

ORGANIC FOOD FEDERATION

NOP STANDARDS



BOOK 9

PROCESSING

OFF – ORGANIC PRODUCTS FOR EXPORT TO USA

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For the convenience of OFF Registrants intending to export their produce / products to the USA, the National Organic Program (NOP) Standards of the United States Department of Agriculture (USDA) have been split into

Book 7 – NOP Standards – General

Book 8 – Agriculture

Book 9 – Processed Products (books 1-6 are UK Standards)

The Organic Food Federation for the guidance of UK producers and processors guidance has added all paragraphs and footnotes in italics only

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;

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- (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 non-organic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and
- (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.
- (b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: Provided, That, the submitted plan meets all the requirements of this subpart.

§ 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 non-organically produced agricultural products allowed under § 205.606 may be used:
- (1) In or on a processed agricultural product intended to be sold, labelled, 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, labelled, 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, labelled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or in or on any ingredients labelled 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, non-organic ingredients in

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products labelled "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 non-synthetic 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 non-synthetic or synthetic substance consistent with the National List may be applied.

(d) If the practices provided for in paragraphs (a), (b), and © 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 non-synthetic 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,

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Provided, That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

§ 205.272 Co-mingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the co-mingling 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 labelled 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.

§§ 205.273 - 205.289 [Reserved]

§ 205.290 Temporary variances.

(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:

(1) Natural disasters declared by the Secretary;

(2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and

(3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

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(b) A State organic program's governing State official or certifying agent may recommend in writing to the Administrator that a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations be established: Provided, That, such variance is based on one or more of the reasons listed in paragraph (a) of this section.

(c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent's certified production or handling operations and specify the period of time it shall remain in effect, subject to extension as the Administrator deems necessary.

(d) A certifying agent, upon notification from the Administrator of the establishment of a temporary variance, must notify each production or handling operation it certifies to which the temporary variance applies.

(e) Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105.

Subpart D - Labels, Labelling, and Market Information

§ 205.300 Use of the term, "organic."

(a) The term, "organic," may only be used on labels and in labelling 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 non-organic ingredient in the product.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labelled in accordance with the organic labelling requirements of the receiving country or contract buyer: Provided, That, the shipping containers and shipping documents meet the labelling 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 labelled pursuant to this subpart D.

(d) Livestock feeds produced in accordance with the requirements of this part must be labelled in accordance with the requirements of § 205.306.

§ 205.301 Product composition.

(a) Products sold, labelled, or represented as "100 percent organic." A raw or processed agricultural product sold, labelled, or represented as

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"100 percent organic" must contain (by weight or fluid volume, excluding water and salt)* 100 percent organically produced ingredients. If labelled as organically produced, such product must be labelled pursuant to § 205.303. **(In the EU the organic content is expressed as the percentage of agriculturally derived materials)*

(b) Products sold, labelled, or represented as "organic." A raw or processed agricultural product sold, labelled, 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 non-organically produced agricultural products produced consistent with the National List in subpart G of this part. If labelled as organically produced, such product must be labelled pursuant to § 205.303. **(In the EU the organic content is expressed as the percentage of agriculturally derived materials)*

(c) Products sold, labelled, or represented as "made with organic (specified ingredients or food group(s))." Multi-ingredient agricultural product sold, labelled, 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 (1), (2), and (3) of § 205.301(f). Non-organic ingredients may be produced without regard to paragraphs (4), (5), (6), and (7) of § 205.301(f). If labelled as containing organically produced ingredients or food groups, such product must be labelled pursuant to § 205.304. **(In the EU the organic content is expressed as the percentage of agriculturally derived materials)*

(d) Products with less than 70 percent organically produced ingredients. The organic ingredients in multi-ingredient agricultural product containing less than 70 percent organically produced ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The non-organic ingredients may be produced and handled without regard to the requirements of this part. Multi-ingredient agricultural product containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

(e) Livestock feed:

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(1) A raw or processed livestock feed product sold, labelled, 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, labelled, or represented as "organic" must be produced in conformance with § 205.237.

(f) All products labelled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:

(1) Be produced using excluded methods, pursuant to § 201.105(e);

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

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

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labelled 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 labelled "made with organic grapes";

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

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

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labelled, 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:

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(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. **(In the EU the organic content is expressed as the percentage of agriculturally derived materials)*

(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 labelled "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 labelling 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 labelled "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

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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 labelled "100 percent organic";

(4) The USDA seal; and/or

(5) The seal, logo, or other identifying mark of the certifying agent (*use of OFF logo is subject to conditions in OFF Guidance Note 10*) 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 labelled "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 labelled "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 labelling or market information concerning the product:

(1) The statement:

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(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 colour 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 colour without highlighting.

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

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(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 Labelling 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:

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(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:

(i) 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.

(ii) Comply with other Federal agency or State feed labelling requirements as applicable.

§ 205.307 Labelling of non-retail containers used for only shipping or storage of raw or processed agricultural products labelled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(a) Non-retail containers used only to ship or store raw or processed agricultural product labelled 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;

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(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) Non-retail containers used to ship or store raw or processed agricultural product labelled as containing organic ingredients must display the production lot number of the product if applicable.

(c) Shipping containers of domestically produced product labelled as organic intended for export to international markets may be labelled in accordance with any shipping container labelling requirements of the foreign country of destination or the container labelling 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 record keeping 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, labelled, 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, labelling, 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, labelling, 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, labelled, 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

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with organic (specified ingredients or food group(s))," to modify the name of the product in retail display, labelling, 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 labelled 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:

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- (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.

List of Allowed and Prohibited Substances in USA

NOTE: *products intended for export to the USA may use any of the allowable ingredients or process aids described above, but only if the product concerned is EXCLUSIVELY for export to the United States.*

§ 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 non-synthetic 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;

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

(5) The substance is listed as generally recognized as safe (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) Non-synthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

§ 205.605 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s))."

All organic raw materials used in processed products must also be produced to NOP Standards and certified by a body which is accredited to do so by the USDA

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

(a) Non-synthetics allowed:

(1) Acids

(i) Alginic

(ii) Citric - produced by microbial fermentation of carbohydrate substances

(iii) Lactic

(2) Bentonite

(3) Calcium carbonate

(4) Calcium chloride

(5) Colours, non-synthetic sources only (*not permitted in EU*)

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- (6) Dairy cultures (*not permitted in EU*)
- (7) Diatomaceous earth - food filtering aid only
- (8) Enzymes - must be derived from edible, non-toxic plants, non-pathogenic fungi, or non-pathogenic bacteria
- (9) Flavours, non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative. (*in EU must be natural flavours in accordance with Directive 88/388/EEC*)
- (10) Kaolin
- (11) Magnesium sulphate, non-synthetic sources only (*not permitted in EU*)
- (12) Nitrogen - oil-free grades
- (13) Oxygen - oil-free grades
- (14) Perlite - for use only as a filter aid in food processing
- (15) Potassium chloride (*not permitted in EU*)
- (16) Potassium iodide (*not permitted in EU*)
- (17) Sodium bicarbonate
- (18) Sodium carbonate
- (19) Waxes – non-synthetic
 - (i) Carnauba wax
 - (ii) Wood resin (*care required - needs definition*)
- (20) Yeast - non-synthetic, growth on petrochemical substrate and sulphite waste liquor is prohibited
 - (i) Autolysate
 - (ii) Bakers
 - (iii) Brewers
 - (iv) Nutritional

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(v) Smoked - non-synthetic smoke, flavouring process must be documented.

(b) Synthetics allowed:

(1) Alginates

(2) Ammonium bicarbonate - for use only as a leavening agent *(not permitted in EU)*

(3) Ammonium carbonate - for use only as a leavening agent *(not permitted in EU)*

(4) Ascorbic acid

(5) Calcium citrate

(6) Calcium hydroxide

(7) Calcium phosphates (monobasic, dibasic, and tribasic) *(only mono-calciumphosphate in EU)*

(8) Carbon dioxide

(9) 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.

(i) Calcium hypochlorite *(not permitted in EU)*

(ii) Chlorine dioxide *(not permitted in EU)*

(iii) Sodium hypochlorite *(not permitted in EU)*

(10) Ethylene - allowed for post-harvest ripening of tropical fruit *(not permitted in EU)*

(11) Ferrous sulphate - for iron enrichment or fortification of foods when required by regulation or recommended (independent organization) *(not permitted in EU)*

(12) Glycerides (mono and di) - for use only in drum drying of food *(not permitted in EU)*

(13) Glycerin - produced by hydrolysis of fats and oils *(only plant extracted glycerol in EU)*

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- (14) Hydrogen peroxide (*not permitted in EU*)
- (15) Lecithin - bleached (*only plant derived in EU*)
- (16) Magnesium carbonate - for use only in agricultural products labelled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labelled "organic"
- (17) Magnesium chloride - derived from sea water (*only as Nigari in EU*)
- (18) Magnesium stearate - for use only in agricultural products labelled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labelled "organic" (*not permitted in EU*)
- (19) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods (*not permitted in EU*)
- (20) Ozone (*not permitted in EU*)
- (21) Pectin (low-methoxy)
- (22) Phosphoric acid - cleaning of food-contact surfaces and equipment only
- (23) Potassium acid tartrate
- (24) Potassium tartrate made from tartaric acid
- (25) Potassium carbonate
- (26) Potassium citrate (*not permitted in EU*)
- (27) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables
- (28) Potassium iodide - for use only in agricultural products labelled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labelled "organic" (*not permitted in EU*)
- (29) Potassium phosphate - for use only in agricultural products labelled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labelled "organic" (*not permitted in EU*)
- (30) Silicon dioxide
- (31) Sodium citrate (*not permitted in EU*)

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(32) Sodium hydroxide - prohibited for use in lye peeling of fruits and vegetables

(33) Sodium phosphates - for use only in dairy foods *(not permitted in EU)*

(34) Sulfur dioxide - for use only in wine labelled "made with organic grapes," Provided, That, total sulphite concentration does not exceed 100 ppm.

(35) Tocopherols - derived from vegetable oil when rosemary extracts are not a suitable alternative

(36) Xanthan gum

(c)-(z) [Reserved]

§ 205.606 Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as organic or made with organic ingredients.

The following non-organically produced agricultural products may be used as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

Any non-organically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

(a) Cornstarch (native) *(not permitted in EU in EU only rice or waxy maize, not chemically modified)*

(b) Gums - water extracted only (arabic, guar, locust bean, carob bean)

(c) Kelp - for use only as a thickener and dietary supplement

(d) Lecithin - unbleached

(e) Pectin (high-methoxy) *(not permitted in EU)*

§ 205.607 Amending the National List.

(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to

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the Secretary for inclusion on or deletion from the National List in accordance with the Act.

(b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in § 205.607(c).

(c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TMP/NOP, Room 2945, South Building, P.O. Box 96456, Washington, DC 20090-6456.

§ 205.661 Investigation of certified operations.

(a) A certifying agent may investigate complaints of non-compliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part.

(b) A State organic program's governing State official may investigate complaints of non-compliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

§ 205.662 Non-compliance procedure for certified operations.

(a) Notification. When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any non-compliance with the Act or regulations in this part, a written notification of non-compliance shall be sent to the certified operation. Such notification shall provide:

- (1) A description of each non-compliance;
- (2) The facts upon which the notification of non-compliance is based; and
- (3) The date by which the certified operation must rebut or correct each non-compliance and submit supporting documentation of each such correction when correction is possible.

(b) Resolution. When a certified operation demonstrates that each non-compliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of non-compliance resolution.

(c) Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the non-compliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official

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shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the non-compliance. When correction of a non-compliance is not possible, the notification of non-compliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of such suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for certification; and
- (4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to § 205.681.

(d) Willful violations. Notwithstanding paragraph (a) of this section, if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has wilfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the non-compliance.

(e) Suspension or revocation.

(1) If the certified operation fails to correct the non-compliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.

(2) A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to § 205.663 or filed an appeal pursuant to § 205.681, while final resolution of either is pending.

(f) Eligibility.

(1) A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence

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demonstrating correction of each non-compliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, Except, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

(g) Violations of Act. In addition to suspension or revocation, any certified 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 \$10,000 per violation.

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

§ 205.663 Mediation.

Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal, pursuant to § 205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to § 205.681. Any

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agreement reached during or as a result of the mediation process shall be in compliance with the Act and these regulations. The Secretary may review any mediated agreement for conformity to the Act and these regulations and may reject any agreement or provision not in conformance with the Act or these regulations.

§ 205.664 [Reserved]

§ 205.665 Non-compliance procedure for certifying agents.

(a) Notification. When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any non-compliance with the Act or regulations in this part, a written notification of non-compliance shall be sent to the certifying agent. Such notification shall provide:

- (1) A description of each non-compliance;
- (2) The facts upon which the notification of non-compliance is based; and
- (3) The date by which the certifying agent must rebut or correct each non-compliance and submit supporting documentation of each correction when correction is possible.

(b) Resolution. When the certifying agent demonstrates that each non-compliance has been resolved, the Program Manager shall send the certifying agent a written notification of non-compliance resolution.

(c) Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the non-compliance is not completed within the prescribed time period, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a non-compliance is not possible, the notification of non-compliance and the proposed suspension or revocation may be combined in one notification. The notification of proposed suspension or revocation of accreditation shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of the suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for accreditation; and

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(4) The right to file an appeal pursuant to § 205.681.

(d) Willful violations. Notwithstanding paragraph (a) of this section, if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent.

(e) Suspension or revocation. When the accredited certifying agent fails to file an appeal of the proposed suspension or revocation of accreditation, the Program Manager shall send a written notice of suspension or revocation of accreditation to the certifying agent.

(f) Cessation of certification activities. A certifying agent whose accreditation is suspended or revoked must:

(1) Cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked.

(2) Transfer to the Secretary and make available to any applicable State organic program's governing State official all records concerning its certification activities that were suspended or revoked.

(g) Eligibility.

(1) A certifying agent whose accreditation is suspended by the Secretary under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each non-compliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certifying agent whose accreditation is revoked by the Secretary shall be ineligible to be accredited as a certifying agent under the Act and the regulations in this part for a period of not less than 3 years following the date of such revocation.

§§ 205.666 and 205.667 [Reserved]

§ 205.668 Non-compliance procedures under State organic programs.

(a) A State organic program's governing State official must promptly notify the Secretary of commencement of any non-compliance proceeding against a certified operation and forward to the Secretary a copy of each notice issued.

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(b) A non-compliance proceeding, brought by a State organic program's governing State official against a certified operation, shall be appealable pursuant to the appeal procedures of the State organic program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

(c) A State organic program's governing State official may review and investigate complaints of non-compliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any non-compliance, the State organic program's governing State official shall send a written report of non-compliance to the Program Manager. The report shall provide a description of each non-compliance and the facts upon which the non-compliance is based.

§ 205.669 [Reserved]

Inspection and Testing, Reporting, and Exclusion from Sale

§ 205.670 Inspection and testing of agricultural product to be sold or labelled "organic."

(a) All agricultural products that are to be sold, labelled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labelled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) The preharvest or postharvest tissue test sample collection pursuant to paragraph (b) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the Official Methods of Analysis of the AOAC

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International or other current applicable validated methodology determining the presence of contaminants in agricultural products.

(d) Results of all analyses and tests performed under this section:

(1) Must be promptly provided to the Administrator; Except, That, where a State organic program exists, all test results and analyses shall be provided to the State organic program's governing State official by the applicable certifying party that requested testing; and

(2) Will be available for public access, unless the testing is part of an ongoing compliance investigation.

(e) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded.

§ 205.671 Exclusion from organic sale.

When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labelled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance.

§ 205.672 Emergency pest or disease treatment.

When a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: Provided, That:

(a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labelled, or represented as organically produced; and

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(b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labelled, or represented as organically produced: Except, That:

(1) Milk or milk products may be sold, labelled, or represented as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and

(2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic: Provided, That, the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

§§ 205.673-205.679 [Reserved]

Adverse Action Appeal Process

§ 205.680 General.

(a) Persons subject to the Act who believe they are adversely affected by a non-compliance decision of the National Organic Program's Program Manager may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe that they are adversely affected by a non-compliance decision of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

(c) Persons subject to the Act who believe that they are adversely affected by a non-compliance decision of a certifying agent may appeal such decision to the Administrator, Except, That, when the person is subject to an approved State organic program, the appeal must be made to the State organic program.

(d) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.

(e) All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed.

§ 205.681 Appeals.

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(a) Certification appeals. An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator, Except, That, when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.

(1) If the Administrator or State organic program sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.

(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice or the State organic program's rules of procedure.

(b) Accreditation appeals. An applicant for accreditation and an accredited certifying agent may appeal the Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR Part 1, Subpart H.

(c) Filing period. An appeal of a non-compliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. A decision to deny, suspend, or revoke certification or accreditation will become final and non appealable unless the decision is appealed in a timely manner.

(d) Where and what to file.

These standards have been extracted from the National Organic Program Standards of the United States Department of Agriculture for the convenience of UK companies intending to export organic products to the USA. The paragraph numbers are the same as used in the full NOP standards which are available on request from the Organic Food Federation.

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(1) Appeals to the Administrator must be filed in writing and addressed to Administrator, USDA-AMS, and Room 3071-S, P.O. BOX 96456, WASHINGTON, DC 20090-6456.

(2) Appeals to the State organic program must be filed in writing to the address and person identified in the letter of notification.

(3) All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

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