of the manufacturer, required by FDA. We believe these provisions are sufficient to meet the State's labeling requirements. The NOP will be available to consult with States regarding alternative labeling required to be used in the State.

(7) Clarifying Labeling of Products in Other Than Packaged Form. We have modified sections 205.308 and 205.309 to clarify that products in other than packaged form at the point of retail sale that are prepared by an exempt or excluded operation may be labeled as "100 percent organic," "organic," or "made with..." as appropriate. Consistent with the general restrictions on the labeling of products from such operations, which are found in section 205.310, such products may not display the USDA seal or any certifying agent's seal or other identifying mark or otherwise be represented as a certified organic product.