

# International Organic Standards

Contains **USDA Organic Regulations, 7 CFR Part 205** - as of July 6, 2017 final ruling  
plus additional requirements of:

**India NSOP**

**JAS**

**EC 834/2007**

(including EC 889/2008-detailed rules)

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## Introduction

The International Organic Standards is a compilation of the standards required in the major organic importing countries of the world. It is designed to provide a single reference document for anyone seeking certification to multiple programs.

The following program requirements are included:

- US National Organic Program (NOP), from USDA Organic Regulations 7 CFR Part 205
- European Regulation (EU), from EC 834/2007 & 889/2008
- Japan Agricultural Standards (JAS)
- India National Standards for Organic Products (India NSOP)

The following Equivalence requirements are included:

- US-Canada Organic Equivalence Agreement (USCOEA)

This manual uses the NOP as the base standard. Requirements listed for the other programs are in addition to the NOP standards. Each program's requirements are specifically identified by the name in parentheses as listed above.

Some programs include both the NOP and EU 834/2007, 889/2008 requirements as the base. For example, for India NSOP, you must first meet the requirements of the NOP and EU programs.

Under USCOEA, NOP-certified by certification agencies directly accredited by the USDA product from anywhere in the world can enter the Canadian market as "organic", and/or bear the federal Canadian organic logo as long as a) it does not come from hydroponic operations; b) sodium nitrate was not applied to fields; and c) agricultural products derived from animals are produced according to livestock stocking rates set in the Canadian regulation. Labeling should comply with the Canadian rules.

**Although every effort has been made to represent additional requirements and restrictions accurately and completely, the full standards for each certification program are the final authority.** Links to current versions of these international standards can be found on the OneCert website .

### JAS Certification and the NOP

JAS standards generally match the NOP standards except for some additional restrictions on materials use. JAS certification also requires that you have an established "grading system", which includes appointing a grading manager and define grading procedures. An alternative to JAS certification is available to US-based producers. A special export certificate can be used for NOP-certified products that will be sold to a JAS-certified importer in Japan. Please refer to *Information for Exporting to Japan* for more details.

### **Input Materials, Ingredients, and Processing Aids**

An important difference among certification programs is the list of materials that are allowed as production inputs, ingredients, or processing aids. §205.601 to §205.606 are annotated to indicate if any item will not be allowed or is restricted under any program other than the NOP. You may also want to refer to the full list for that program to assure compliance. Materials lists from the EU and JAS are included as appendices. Some of the EU standards included in these standards refer to the EU lists. You should also refer to the NOP list to assure full compliance. Please contact the OneCert office to obtain written confirmation of acceptability for any input material that has not already been approved as part of your organic system plan.

### **Which program should you choose?**

This is an important question. A grower will need to know the location of their buyer and also the requirements of the markets where their buyer will eventually sell the product. If you already know who will be buying your product, ask your buyer what program requirement(s) they need you to meet. Complying with all programs will give you the most options for selling your products.

### **How to use this manual:**

The basic text of this manual consists of the NOP Standards and sections of the NOP rule describing certification procedures. These are the standards that must be met for NOP certification. These are also the base standards that must be met for all other programs included in this manual.

The text of additional **Guidance** and other **Requirements** is enclosed by a box (like the box that surrounds this paragraph). *Sources for Guidance and other Standards are indicated by italicized text.*

**Guidance** indicates or clarifies how standards will be interpreted, defined, or applied. If the guidance is followed, the operator will be considered to have met the related standard. If the guidance is not followed, the operator must use an alternative method to demonstrate compliance with the standard.

Other **Requirements** are standards that must be complied with to achieve certification to that Program. These are optional additional program requirements that are not necessary for compliance with the NOP. Other Requirements can also be considered as guidance for meeting the NOP standards. While not required for NOP, the requirements do not contradict the NOP Standards.

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## Subpart A - Definitions

### § 205.1 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

### § 205.2 Terms defined.

*Accreditation.* A determination made by the Secretary that authorizes a private, foreign, or State entity to conduct certification activities as a certifying agent under this part.

*Act.* The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 et seq.).

*Action level.* The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on unavailability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable.

*Administrator.* The Administrator for the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

*Aeroponics:* A soil-free cultivation method whereby plants are suspended with their roots partially or even totally exposed to the air. (Canada Organic Standards 3.1) Aeroponic production is also prohibited for NOP certified operations wishing to import products into Canada under USCOEA.

*Agricultural inputs.* All substances or materials used in the production or handling of organic agricultural products.

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

*Agricultural Marketing Service (AMS).* The Agricultural Marketing Service of the United States Department of Agriculture.

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

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

*Animal drug.* Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.

*Annual seedling.* A plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.

*Area of operation.* The types of operations: crops, livestock, wild-crop harvesting or handling, or any combination thereof that a certifying agent may be accredited to certify under this part.

*Audit trail.* Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as “100 percent organic,” the organic ingredients of any agricultural product labeled as “organic” or “made with organic (specified ingredients)” or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement.

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

*Biodegradable biobased mulch film.* A synthetic mulch film that meets the following criteria:

- (1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3);
- (2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and
- (3) Must be biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

*Biologics.* All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

*Breeder stock.* Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

*Buffer zone.* An area located between a certified production operation or portion of a production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or



other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.

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

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

*Certified operation.* A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

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

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

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

*Class of animal.* A group of livestock that shares a similar stage of life or production. The classes of animals are those that are commonly listed on feed labels.

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

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

*Compost.* The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times.

*Control.* Any method that reduces or limits damage by populations of pests, weeds, or diseases to levels that do not significantly reduce productivity.

*Conversion period EU:*(plant products) Definition: **conversion** means the transition from non organic to organic farming within a given period of time, during which the provisions concerning the organic production have been applied [EC 834/2007 Article 2(h)].

Length: For annuals, conversion must be at least two years before sowing, or, in the case of grassland or perennial forage, at least two years before its use as feed from organic farming, or, in the case of perennial crops other than grassland, at least three years before the first harvest of organic products [EC 889/2008 Article 36(1)].

Beginning: The conversion period must commence at the earliest on the date on which the producer notified his activity in accordance with EC 834/2007 Article 17(c) and 28(1) and submitted his holding to the inspection system.

A certifying body is allowed to recognize previous years as part of the conversion period if the land was part of a land management agreement that excludes non-permitted inputs OR where the certification body is satisfied that there is sufficient evidence that the parcels were natural or agriculture areas not treated with products not authorized for organic production for a period of at least three years, and all the European Regulation has been applied [EC 834/2007 Article 17(b & e) and 889/2008 Article 36(2)].

*Crop.* Pastures, cover crops, green manure crops, catch crops, or any plant or part of a plant intended to be marketed as an agricultural product, fed to livestock, or used in the field to manage nutrients and soil fertility.

*Crop residues.* The plant parts remaining in a field after the harvest of a crop, which include stalks, stems, leaves, roots, and weeds.

*Crop rotation.* The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on

the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.

*Crop year.* That normal growing season for a crop as determined by the Secretary.

*Cultivation.* Digging up or cutting the soil to prepare a seed bed; control weeds; aerate the soil; or work organic matter, crop residues, or fertilizers into the soil.

*Cultural methods.* Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

*Detectable residue.* The amount or presence of chemical residue or sample component that can be reliably observed or found in the sample matrix by current approved analytical methodology.

*Disease vectors.* Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

*Drift.* The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.

*Dry lot.* A fenced area that may be covered with concrete, but that has little or no vegetative cover.

*Dry matter.* The amount of a feedstuff remaining after all the free moisture is evaporated out.

*Dry matter demand.* The expected dry matter intake for a class of animal.

*Dry matter intake.* Total pounds of all feed, devoid of all moisture, consumed by a class of animals over a given period of time.

*Emergency pest or disease treatment program.* A mandatory program authorized by a Federal, State, or local agency for the purpose of controlling or eradicating a pest or disease.

*Employee.* Any person providing paid or volunteer services for a certifying agent.

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

*Excluded methods.* A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

*Guidance:* “recombinant DNA technology” as defined by article 3, is prohibited by article 4 of the JAS Standards for organic plants, feed and processed food (Notifications 1605, 1606 and 1607).

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

*Feedingstuff.* Any substance or product, including additives, whether processed, partially processed or unprocessed intended to be used for oral feeding to animals. *EU*

*In-Conversion Feedingstuff.* Feedingstuffs produced during the conversion period to organic production, with the exclusion of those harvested in the 12 months following the beginning of the conversion [*EC 889/2008 Article 2(i)*].

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

*Feedlot.* A dry lot for the controlled feeding of livestock.

*Feed supplement.* A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be:

- (1) Diluted with other feeds when fed to livestock;
- (2) Offered free choice with other parts of the ration if separately available; or
- (3) Further diluted and mixed to produce a complete feed.

**Fertilizer.** A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

**Field.** An area of land identified as a discrete unit within a production operation.

**Forage.** Vegetative material in a fresh, dried, or ensiled state (pasture, hay, or silage), which is fed to livestock.

**Genetic Engineering.** See definition for *Excluded Methods*.

**GMO.** See definition for *Excluded Methods*.

**Governmental entity.** Any domestic government, tribal government, or foreign governmental subdivision providing certification services.

**Graze.** (1) The consumption of standing or residual forage by livestock.

(2) To put livestock to feed on standing or residual forage.

**Grazing.** To graze.

**Grazing season.** The period of time when pasture is available for grazing, due to natural precipitation or irrigation. Grazing season dates may vary because of mid-summer heat/humidity, significant precipitation events, floods, hurricanes, droughts or winter weather events. Grazing season may be extended by the grazing of residual forage as agreed in the operation's organic system plan. Due to weather, season, or climate, the grazing season may or may not be continuous. Grazing season may range from 120 days to 365 days, but not less than 120 days per year.

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

**Handler.** Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

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

**Holding:** for the European Regulation means all the production units operated under a single management for the purpose of producing agricultural product [EC 889/2008 Article 2(e)]

**Hydroponic Production.** The method of growing plants with their roots in a mineral nutrient solution only or in an inert medium, such as perlite, gravel or mineral wool to which a nutrient solution is added EC 889/2008 Article 2(g). Hydroponic production is prohibited under the European Regulation [EC 889/2008, Article 4]. Hydroponic production is also prohibited for NOP certified operations wishing to import products into Canada under the USCOEA.

**Immediate family.** The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

**Inclement weather.** Weather that is violent, or characterized by temperatures (high or low), or characterized by excessive precipitation that can cause physical harm to a given species of livestock. Production yields or growth rates of livestock lower than the maximum achievable do not qualify as physical harm.

**Inert ingredient.** Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

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

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

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

**Inspection.** The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

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

*Ionizing Radiation.* Radiation of the type produced by gamma rays from radionuclides such as cobalt-60 or cesium-137, electrons generated from machine sources, or X-rays generated from machine sources. Food and Drug Administration regulation, 21 CFR 179.26 describes the types of radiation that are acceptable for treatment of convention foods. No type of ionizing radiation is permitted of organic products.

*Label.* A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.

*Labeling.* All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.

*Livestock.* Any cattle, sheep, goats, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals for the production of food, fiber, feed, or other agricultural-based consumer products.

*Livestock defined under the EU means the production of domestic or domesticated terrestrial animals (including insects) [EC 834/2007, Article 2] and lays down detailed production standards for bovine, bison, equidae (horses), porcine, ovine, caprine, poultry and bees.*

*Lot.* Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing house and which are available for inspection at the same time.

*Manure.* Feces, urine, other excrement, and bedding produced by livestock that has not been composted.

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

*Mulch.* Any nonsynthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.

*Narrow range oils.* Petroleum derivatives, predominately of paraffinic and naphthenic fractions with 50 percent boiling point (10 mm Hg) between 415 °F and 440 °F.

*National List.* A list of allowed and prohibited substances as provided for in the Act.

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

*National Organic Standards Board (NOSB).* A board established by the Secretary under 7 U.S.C. 6518 to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the National Organic Program.

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

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

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

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

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

*Operator.* Means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the organic business under their control [EC 834/2007 Article 2(d), Definitions].

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

*EC Organic* : a term that refers to products coming from or related to organic production/processing only if the production method complies with the rules established in the European Regulation, at all stages of production, preparation and distribution [EC 834/2007, Article 2, Definitions].

*Organic matter.* The remains, residues, or waste products of any organism.

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

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

*Parallel production.* Please see "Split Operations and Parallel Production" under § 205.201

*Pasture.* Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.

*Peer review panel.* A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

*Person.* An individual, partnership, corporation, association, cooperative, or other entity.

*Pesticide.* Any substance which alone, in chemical combination, or in any formulation with one or more substances is defined as a pesticide in section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) *et seq.*).

*Petition.* A request to amend the National List that is submitted by any person in accordance with this part.

*Planting stock.* Any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.

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

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

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

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

*Processing aid.* (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;

(2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and

(3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

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

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

*Production unit:* for the European Regulation means all assets to be used for a production sector such as production premises, land parcels, pasturages, open air areas, livestock buildings, the premises for the storage of crops, crop products, livestock products, raw materials and any other input relevant for this specific production sector [EC 889/2008 Article 2(f)].

*Prohibited substance.* A substance the use of which in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations of this part.

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

*Residual forage.* Forage cut and left to lie, or windrowed and left to lie, in place in the pasture.

*Residue testing.* An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradation products in or on raw or processed agricultural products.

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

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

*Routine use of parasiticide.* The regular, planned, or periodic use of parasiticides.

*Secretary.* The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

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

*Shelter.* Structures such as barns, sheds, or windbreaks; or natural areas such as woods, tree lines, large hedge rows, or geographic land features, that are designed or selected to provide physical protection or housing to all animals.

*Slaughter stock.* Any animal that is intended to be slaughtered for consumption by humans or other animals.

*Soil and water quality.* Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

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

*Stage of life.* A discrete time period in an animal's life which requires specific management practices different than during other periods (e.g., poultry during feathering). Breeding, freshening, lactation and other recurring events are not a stage of life.

*State.* Any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

*State certifying agent.* A certifying agent accredited by the Secretary under the National Organic Program and operated by the State for the purposes of certifying organic production and handling operations in the State.

*State organic program (SOP).* A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

*State organic program's governing State official.* The chief executive official of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official who administers a State organic certification program.

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

*Temporary and Temporarily.* Occurring for a limited time only (e.g., overnight, throughout a storm, during a period of illness, the period of time specified by the Administrator when granting a temporary variance), not permanent or lasting.

*Tolerance.* The maximum legal level of a pesticide chemical residue in or on a raw or processed agricultural commodity or processed food.

*Transplant.* A seedling which has been removed from its original place of production, transported, and replanted.

*Unavoidable residual environmental contamination (UREC).* Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.

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

*Yards/Feeding pad.* An area for feeding, exercising, and outdoor access for livestock during the non-grazing season and a high traffic area where animals may receive supplemental feeding during the grazing season.

[65 FR 80637, Dec. 21, 2000, as amended at 72 FR 70484, Dec. 12, 2007; 75 FR 7192, Feb. 17, 2010; 79 FR 58662, Sept. 30, 2014; 80 FR 6429, Feb. 5, 2015]

### §205.3 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, we must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the USDA Agricultural Marketing Service, National Organic Program, 1400 Independence Avenue SW., Washington, DC 20250; (202) 720-3252, and is available from the sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428; phone 1-877-909-2786; <http://www.astm.org/>.

(1) ASTM D5988-12 (“ASTM D5988”), “Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil,” approved May 1, 2012, IBR approved for §205.2.

(2) ASTM D6400-12 (“ASTM D6400”), “Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities,” approved May 15, 2012, IBR approved for §205.2.

(3) ASTM D6866-12 (“ASTM D6866”), “Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis,” approved April 1, 2012, IBR approved for §205.2.

(4) ASTM D6868-11 (“ASTM D6868”), “Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities,” approved February 1, 2011, IBR approved for §205.2.

(c) European Committee for Standardization; Avenue Marnix, 17-B-1000 Brussels; phone 32 2 550 08 11; [www.cen.eu](http://www.cen.eu).

(1) EN 13432:2000:E (“EN 13432”), September, 2000, “Requirements for packaging recoverable through composting and biodegradation—Test scheme and evaluation criteria for the final acceptance of packaging,” IBR approved for §205.2.

(2) EN 14995:2006:E (“EN 14995”), December, 2006, “Plastics—Evaluation of compostability—Test scheme and specifications,” IBR approved for §205.2.

(d) International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland; phone 41 22 749 01 11; [www.iso.org](http://www.iso.org).

(1) ISO 17088:2012(E), (“ISO 17088”), “Specifications for compostable plastics,” June 1, 2012, IBR approved for §205.2.

(2) ISO 17556:2012(E) (“ISO 17556”), “Plastics—Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved,” August 15, 2012, IBR approved for §205.2.

[79 FR 58662, Sept. 30, 2014]

## Subpart B—Applicability

### § 205.100 What has to be certified.

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,”

“organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

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

(c) Any operation that:

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

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

[65 FR 80637, Dec. 21, 2000, as amended at 70 FR 29579, May 24, 2005; 80 FR 6429, Feb. 5, 2015]

**Guidance:** Product from hydroponic operations cannot be certified under the European Regulation. Hydroponic production is also not allowed for products being imported to Canada by NOP certified operations under the US-Canada Equivalence Agreement. (USCOEA)

### § 205.101 Exemptions and exclusions from certification.

(a) *Exemptions.*

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

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

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

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

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

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

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

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

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

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

(b) *Exclusions.*

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

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

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



**Guidance:** Contact the office for guidelines on criteria that must be met to qualify for this exclusion. Operations buying organic product from an operation excluded from certification must verify and document that these criteria have been met to assure that the organic integrity of the product has been maintained.

**EC Requirement:** there are no exemptions or exclusions from certification, and the regulation must apply to any operator involved in activities, at any stage of production, preparation and distribution, relating to organic products [EC 834/2007, Article 1, paragraph 3, Aim and scope]

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

- (i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and
- (ii) The labeling provisions of § 205.310.

(c) *Records to be maintained by exempt operations.*

(1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

- (i) Prove that ingredients identified as organic were organically produced and handled; and
- (ii) Verify quantities produced from such ingredients.

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

#### **§ 205.102 Use of the term, “organic.”**

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

- (a) Produced in accordance with the requirements specified in §205.101 or §§205.202 through 205.207 or §§205.236 through 205.240 and all other applicable requirements of part 205; and
- (b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205.

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

#### **§ 205.103 Recordkeeping by certified operations.**

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(b) Such records must:

- (1) Be adapted to the particular business that the certified operation is conducting;
- (2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;
- (3) Be maintained for not less than 5 years beyond their creation; and
- (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent.

**Guidance:** Contact the OneCert office for information on specific recordkeeping questions.

§ 205.104 [Reserved]

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

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

- (a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;
- (b) Nonsynthetic substances prohibited in § 205.602 or § 205.604;
- (c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;

- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;
- (e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with § 205.600(a);
- (f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and
- (g) Sewage sludge.

**Guidance:** See the definition for "Excluded methods", which refers to all types of genetically modified organisms (GMO).

**Guidance:** Certification programs have differences in the list of materials that are allowed or prohibited in organic production. See the appendices for lists of allowed substances for JAS and EC Requirements.

**EC requirement:** GMO presence above 0.9% in agricultural or processed products, even if unintended or accidental, precludes the sale as organic. GMOs and products produced from or by GMOs must not be used as food, feed, processing aids, plant protection products, fertilizers, soil conditioners, seeds, vegetative propagating material, micro-organisms and animals in organic production [EC 834/2007, Article 9 Prohibition on the use of GMOs].

## §§ 205.106-205.199 [Reserved]

# 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.

**Guidance:** Only the NOP has the "100 percent organic" category. See § 205.300 for more details.

**EC Requirement:** EU allows only products with at least 95% organic ingredients to be labeled organic. For products that are less than 95%, the term organic can only be used on the list of ingredients to indicate individual organic ingredients.

**JAS Requirement:** JAS allows products with more than 95% organic ingredients to be labeled organic. JAS for Processed Food, Article 4, Notif. 1606, MAFF.

**India Requirement:** NSOP 3.5.1.3. India NSOP has similar requirements. See § 205.300 for more details.

## § 205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

- (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- (2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable;
- (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- (4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103;
- (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and
- (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

(b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: *Provided*, That, the submitted plan meets all the requirements of this subpart.

**EC Requirement:** the initial submission of an organic system plan providing a complete description of the operation is also required by the European Regulation [EC889/08, Article 63]

**Guidance:** A complete list of required information can be found on the organic management plan questionnaires.

## Split Operations and Parallel Production

**India Requirement:** NSOP 3.1.1.4. Simultaneous production of conventional, in conversion and/or organic crops or animal products which cannot be clearly distinguished from each other, is not allowed.

**EC Requirement:** The entire agricultural holding must be managed in compliance with the requirement applicable to [EU] organic production [EC 834/2007, Article 11]. However, a producer may run organic and non-organic production units in the same area when it is necessary in order to ensure that organic production can be initiated or maintained on holdings confronted with climatic, geographical or structural constraints [EC 834/2007, Article 22]. Non-organic and organic units in the same area are subject to specific control requirements to satisfy the certification body that could include physical, financial, and operational separation (including storage premises) and that all measures are in place to prevent commingling and contamination [EC 889/2008, Article 73]

**EC Requirement:** A holding may be split into clearly separated units not all under organic management given that, with animals, different species are involved. In aquaculture, if the same species is involved there is adequate separation between the production sites. With plants, different varieties that can be easily differentiated must be involved.

For perennials, split production is allowed, even of varieties that cannot be easily differentiated, **if** there is a conversion plan, not to exceed five years. The producer must also inform the inspection body 48 hours prior to harvest of such perennial crops. Exact quantities of harvest must be reported immediately upon completion of the harvest. The same is true for products of agricultural research and production of seed, vegetative propagating materials and transplants [EC 889/2008, Article 40].

**EC Requirement:** Storage of input products other than those authorized under the regulation is prohibited in the production unit. Except, allopathic veterinary medicinal products and antibiotics is permitted on holdings provided that they have been prescribed by a veterinarian in connection with treatment of a disease to avoid suffering to the animal [EC 889/2008, Article 35(3)]

**EC Requirement:** [EC 889/2008, Article 17]

1. Non organic livestock may be present on the holding provided they are reared on units where the buildings and parcels are clearly separated from the units producing in accordance with organic production rules and a different species is involved.
2. Non organic livestock may use organic pasturage for a limited period of time each year, provided that such animals come from a farming system designed to protect the environment (as described in Article 36 of (EC) 1698/2005 or Article 22 of (EC) 1257/1999) and that organic animals are not present at the same time on that pasture.
3. Organic animals may be grazed on common land, providing that the land has not been treated with prohibited substances for at least three years, non-organic animals which also use the land come from a farming system designed to protect the environment, and products from the organic livestock can only be labeled as organic if adequate segregation from non-organic animals can be proved.

## Split Processing

Production of processed organic feed/organic food must be kept separate in time or space from production of processed non organic feed/ non organic food, including effective physical separation during storage, packaging and transport. [EC834/2007, Article 18(1) & 19(2), 31, 32].

Operators producing processed feed or food must establish and update appropriate procedures to guarantee at all times that the produced processed products comply with the organic production rules. When non-organic products are also prepared or stored in the processing unit concerned, the operator must:

- (a) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;
- (b) store organic products, before and after the operations, separate by place or time from non-organic products;
- (c) inform the control authority or control body thereof and keep available an updated register of all operations and quantities processed;
- (d) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;
- (e) carry out operations on organic products only after suitable cleaning of the production equipment;
- (f) During transport, organically produced feed, and non-organic feed shall be effectively physically separated if used for both organic and non-organic feed. The transport of finished organic feed shall be separated physically or in time from the

transport of other finished products. Suitable cleaning measures must be in place before commencing the transport of organic products with proper documentation. The quantity of products at the start and each individual product quantity delivered in the course of delivery round shall be recorded. All Records shall be made available for CB verification. [EC889/08, Article 26(2 & 5), 32, 32a].

**Guidance:** Parallel production for livestock may be approved subject to inspection provided:

- a. The stocks are not kept together or organic stock can be easily distinguished from non-organic stock, i.e. distinguishable breeds.
- b. Areas for storing feed are separated and clearly marked.
- c. Accurate documentation is maintained of stock, feed handling, medications, etc. and non-organic stocks.
- d. Organic livestock must be securely excluded from storage, feeding, mixing and handling areas of non-organic feed and prohibited materials.

### § 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as “organic,” must:

- (a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;
- (b) Have had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop; and

**Guidance:** An operation may be certified to the NOP program after a single inspection, provided that adequate documentation is in place to verify compliance with the standards. India, EU, and Bio Suisse standards expect an inspection during the conversion period beginning at least one year prior to the year in which the first organic crop will be harvested (see Conversion Period below).

**Canada Equivalency :** no NOP-certified agricultural products produced with the use of sodium nitrate can be marketed as organic in Canada. The organic system plan and field histories must documents this.

- (c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

### Conversion Period

**EC Requirements:** The conversion period must commence at the earliest on the date on which the producer notified the certifier [EC 834/2007, Article 17].

On a holding or unit partly under organic production and partly in conversion to organic production, the operator shall keep the organically produced and in-conversion products separate and the animals separate or readily separable and keep adequate records to show the separation. [834/2007, Article 17 (d)]

Organic practices must have been applied on the parcels during a conversion period of at least two years before sowing, or, in the case of grassland, at least two years before its exploitation as feedingstuff from organic farming; or, in the case of perennial crops other than grassland, at least three years before the first harvest of products that will be sold as organic. However, the certifier may decide to recognize retroactively as being part of the conversion period any previous period in which the parcels were natural or agricultural areas which were not treated with prohibited products. This period can be taken into consideration retroactively only under the condition that satisfactory proof has been furnished to the certifier allowing it to satisfy itself that the conditions were met for a period of at least three years. The certifier may decide, in certain cases, to extend the conversion period beyond the period laid down above having regard to previous parcel use [EC 889/2008, Article 36(1)].

**India Requirement:** NSOP 3.1.1.3, 3.2.2, & 3.3.2. Meeting EU conversion requirements will also comply with India requirements.

### § 205.203 Soil fertility and crop nutrient management practice standard.

- (a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.
- (b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

**EC Requirement:** [EC 834/2007, Article 12(1) (a-c)].

— Organic plant production must use tillage and cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil, compaction and soil erosion;

— the fertility and biological activity of the soil must be maintained or increased, in the first instance, by (a) multi-annual crop rotation including legumes, green manures ; (b) incorporation of livestock manure or organic material both preferably composted, from organic production

Other organic or mineral fertilizers, only those mentioned in Annex I (EU 889/2008 list of fertilizers and soil conditioners) may, exceptionally, be applied, as a complement to the extent that:

— adequate nutrition of the crop being rotated or soil conditioning are not possible by the methods set out under the two preceding subparagraphs.

— the incorporation of livestock manure must not exceed 170 kg of Nitrogen per hectare per year (152 lb per acre— see Stocking Rate chart below for equivalent stocking rates) [EC 889/2008 Article 3].

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

(1) Raw animal manure, which must be composted unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

**Guidance:** If a producer believes that there may be a source of contamination of a manure input, then the manure must be tested, and if the tests show contamination, the manure may not be used. Contact the OneCert office prior to using off-farm manure to verify the need for testing in your situation.

**EC Requirement:** Manure and compost from intensive or landless livestock production (factory farms) is prohibited [Annex I. EC 889/2008].

The total amount of livestock manure applied on the holding may not exceed 170 kg of nitrogen per year/hectare of agricultural area used. Organic-production holdings may establish written cooperation agreements exclusively with other holdings and enterprises which comply with the [EC] Regulation, with the intention of spreading surplus manure from organic production. The maximum limit 170 kg of nitrogen per year/hectare, must be calculated on the basis of all of the organic-production units involved in such cooperation [EC 889/2008, Article 3(2-3)].

Environmental pollution of natural resources such as soil and water by nutrients should be avoided [EC 889/2008 preamble (12)], and storage facilities for livestock manure must be of a capacity to preclude the pollution of water by direct discharge, or by run-off and infiltration of the soil.

The number of livestock must be limited with a view to minimizing overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure [EC 834/2007, Article 14, (b) (iv)];

The organic system plan should provide a full description of the installations for the storage of livestock manure, and a plan for spreading manure [EC 889/2008, Article 74 (1-2)].

**EC Requirement: Maximum Stocking Rate. Annex IV,** Maximum number of animals per hectare referred to in article 15(2) in EC 889/2008

(2) Composted plant and animal materials produced through a process that:

(i) Established an initial C:N ratio of between 25:1 and 40:1; and

(ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or

(iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Uncomposted plant materials.

**Guidance:** For the NOP, if there are no complete records to verify 205.203 (c)(2), manure should be considered raw manure and handled according 205.203 (c)(1), unless documentation is available to verify compliance with the definition of “processed manure” (NOP Instruction, July 16, 2007). Therefore, inputs such as vermicompost, compost tea and bocashi should not be considered compost, unless the manure contained has been previously composted according 205.203 (c)(1).

(d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying:

- (1) A crop nutrient or soil amendment included on the National List of synthetic substances allowed for use in organic crop production;
- (2) A mined substance of low solubility;
- (3) A mined substance of high solubility: *Provided*, That, the substance is used in compliance with the conditions established on the National List of nonsynthetic materials prohibited for crop production;
- (4) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: *Provided*, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and
- (5) A plant or animal material that has been chemically altered by a manufacturing process: *Provided*, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in § 205.601.

**EC Requirement:** See EC Requirement listed under § 205.203 (b) above. Only materials listed in Annex I (EU list of fertilizers and soil conditioners) are allowed.

(e) The producer must not use:

- (1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production;
- (2) Sewage sludge (biosolids) as defined in 40 CFR Part 503; and
- (3) Burning as a means of disposal for crop residues produced on the operation: *Except*, That, burning may be used to suppress the spread of disease or to stimulate seed germination.

**EC Requirement:** Manure or compost from intensive livestock production (factory farms) is not allowed.

#### § 205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except*, That,

- (1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: *Except*, That, organically produced seed must be used for the production of edible sprouts;
- (2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;

**Guidance:** Commercial availability: Producers may select varieties based on other criteria, such as taste, quality, days to maturity, yield, etc., before determining availability of organic seed. Growers are not restricted to choosing from organic varieties when non-organic varieties are required to meet production goals. It is necessary for growers to document their efforts to obtain organic seed.

- (3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with § 205.290(a)(2);
- (4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and
- (5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

**Guidance:** in § 205.204(a)(5) above, Federal or State regulations refers to the USA only, not other countries.

(b) [Reserved]

**EC Requirement:** In case of acceptance of non-organic seed of particular crop/ variety, the seed shall be allowed for use in one season only. Operator must use on farm saved certified seeds in next season. Use of non-organic seeds for more than year or season shall not be allowed. [EEC 889, Article 45 (7)]

**§ 205.205 Crop rotation practice standard.**

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

- (a) Maintain or improve soil organic matter content;
- (b) Provide for pest management in annual and perennial crops;
- (c) Manage deficient or excess plant nutrients; and
- (d) Provide erosion control.

**EC Requirement:** The fertility and biological activity of the soil must be maintained and increased by multiannual crop rotation including legumes and other green manure crops, and by the application of livestock manure or organic material, both preferably composted, from organic production [EC 834/2007, preamble (13) and Article 12(1)(b)].

**§ 205.206 Crop pest, weed, and disease management practice standard.**

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:

- (1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205;
- (2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and
- (3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

(b) Pest problems may be controlled through mechanical or physical methods including but not limited to:

- (1) Augmentation or introduction of predators or parasites of the pest species;
- (2) Development of habitat for natural enemies of pests;
- (3) Nonsynthetic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

- (1) Mulching with fully biodegradable materials;
- (2) Mowing;
- (3) Livestock grazing;
- (4) Hand weeding and mechanical cultivation;
- (5) Flame, heat, or electrical means; or
- (6) Plastic or other synthetic mulches: *Provided*, That, they are removed from the field at the end of the growing or harvest season.

**Guidance:** Polyvinyl chloride (PVC) is not allowed. See § 205.601(b)(2)(ii).

(d) Disease problems may be controlled through:

- (1) Management practices which suppress the spread of disease organisms; or
- (2) Application of nonsynthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop production may be applied to prevent, suppress, or control pests, weeds, or diseases: *Provided*, That, the conditions for using the substance are documented in the organic system plan.

**Guidance:** The National List (§ 205.601-606) below has been annotated to indicate materials that may be prohibited or restricted in other countries or certification programs.

(f) The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with soil or livestock.

**Guidance:** Harvest: See § 205.270 for information on organic handling requirements. If washing crops, water meeting safe water standards is required.

**§ 205.207 Wild-crop harvesting practice standard.**

(a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance, as set forth in § 205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

(b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

**EC Requirement:** the collection must not affect the stability of the natural habitat or the maintenance of the species in the collection area [EC 834/2007, Article 12(2)(b)].

**India Requirement:** NSOP 3.2.8.1. Wild harvested products must only be certified organic if derived from a stable and sustainable growing environment. Harvest or gathering the product must not exceed the sustainable yield of the ecosystem, or threaten the existence of plant or animal species.

NSOP 3.2.8.2. Products can only be certified organic if derived from a clearly defined collecting area, which is not exposed to prohibited substances, and which is subject to inspection.

NSOP 3.2.8.3. The collection area must be at an appropriate distance from conventional farming, pollution and contamination.

NSOP 3.2.8.4. The operator managing the harvesting or gathering of the products must be clearly identified and be familiar with the collecting area in question.

## §§ 205.208-205.235 [Reserved]

## LIVESTOCK

**EC Requirement:** Livestock production is fundamental to the organization of agricultural production on organic holdings in so far as it provides the necessary organic matter and nutrients for cultivated land and accordingly contributes towards soil improvement and the development of sustainable agriculture [EC 834/2007 preamble (14)].

As part of this holistic concept, landless production is not in conformity with the rules under this regulation [EC 889/2008, preamble (8)].

Landless livestock production, by which the operator of the livestock does not manage agricultural land and/or has not established a written cooperation agreement with another operator according to Article 3(3), is prohibited. [EC 889/2008, Article 16]

### § 205.236 Origin of livestock.

(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: *Except*, That:

(1) *Poultry*. Poultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life;

(2) *Dairy animals*. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, *Except*,

(i) That, crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products; and

(ii) That, when an entire, distinct herd is converted to organic production, the producer may, *provided* no milk produced under this subparagraph enters the stream of commerce labeled as organic after June 9, 2007:

(a) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and

(b) Provide feed in compliance with § 205.237 for the final 3 months.

(iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.

(3) *Breeder stock*. Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: *Provided*, That, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

**Guidance:** Breeding stock may be listed on the Certificate only if eligible for organic slaughter, otherwise Organic breeding stock (not for slaughter) will be specified only in the certification letter along with the number of head in each category.

**Guidance:** In the case of start-up animal operations or of farms diversifying into new animal enterprises, the type of livestock for which initial certification is requested must be on-site at the time of inspection.



**EC Requirement:** In the choice of breeds or strains, account must be taken of the capacity of animals to adapt to local conditions; their vitality, and their resistance to disease. In addition, breeds or strains of animals must be selected to avoid specific diseases or health problems associated with some breeds or strains used in intensive production (e.g. porcine stress syndrome, PSE Syndrome, sudden death, spontaneous abortion, difficult births requiring caesarean operations, etc.) [EC 889/2008, Article 8].

Livestock must come from organic production units [EC 834/2007, Article 14(1)(a)] with the following exceptions: Subject to a maximum of 10 % of adult equine or bovine (including bubalus and bison species) livestock and 20 % of the adult porcine, ovine and caprine livestock, livestock may be brought in, as female (nulliparous) animals, from non organic production stockfarms per year, for supplementing natural growth and for the renewal of the herd or flock, when organically reared animals are not available, and only when authorized by the control authority or body [EC 889/2008, Article 9(3)]

The percentages laid down in the above derogation must not apply to production units with less than 10 equine or bovine animals, or with less than five porcine, ovine or caprine animals. For these units, any renewal as mentioned above must be limited to a maximum of one animal per year.

These percentages may be increased, up to 40 % following the opinion and agreement of the inspection authority or body, in the following special cases:

- when a major extension to the stockfarm is undertaken;
- when a breed is changed;
- when a new livestock specialization is developed.

Males for breeding may be brought in from non organic-production stockfarms provided that the animals are subsequently reared and always fed in accordance with the rules laid down in this Regulation [EC 889/2008, Article 9(3 & 4)].

**EC Requirement:** In principle, the reproduction of organically reared livestock should be based on natural methods. Nevertheless artificial insemination is permitted. Other forms of artificial or assisted reproduction (for example embryo transfers) are prohibited [EC 834/2007, Article 14(c)].

**India Requirement:** NSOP 3.3.4.4. Hormonal heat treatment and induced birth are not allowed unless applied to individual animals for medical reasons and under veterinary advice.

(b) The following are prohibited:

- (1) Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a nonorganic operation may be not sold, labeled, or represented as organically produced.
- (2) Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled, or represented as organic slaughter stock.

(c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation.

**Guidance:** A record keeping system must be maintained which will permit tracing the sources and amounts of all feeds, supplements, all treatments and medications administered for any reason (including quarantine periods), breeding and/or origins of livestock, stock movements within the unit, transportation, slaughter and/or sales.

[[65 FR 80637, Dec. 21, 2000, as amended at 71 FR 32807, June 7, 2006]

### § 205.237 Livestock feed.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and handled by operations certified to the NOP, except as provided in §205.236(a)(2)(i), except, that, synthetic substances allowed under §205.603 and nonsynthetic substances not prohibited under §205.604 may be used as feed additives and feed supplements, *Provided*, That, all agricultural ingredients included in the ingredients list, for such additives and supplements, shall have been produced and handled organically.

**EC Requirement:** [EC 889/2008, Article 20]

1. The feeding of young mammals must be based on natural milk, preferably maternal milk. All mammals must be fed on natural milk for a minimum period, depending on the species concerned, which must be three months for bovines (including bubalus and bison species) and equidae, 45 days for sheep and goats and 40 days for pigs.

2. Rearing systems for herbivores are to be based on maximum use of pasturage according to the availability of pastures in the different periods of the year. At least 60 % of the dry matter in daily rations is to consist of roughage, fresh or dried

fodder, or silage. Nevertheless, the inspection authority or body can permit a reduction to 50 % for animals in dairy production for a maximum period of three months in early lactation.

3. Roughage, fresh or dried fodder, or silage must be added to the daily ration for pigs and poultry;
4. The production of organic feed from organic feed materials, except where a feed material is not available on the market in organic form;
5. Mineral nitrogen fertilisers shall not be used;
6. Duration of transport of livestock shall be minimised;
7. Primarily obtaining feed for livestock from the holding where the animals are kept or from other organic holdings in the same region;
8. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.

**India Requirement:** *NSOP 3.3.6.2.* The prevailing part (at least more than 50%) of the feed shall come from the farm unit itself or be produced in co-operation with other organic farms in the region. *The certification programme shall allow exceptions with regard to local conditions under a set time limit for implementation.*

**India Requirement:** *NSOP 3.3.6.3.* For the calculation purpose only, feed produced on the farm unit during the first year of organic management, may be classed as organic. This refers only to feed for animals which are themselves being produced within the farm unit and such feed may not be sold or otherwise marketed as organic.

**Guidance:** Refer to § 205.301(e) for information on organic livestock feed composition, § 205.302 for calculating ingredient percentages, and §205.306 for livestock feed labeling requirements.

(b) The producer of an organic operation must not:

- (1) Use animal drugs, including hormones, to promote growth;
- (2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;
- (3) Feed plastic pellets for roughage;
- (4) Feed formulas containing urea or manure;
- (5) Feed mammalian or poultry slaughter by-products to mammals or poultry;
- (6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act;
- (7) Provide feed or forage to which any antibiotic including ionophores has been added; or
- (8) Prevent, withhold, restrain, or otherwise restrict ruminant animals from actively obtaining feed grazed from pasture during the grazing season, except for conditions as described under §205.239(b) and (c).

(c) During the grazing season, producers shall:

- (1) Provide not more than an average of 70 percent of a ruminant's dry matter demand from dry matter fed (dry matter fed does not include dry matter grazed from residual forage or vegetation rooted in pasture). This shall be calculated as an average over the entire grazing season for each type and class of animal. Ruminant animals must be grazed throughout the entire grazing season for the geographical region, which shall be not less than 120 days per calendar year. Due to weather, season, and/or climate, the grazing season may or may not be continuous.
- (2) Provide pasture of a sufficient quality and quantity to graze throughout the grazing season and to provide all ruminants under the organic system plan with an average of not less than 30 percent of their dry matter intake from grazing throughout the grazing season: *Except, That,*
  - (i) Ruminant animals denied pasture in accordance with §205.239(b)(1) through (8), and §205.239(c)(1) through (3), shall be provided with an average of not less than 30 percent of their dry matter intake from grazing throughout the periods that they are on pasture during the grazing season;
  - (ii) Breeding bulls shall be exempt from the 30 percent dry matter intake from grazing requirement of this section and management on pasture requirement of §205.239(c)(2); *Provided, That,* any animal maintained under this exemption shall not be sold, labeled, used, or represented as organic slaughter stock.

(d) Ruminant livestock producers shall:

- (1) Describe the total feed ration for each type and class of animal. The description must include:

- (i) All feed produced on-farm;
  - (ii) All feed purchased from off-farm sources;
  - (iii) The percentage of each feed type, including pasture, in the total ration; and
  - (iv) A list of all feed supplements and additives.
- (2) Document the amount of each type of feed actually fed to each type and class of animal.
- (3) Document changes that are made to all rations throughout the year in response to seasonal grazing changes.
- (4) Provide the method for calculating dry matter demand and dry matter intake.

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

**§ 205.238 Livestock health care practice standard.**

- (a) The producer must establish and maintain preventive livestock health care practices, including:
- (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
  - (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
  - (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
  - (4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;
  - (5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and
  - (6) Administration of vaccines and other veterinary biologics.

**EC Requirement:** Housing, pens, equipment and utensils must be properly cleaned and disinfected to prevent cross-infection and the buildup of disease carrying organisms. Faeces, urine and uneaten or spilt feed must be removed as often as necessary to minimize smell and to avoid attracting insects or rodents [EC 889/2008, Article 23(4)].

Only products listed in Annex VII may be used for cleaning and disinfection of livestock buildings installations and utensils.

**India Requirement:** *NSOP 3.3.5.1.* Mutilations are not allowed. *The certification programme shall allow the following exceptions:*

- castrations
- tail docking of lambs
- dehorning
- ringing
- mulesing (only for breeds that require mulesing)

Suffering shall be minimized and anesthetics used where appropriate.

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: *Provided*, That, such medications are allowed under § 205.603. Parasiticides allowed under § 205.603 may be used on:

- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
- (2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must not:

- (1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604.
- (2) Administer any animal drug, other than vaccinations, in the absence of illness;
- (3) Administer hormones for growth promotion;
- (4) Administer synthetic parasiticides on a routine basis;
- (5) Administer synthetic parasiticides to slaughter stock;
- (6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

#### § 205.239 Livestock living conditions.

(a) The producer of an organic livestock operation must establish and maintain year-round livestock living conditions which accommodate the health and natural behavior of animals, including:

(1) Year-round access for all animals to the outdoors, shade, shelter, exercise areas, fresh air, clean water for drinking, and direct sunlight, suitable to the species, its stage of life, the climate, and the environment: Except, that, animals may be temporarily denied access to the outdoors in accordance with §§205.239(b) and (c). Yards, feeding pads, and feedlots may be used to provide ruminants with access to the outdoors during the non-grazing season and supplemental feeding during the grazing season. Yards, feeding pads, and feedlots shall be large enough to allow all ruminant livestock occupying the yard, feeding pad, or feedlot to feed simultaneously without crowding and without competition for food. Continuous total confinement of any animal indoors is prohibited. Continuous total confinement of ruminants in yards, feeding pads, and feedlots is prohibited.

**Guidance:** Operations to be inspected for the European Regulation or planning to export to Canada must provide livestock density ratios for all operations certified for livestock, poultry, and eggs. Data required are animal units per acre or per square foot for all certified operations. NOP-certified agricultural products derived from animals must be produced according to livestock stocking rates as set out in the Canadian Regulation and documented as part of the organic system plan.

**EC Requirement:** In the case of poultry natural light may be supplemented by artificial means to provide a maximum of 16 hours light per day with a continuous nocturnal rest period without artificial light of at least eight hours [EC 889/2008, Article 12(4)].

Poultry houses must be constructed in a manner allowing all birds easy access to open air area [EC 889/2008, Article 12(3)(g)].

Poultry must have access to an open air area for at least one third of their life. Open air areas for poultry must be mainly covered with vegetation and be provided with protective facilities and permit fowl to have easy access to adequate numbers of drinking and feeding troughs [EC 889/2008, Article 14(5-6)].

**EC Requirement:** The livestock must have permanent access to open air areas, preferably pasture, whenever weather conditions and the state of the ground allow this unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of Community legislation [EC 834/2007, Article 14(1)(b)(iii)].

All herbivores must have access to pasturage for grazing or an open-air exercise area, which may be partially covered, whenever conditions allow [EC 889/2008, Article 14(1-2)]

Bulls over one year old must have access to pasturage or an open-air exercise area or an open-air run [EC 889/2008, Article 14(4)]

(2) For all ruminants, management on pasture and daily grazing throughout the grazing season(s) to meet the requirements of §205.237, except as provided for in paragraphs (b), (c), and (d) of this section.

(3) Appropriate clean, dry bedding. When roughages are used as bedding, they shall have been organically produced in accordance with this part by an operation certified under this part, except as provided in §205.236(a)(2)(i), and, if applicable, organically handled by operations certified to the NOP.

(4) Shelter designed to allow for:

- (i) Natural maintenance, comfort behaviors, and opportunity to exercise;
- (ii) Temperature level, ventilation, and air circulation suitable to the species; and
- (iii) Reduction of potential for livestock injury;

**EC Requirement:** *Mammals:* Livestock housing must have smooth, but not slippery floors. At least half of the total floor area must be solid, that is, not of slatted or of grid construction [EC 889/2008, Article 11(1)]

The housing must be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material must be provided in the rest area. The litter must comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product for use in organic farming listed in Annex I [EC 889/2008, Article 11(2)]

The housing of calves in individual boxes is forbidden after the age of one week [EC 889/2008, Article 11(3)]

As regards the rearing of pigs, all holdings must comply with Council Directive 91/630/EEC(4) laying down minimum standards for the protection of pigs. Sows must be kept in groups, except in the last stages of pregnancy and during the

suckling period. Piglets must not be kept on flat decks or in piglet cages. Exercise areas must permit dunging and rooting by the animals. For the purposes of rooting different substrates can be used [EC 834/2007, Article 11(4-6)]

Notwithstanding Article 3(8) of Council Directive 91/630/EEC sows must be kept in groups, except in the last stages of pregnancy and during the suckling period. Piglets must not be kept on flat decks or in piglet cages. Exercise areas must permit dunging and rooting by porcine animals. For the purposes of rooting different substrates can be used.

*Poultry:* Poultry must be reared in open-range conditions and cannot be kept in cages [EC 889/2008, Article 12(1)]

Water fowl must have access to a stream, pond, lake or a pool whenever the weather and hygienic conditions permit in order to respect their species-specific needs and animal welfare requirements [EC 889/2008, Article 12(2)]

Buildings for all poultry must meet the following minimum conditions: [EC 889/2008, Article 12(3)(a-d)]

- at least one third of the floor area must be solid, that is, not of slatted or of grid construction, and covered with a litter material such as straw, wood shavings, sand or turf;
- in poultry houses for laying hens, a sufficiently large part of the floor area available to the hens must be available for the collection of bird droppings;
- they must have perches of a size and number commensurate with the size of the group and of the birds as laid down in Annex III;
- they must have exit/entry pop-holes of a size adequate for the birds, and these pop-holes must have a combined length of at least 4 m per 100 m<sup>2</sup> (1.2 ft per 100 sq ft) area of the house available to the birds;
- each poultry house must not contain more than: [EC 889/2008, Article 12(3)(e-f)]
  - 4800 chickens,
  - 3000 laying hens,
  - 5200 guinea fowl,
  - 4000 female Muscovy or Peking ducks or 3200 male Muscovy or Peking ducks or other ducks,
  - 2500 capons, geese or turkeys;
- the total usable area of poultry houses for meat production on any single production unit, must not exceed 1600 m<sup>2</sup> (17,220 sq ft).

**EC Requirement:** Minimum surface areas indoors and outdoors and other characteristics of housing in the different species and types of production referred to in article 10(4) [EC 889/2008, Annex III]

(5) The use of yards, feeding pads, feedlots and laneways that shall be well-drained, kept in good condition (including frequent removal of wastes), and managed to prevent runoff of wastes and contaminated waters to adjoining or nearby surface water and across property boundaries.

(b) The producer of an organic livestock operation may provide temporary confinement or shelter for an animal because of:

- (1) Inclement weather;
- (2) The animal's stage of life: Except, that lactation is not a stage of life that would exempt ruminants from any of the mandates set forth in this regulation;

For a transition period expiring 31 December 2010 the final fattening phase of sheep and pigs for meat production may take place indoors under the condition that the controls visits referred to in Article 65(1) are carried out at least twice a year [EC 889/2008, Article 95(3)]

- (3) Conditions under which the health, safety, or well-being of the animal could be jeopardized;
- (4) Risk to soil or water quality;
- (5) Preventive healthcare procedures or for the treatment of illness or injury (neither the various life stages nor lactation is an illness or injury);
- (6) Sorting or shipping animals and livestock sales: *Provided*, that, the animals shall be maintained under continuous organic management, including organic feed, throughout the extent of their allowed confinement;
- (7) Breeding: Except, that, bred animals shall not be denied access to the outdoors and, once bred, ruminants shall not be denied access to pasture during the grazing season; or
- (8) 4-H, Future Farmers of America and other youth projects, for no more than one week prior to a fair or other demonstration, through the event and up to 24 hours after the animals have arrived home at the conclusion of the event. These animals must have been maintained under continuous organic management, including organic feed, during the extent of their allowed confinement for the event.

(c) The producer of an organic livestock operation may, in addition to the times permitted under §205.239(b), temporarily deny a ruminant animal pasture or outdoor access under the following conditions:

- (1) One week at the end of a lactation for dry off (for denial of access to pasture only), three weeks prior to parturition (birthing), parturition, and up to one week after parturition;
- (2) In the case of newborn dairy cattle for up to six months, after which they must be on pasture during the grazing season and may no longer be individually housed: *Provided*, That, an animal shall not be confined or tethered in a way that prevents the animal from lying down, standing up, fully extending its limbs, and moving about freely;
- (3) In the case of fiber bearing animals, for short periods for shearing; and
- (4) In the case of dairy animals, for short periods daily for milking. Milking must be scheduled in a manner to ensure sufficient grazing time to provide each animal with an average of at least 30 percent DMI from grazing throughout the grazing season. Milking frequencies or duration practices cannot be used to deny dairy animals pasture.

(d) Ruminant slaughter stock, typically grain finished, shall be maintained on pasture for each day that the finishing period corresponds with the grazing season for the geographical location: Except, that, yards, feeding pads, or feedlots may be used to provide finish feeding rations. During the finishing period, ruminant slaughter stock shall be exempt from the minimum 30 percent DMI requirement from grazing. Yards, feeding pads, or feedlots used to provide finish feeding rations shall be large enough to allow all ruminant slaughter stock occupying the yard, feeding pad, or feed lot to feed simultaneously without crowding and without competition for food. The finishing period shall not exceed one-fifth (1/5) of the animal's total life or 120 days, whichever is shorter.

(e) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients and must manage pastures and other outdoor access areas in a manner that does not put soil or water quality at risk.

**EC Requirement:** The outdoor stocking density of livestock kept on pasturage, other grassland, heathland, wetland, heather, and other natural or semi-natural habitats, must be low enough to minimizing overgrazing and prevent poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure [EC 834/2007, Article 14(1)(b) (iv)] [Poaching – the puddling of soil in grassland and forage fields by stock grazing in wet conditions. While poached fields may appear very wet, the soil can be quite dry below the puddled layer because of the sealing effect that poaching has.]

**Guidance:** Refer to § 205.203(c) for standards on manure application and composting.

## Livestock Transportation and Slaughter

**EC Requirement:** Minimum Days to Slaughter – Poultry referred to in article 12(5) [EC 889/2008].

For poultry, the minimum age at slaughter must be:

- 81 days for chickens,
- 150 days for capons,
- 49 days for Peking ducks,
- 70 days for female Muscovy ducks,
- 84 days for male Muscovy ducks,
- 92 days for Mallard ducks,
- 94 days for guinea fowl,
- 140 days for male turkeys and roasting geese and
- 100 days for female turkeys.

Where producers do not apply these minimum slaughter ages, they must use slow-growing strains.

**EC Requirement:** Loading and unloading of animals shall be carried out without the use of any type of electrical stimulation to coerce the animals. The use of allopathic tranquillisers, prior to or during transport, is prohibited.

**India Requirement:** NSOP 3.3.8.2. Handling during transport and slaughter shall be calm and gentle. The use of electric sticks and such instruments are prohibited.

**EC Requirement:** EC 889/2008 Article 27(d) colours for stamping meat in accordance with Article 2(8) of European Parliament and Council Directive 94/36/EC;

**From Directive 94/36/EC Article 2(8):**

8. For the purpose of health marking as provided in Directive 91/497/EEC and other marking required on meat products, only E 155 Brown HT, E 133 Brilliant Blue FCF or E 129 Allura Red AC or an appropriate mixture of E 133 Brilliant Blue FCF and E 129 Allura Red AC may be used.

§§ 205.240 - [65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7193, Feb. 17, 2010]

**§ 205.240 Pasture practice standard.**

The producer of an organic livestock operation must, for all ruminant livestock on the operation, demonstrate through auditable records in the organic system plan, a functioning management plan for pasture.

(a) Pasture must be managed as a crop in full compliance with §§205.202, 205.203(d) and (e), 205.204, and 205.206(b) through (f). Land used for the production of annual crops for ruminant grazing must be managed in full compliance with §§205.202 through 205.206. Irrigation shall be used, as needed, to promote pasture growth when the operation has irrigation available for use on pasture.

(b) Producers must provide pasture in compliance with §205.239(a)(2) and manage pasture to comply with the requirements of: §205.237(c)(2), to annually provide a minimum of 30 percent of a ruminant's dry matter intake (DMI), on average, over the course of the grazing season(s); §205.238(a)(3), to minimize the occurrence and spread of diseases and parasites; and §205.239(e) to refrain from putting soil or water quality at risk.

(c) A pasture plan must be included in the producer's organic system plan, and be updated annually in accordance with §205.406(a). The producer may resubmit the previous year's pasture plan when no change has occurred in the plan. The pasture plan may consist of a pasture/rangeland plan developed in cooperation with a Federal, State, or local conservation office: *Provided*, that, the submitted plan addresses all of the requirements of §205.240(c)(1) through (8). When a change to an approved pasture plan is contemplated, which may affect the operation's compliance with the Act or the regulations in this part, the producer shall seek the certifying agent's agreement on the change prior to implementation. The pasture plan shall include a description of the:

- (1) Types of pasture provided to ensure that the feed requirements of §205.237 are being met.
- (2) Cultural and management practices to be used to ensure pasture of a sufficient quality and quantity is available to graze throughout the grazing season and to provide all ruminants under the organic system plan, except exempted classes identified in §205.239(c)(1) through (3), with an average of not less than 30 percent of their dry matter intake from grazing throughout the grazing season.
- (3) Grazing season for the livestock operation's regional location.
- (4) Location and size of pastures, including maps giving each pasture its own identification.
- (5) The types of grazing methods to be used in the pasture system.
- (6) Location and types of fences, except for temporary fences, and the location and source of shade and the location and source of water.
- (7) Soil fertility and seeding systems.
- (8) Erosion control and protection of natural wetlands and riparian areas practices.

[75 FR 7194, Feb. 17, 2010]

**§§ 205.241-205.269 [Reserved]**

**§ 205.270 Organic handling requirements.**

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

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

- (1) In or on a processed agricultural product intended to be sold, labeled, or represented as “organic,” pursuant to § 205.301(b), if not commercially available in organic form.
- (2) In or on a processed agricultural product intended to be sold, labeled, or represented as “made with organic (specified ingredients or food group(s)),” pursuant to § 205.301(c).

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

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

**Guidance: No GMOs or irradiation**

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

**EC Requirement:** Additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice. [EC 889/2008, Article 26(1)]

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

- (a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:
- (1) Removal of pest habitat, food sources, and breeding areas;
  - (2) Prevention of access to handling facilities; and
  - (3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.
- (b) Pests may be controlled through:
- (1) Mechanical or physical controls including but not limited to traps, light, or sound; or
  - (2) Lures and repellents using nonsynthetic or synthetic substances consistent with the National List.
- (c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.
- (d) If the practices provided for in paragraphs (a), (b), and (c) of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied: *Provided*, That, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.
- (e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.
- (f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations: *Provided*, That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

**Guidance:** For NOP-certified handlers, application of materials not on the allowed materials list must be pre-approved by OneCert. All applications of these materials must be documented. These documents must be available to the certification inspector.

Any application of materials that do not appear on the allowed materials list may only be applied by a certified, trained pesticide applicator(s), to reduce risk of misapplication.

In the case of fogging, broad surface treatment, and spot treatment, no product may be brought into the treatment area for a minimum of three days (72hrs.) after application.

In the case of fumigants, no product may be brought into the area of treatment, either for storage or processing for a minimum of 5 days. These actions must be documented and available to OneCert at any time, and during the annual inspection. In the case of known applications of prohibited materials, failure to provide these reports may be cause for immediate revocation of certification.

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

- (a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.
- (b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:
- (1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;



(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

**EC Requirement:** When operators handle both EC-organic and non-EC-organic product, for the storage of products, areas must be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products and/or substances not in compliance with the EC-organic production rules. This includes suitable cleaning measures, the effectiveness of which has been checked, have been carried out before the storage of organic products. Organic products must be clearly identifiable at all times. Every measure must be taken to ensure identification of consignments and to avoid mixtures or exchanges with non-EC-organic products [EC 889/2008, Article 35(1 & 4)]

**EC Requirement:** The processing of EU-organic and non-EU-organic product separated in time requires the application of appropriate cleaning measures to guarantee the integrity of organic production, particularly when there is only one processing line. Production of processed organic feed/organic food must be kept separate in time or space from production of processed non organic feed/ non organic food [EC834/2007, Article 18(1) & 19(2)ff].

**EC Requirement:** Substances and techniques that reconstitute properties that are lost in the processing and storage of organic food [or feed], that correct the results of negligence in the processing of these products or that otherwise may be misleading as to the true nature of these products shall not be 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 205.240 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.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7194, Feb. 17, 2010]

#### §§ 205.291-205.299 [Reserved]

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

#### § 205.300 Use of the term, “organic.”

(a) The term, “organic,” may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part. The term, “organic,” may not be used in a product name to modify a nonorganic ingredient in the product.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: *Provided*, That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.307(c).

**Guidance:** §205.300(b) only applies to export products that will not be sold in the US. If the product will be sold in the US, it must still comply with the NOP standards.

**All labels/art work and market information must be pre-approved by OneCert.**

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.

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

**EC Requirement: Labelling.** For the full text of EC Labelling Requirements see the “Additional Requirements and Guidelines” section.

**Table 1: Prohibited Production and Handling Practices for NOP 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
<b>"100 percent organic"</b> Single/multiple ingredients & processing aids completely organic	NO	NO	NO	NO	NO	NO	NO
<b>"Organic"</b> Organic ingredients (95% or more) Nonorganic ingredients (5% or less)	NO NO	NO NO	NO NO	NO NO	NO NO	NO NO	NO NO
<b>"Made with organic ingredients"</b> Organic ingredients (70-95%) Nonorganic ingredients (30% or less)	NO NO	NO NO	NO NO	NO OK	NO-except wine OK	NO N/A*	NO N/A*
<b>Less than 70% organic ingredients</b> Organic Ingredients (70% or less) Nonorganic Ingredients (30% or more)	NO OK	NO OK	NO OK	NO OK	NO-except wine OK	NO N/A*	NO N/A*

\* 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.

**§ 205.301 Product composition.**

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

**Guidance:** the 100 % organic category does not exist under the European Regulation, Canadian Organic Product Regulation, or JAS.

(b) *Products sold, labeled, or represented as “organic.”* A raw or processed agricultural product sold, labeled, or represented as “organic” must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

**“95 percent products”**

**EC Requirement:** Labeling and advertising may refer to the organic production method (in the product sales description) when at least 95 % by weight of the ingredients of agricultural origin are organic [Article 23(4) EC 834/2007]. Any terms, including terms used in trademarks, or practices used in labeling or advertising liable to mislead the consumer or user by

suggesting that a product or its ingredients satisfy the requirements set out under the EC Regulation must not be used [EC 834/2007, Article 23(2)].

**India Requirement:** NSOP 3.5.1.3. Mixed products where not all ingredients, including additives, are of organic origin may be labeled in the following way (raw material weight): Where a minimum of 95% of the ingredients are of certified organic origin, products may be labeled "certified organic" or similar and should carry the logo of the certification program.

(c) *Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."* Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of § 205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of § 205.301. If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.

**"70 percent products"**

**EC Requirement:** Only under certain restrictions can reference be made to the organic production method in the advertising of foods when between 70 and 95 % by weight of the ingredients of agricultural origin are organic. In this case the product sales description must not bear any indication about organic production. The references to the organic production method may only appear in relation to the organic ingredients and the list of ingredients must include an indication of the total percentage of organic ingredients in proportion to the total quantity of ingredients of agricultural origin. Of course, this indication must not be more prominent (by color, size or style of lettering) than the product sales description as the other indications in the list of ingredients [EC 834/2007, Article 23(4)(b & c)].

**India Requirement:** NSOP 3.5.1.3. Where less than 95% but not less than 70% of the ingredients are of certified organic origin, products may not be called "organic". The word "organic" may be used on the principal display in statements like "made with organic ingredients" provided there is a clear statement of the proportion of the organic ingredients. An indication that the product is covered by the certification programme may be used, close to the indication of proportion of organic ingredients.

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

**India Requirement:** NSOP 3.5.1.3. Where less than 70% of the ingredients are of certified organic origin, the indication that an ingredient is organic may appear in the ingredients list. Such product may not be called "organic".

(e) *Livestock feed.*

(1) A raw or processed livestock feed product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.

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

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

(1) Be produced using excluded methods, pursuant to § 205.105(e) of this chapter;

(2) Be produced using ionizing radiation, pursuant to § 205.105(f) of this chapter;

(3) Be processed using sewage sludge, pursuant to § 205.105(g) of this chapter;

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: *Except*, That, products labeled as "100 percent organic," if processed, must be processed using organically produced processing aids;

(5) Contain sulfites, nitrates, or nitrites added during the production or handling process, *Except*, that, wine containing added sulfites may be labeled "made with organic grapes";

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

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

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

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

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” or that include organic ingredients must be calculated by:

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

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

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

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

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

**EC Requirement:** The product shall be produced mainly from ingredients of agricultural origin; in order to determine whether a product is produced mainly from ingredients of agricultural origin added water and cooking salt shall not be taken into account. [EC 834/2007, Article 19(2)(a)].

**EC Requirement:** For determining the percentage of organic ingredients, food additives listed in Annex VIII and marked with an asterisk, must be included in the calculations as if they were ingredients of agricultural origin [EC 889/2008, Article 27(2)].

**Table 2: Labeling for NOP Certified consumer Product Packages (NOP 205.303-305)**

Labeling category	Principal 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 OneCert seal (optional)	"100% organic" (optional)  OneCert name (required); business/Internet address, tele. # (optional)	If multi-ingredient product, identify each ingredient as "organic" (optional)	"100 percent organic" (optional)  USDA seal and OneCert seal (optional)
"Organic" (95% or more organic ingredients)	"Organic" (plus product name) (optional)  "X% organic" (optional)  USDA seal and OneCert seal (optional)	"X % organic" (optional)  OneCert 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 OneCert seal (optional)
"Made with Organic Ingredients" (70 to 95% organic ingredients)	"made with organic (ingredients or food group(s))" (optional)  "X % organic" (optional)  "OneCert seal (optional)"  <u>Prohibited: USDA seal</u>	"X % organic ingredients" (optional)  OneCert name (required); business/Internet address, tele. # (optional)  "OneCert seal (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)  "OneCert seal (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 &amp; OneCert seal</u>	"X % organic" (optional)  <u>Prohibited: USDA seal &amp; OneCert seal</u>	Identify organic ingredients as "organic" (optional) (required if % organic is displayed)	<u>Prohibited: USDA seal &amp; OneCert seal</u>

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

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

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

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

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

(4) The USDA seal; and/or

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

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

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

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

**Guidance:** Labels of NOP-certified foods and feeds intended for sale in Canada may need the Canadian organic logo and the words “imported by” or “imported for”. Please contact your buyer in Canada or OneCert for additional information.

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

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

(1) The statement:

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

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

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

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

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

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

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

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

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

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

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

- (1) Identifying each organically produced ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced, and
- (2) If the organically produced ingredients are identified in the ingredient statement, displaying the product's percentage of organic contents on the information panel.

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

- (1) The USDA seal; and
- (2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

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

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

- (1) The statement, “100 percent organic” or “organic,” as applicable, to modify the name of the feed product;
- (2) The USDA seal;
- (3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, *Provided*, That, such seals or marks are not displayed more prominently than the USDA seal;
- (4) The word, “organic,” or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

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

- (1) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by \* \* \*,” or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.
- (2) Comply with other Federal agency or State feed labeling requirements as applicable.

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

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

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

**Guidance:** This section is only applicable to nonretail containers that hold product that is labeled in accordance with the mandatory portions of sections 205.303 through 205.306. See the definitions of label and labeling at the beginning of this document. Labeling is not limited to retail or final consumer packaging, and is a key element to ensure traceability, including transfer of ownership.

**EC Requirement:** If the transportation of products is not direct between two EU certified operation, then the shipping operators must ensure that organic products are transported to other units, including wholesalers and retailers, only in manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating: (a) the name and address of the operator and, where different, of the owner or seller of the product, (b) reference to its EC-organic condition; (c) the name and/or the code number of the control body or authority to which the operator is subject; and (d) where relevant, the lot identification mark which permits to link the lot with the accounts referred to in Article 66, and complete traceability [EC 889/2008, Art 31].

On receipt of an organic product, the operator must check the closing of the packaging or container where it is required and the presence of the indications provided to in Article 31. The operator must crosscheck the information on the label referred to in Article 31 with the information on the accompanying documents. The result of these verifications must be explicitly documented [EC 889/2008, Art 33].

**JAS Requirement:** The label is the sign of conformity with the standard. Labeling is mandatory and it must include the JAS seal, identify the certifier, operator's ID number, generic product name, country of origin and usually lot number [Law for Standardization and Labeling of Agricultural & Forest Products No. 175].

**EC Requirement:** Where an operator considers or suspects that a product which he has produced, processed, imported or that he has received from another operator, is not in compliance with EC-organic production rules, he must initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. In case of such doubt, the operator must immediately inform the control body [EC889/2008, Article 91(1)].

**JAS Requirement:** When an operator finds that a label is attached or linked to product not conforming to JAS standards, the operator must remove or erase the JAS-label without delay [Law for Standardization and Labeling of Agricultural & Forest Products No. 175, Article 14(7) & 19(12)]. Additionally, any packaging material or container with a JAS label must not be reused as packaging material or container, unless the label is removed or erased [Law for Standardization and Labeling of Agricultural & Forest Products No. 175, Article 19].

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

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: *Provided*, That, the shipping containers and shipping documents accompanying such organic products are clearly marked "For Export Only" and: *Provided further*, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under § 205.101.

**Guidance:** §205.307(c) only applies to export products that will not also be sold in the US.

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

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

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

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

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

(a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, "made with organic (specified ingredients or food group(s))," to modify the name of the product in retail display, labeling, and display containers.

- (1) Such statement must not list more than three organic ingredients or food groups, and
- (2) In any such display of the product's ingredient statement, the organic ingredients are identified as "organic."

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

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

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



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

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

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

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

#### § 205.311 USDA Seal.

(a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.

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

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

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

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



#### §§ 205.312-205.399 [Reserved]

## Subpart E—Certification

### § 205.400 General requirements for certification.

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

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

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

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

(d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.103;

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

(f) Immediately notify the certifying agent concerning any:

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

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

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

**EC Requirement:** With regard to the operations, which are contracted out to third parties, the full description of the unit referred to in Article 63(1)(a) shall include: (a) a list of the subcontractors with a description of their activities and an indication of the control bodies or authorities to which they are subject; (b) written agreement by the subcontractors that their holding will be subject to the control regime of Title V of Regulation (EC) No 834/2007; (c) all the practical measures, including inter alia an appropriate system of documentary accounts, to be taken at the level of the unit to ensure that the products the operator places on the market can be traced to, as appropriate, their suppliers, sellers, consignees and buyers. [EC 889/2008, Article 86].

#### **§ 205.401 Application for certification.**

A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:

- (a) An organic production or handling system plan, as required in § 205.200;
- (b) The name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf;
- (c) The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and
- (d) Other information necessary to determine compliance with the Act and the regulations in this part.

#### **§ 205.402 Review of application.**

- (a) Upon acceptance of an application for certification, a certifying agent must:
  - (1) Review the application to ensure completeness pursuant to § 205.401;
  - (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;
  - (3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance or denial of certification, pursuant to § 205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in § 205.405(e); and
  - (4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.
- (b) The certifying agent shall within a reasonable time:
  - (1) Review the application materials received and communicate its findings to the applicant;
  - (2) Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed; and
  - (3) Provide the applicant with a copy of the test results for any samples taken by an inspector.
- (c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

#### **§ 205.403 On-site inspections.**

- (a) *On-site inspections.*
  - (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

- (2) (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.
- (ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.
- (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) *Scheduling.*

- (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: *Except*, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.
- (2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) *Verification of information.* The on-site inspection of an operation must verify:

- (1) The operation's compliance or capability to comply with the Act and the regulations in this part;
- (2) That the information, including the organic production or handling system plan, provided in accordance with §§ 205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;
- (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) *Exit interview.* The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

**EC Requirement:** a control report must be drawn up after each visit, countersigned by the operator of the unit or his representative [EC 889/2008, Article 65(3)].

(e) *Documents to the inspected operation.*

- (1) At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.
- (2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

**§ 205.404 Granting certification.**

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification.

(b) The certifying agent must issue a certificate of organic operation which specifies the:

- (1) Name and address of the certified operation;
- (2) Effective date of certification;
- (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and
- (4) Name, address, and telephone number of the certifying agent.

(c) Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator.

**§ 205.405 Denial of certification.**

(a) When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification. The notification of noncompliance shall provide:

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

(b) Upon receipt of such notification of noncompliance, the applicant may:

- (1) Correct noncompliances and submit a description of the corrective actions taken with supporting documentation to the certifying agent;
- (2) Correct noncompliances and submit a new application to another certifying agent: *Provided*, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or
- (3) Submit written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

- (1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and
  - (i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to § 205.404; or
  - (ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.
- (2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.
- (3) Provide notice of approval or denial to the Administrator, pursuant to § 205.501(a)(14).

(d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

- (1) Reapply for certification pursuant to §§ 205.401 and 205.405(e);
- (2) Request mediation pursuant to § 205.663 or, if applicable, pursuant to a State organic program; or
- (3) File an appeal of the denial of certification pursuant to § 205.681 or, if applicable, pursuant to a State organic program.

(e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§ 205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.

(f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to § 205.402.

(g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

**§ 205.406 Continuation of certification.**

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:

- (1) An updated organic production or handling system plan which includes:
  - (i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and
  - (ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.200;
- (2) Any additions to or deletions from the information required pursuant to § 205.401(b);
- (3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and
- (4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

**EC Requirement:** operators must notify OneCert of any change to the organic system plan [EC 889/2008, Article 65(3)].

(b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to § 205.403: *Except*, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: *Provided*, That, the annual on-site inspection, required pursuant to § 205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with § 205.662.

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).

§§ 205.407-205.499 [Reserved]

## Subpart F—Accreditation of Certifying Agents

### § 205.500 Areas and duration of accreditation.

(a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

(b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to § 205.506.

(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:

- (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or
- (2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.

### § 205.501 General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must:

- (1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;
- (2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;
- (3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;

- (4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;
- (5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.
- (6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;
- (7) Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;
- (8) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;
- (9) Maintain all records pursuant to § 205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official;
- (10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.504(b)(5);
- (11) Prevent conflicts of interest by:
  - (i) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;
  - (ii) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;
  - (iii) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected: *Except*, That, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations;
  - (iv) Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification;
  - (v) Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report; and
  - (vi) Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.
- (12)
  - (i) Reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under § 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. All costs associated with a reconsideration of application, including onsite inspection costs, shall be borne by the certifying agent.
  - (ii) Refer a certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification when it is determined that any person covered under § 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant.

- (13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500;
- (14) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;
- (15) Submit to the Administrator a copy of:
- (i) Any notice of denial of certification issued pursuant to § 205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to § 205.662 simultaneously with its issuance; and
  - (ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year;
- (16) Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator;
- (17) Pay and submit fees to AMS in accordance with § 205.640;
- (18) Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances;
- (19) Accept all production or handling applications that fall within its area(s) of accreditation and certify all qualified applicants, to the extent of its administrative capacity to do so without regard to size or membership in any association or group; and
- (20) Demonstrate its ability to comply with a State's organic program to certify organic production or handling operations within the State.
- (21) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.
- (b) A private or governmental entity accredited as a certifying agent under this subpart may establish a seal, logo, or other identifying mark to be used by production and handling operations certified by the certifying agent to indicate affiliation with the certifying agent: *Provided*, That, the certifying agent:
- (1) Does not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification and
  - (2) Does not require compliance with any production or handling practices other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark: *Provided*, That, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.
- (c) A private entity accredited as a certifying agent must:
- (1) Hold the Secretary harmless for any failure (1) on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;
  - (2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and
  - (3) Transfer to the Administrator and make available to any applicable State organic program's governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation; *Provided*, That, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.
- (d) No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

#### **§ 205.502 Applying for accreditation.**

- (a) A private or governmental entity seeking accreditation as a certifying agent under this subpart must submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.503 through 205.505 and the fees required in § 205.640 to: Program Manager, USDA-AMS-NOP, 1400 Independence Ave. SW., Room 2648 So. Bldg., Ag Stop 0268, Washington, DC 20250-0268.

(b) Following the receipt of the information and documents, the Administrator will determine, pursuant to § 205.506, whether the applicant for accreditation should be accredited as a certifying agent.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

**§ 205.503 Applicant information.**

A private or governmental entity seeking accreditation as a certifying agent must submit the following information:

- (a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, and Internet address) of the applicant, and, for an applicant who is a private person, the entity's taxpayer identification number;
- (b) The name, office location, mailing address, and contact numbers (telephone, facsimile, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;
- (c) Each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;
- (d) The type of entity the applicant is (e.g., government agricultural office, for-profit business, not-for-profit membership association) and for:
  - (1) A governmental entity, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part,
  - (2) A private entity, documentation showing the entity's status and organizational purpose, such as articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment; and
- (e) A list of each State or foreign country in which the applicant currently certifies production and handling operations and a list of each State or foreign country in which the applicant intends to certify production or handling operations.

**§ 205.504 Evidence of expertise and ability.**

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in § 205.501:

(a) *Personnel.*

- (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;
- (2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;
- (3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:
  - (i) Each inspector to be used by the applicant and
  - (ii) Each person to be designated by the applicant to review or evaluate applications for certification; and
- (4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

(b) *Administrative policies and procedures.*

- (1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;
- (2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;
- (3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.501(a)(9);
- (4) A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);
- (5) A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request:



- (i) Certification certificates issued during the current and 3 preceding calendar years;
  - (ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years;
  - (iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and
  - (iv) Other business information as permitted in writing by the producer or handler; and
- (6) A copy of the procedures to be used for sampling and residue testing pursuant to §205.670.
- (c) *Conflicts of interest.*
- (1) A copy of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in § 205.501(a)(11).
  - (2) For all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent, a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest.
- (d) *Current certification activities.* An applicant who currently certifies production or handling operations must submit:
- (1) A list of all production and handling operations currently certified by the applicant;
  - (2) Copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and
  - (3) The results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities.
- (e) *Other information.* Any other information the applicant believes may assist in the Administrator's evaluation of the applicant's expertise and ability.

**§ 205.505 Statement of agreement.**

- (a) A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including:
- (1) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500;
  - (2) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;
  - (3) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;
  - (4) Have an annual internal program review conducted of its certification activities by certifying agent staff, an outside auditor, or a consultant who has the expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part;
  - (5) Pay and submit fees to AMS in accordance with § 205.640; and
  - (6) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.
- (b) A private entity seeking accreditation as a certifying agent under this subpart must additionally agree to:
- (1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;
  - (2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and
  - (3) Transfer to the Administrator and make available to the applicable State organic program's governing State official all records or copies of records concerning the certifying agent's certification activities in the event that

the certifying agent dissolves or loses its accreditation; *Provided*, That such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

#### **§ 205.506 Granting accreditation.**

(a) Accreditation will be granted when:

- (1) The accreditation applicant has submitted the information required by §§ 205.503 through 205.505;
- (2) The accreditation applicant pays the required fee in accordance with § 205.640(c); and
- (3) The Administrator determines that the applicant for accreditation meets the requirements for accreditation as stated in § 205.501, as determined by a review of the information submitted in accordance with §§ 205.503 through 205.505 and, if necessary, a review of the information obtained from a site evaluation as provided for in § 205.508.

(b) On making a determination to approve an application for accreditation, the Administrator will notify the applicant of the granting of accreditation in writing, stating:

- (1) The area(s) for which accreditation is given;
- (2) The effective date of the accreditation;
- (3) Any terms and conditions for the correction of minor noncompliances; and
- (4) For a certifying agent who is a private entity, the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.

(c) The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as provided in § 205.510(c), the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to § 205.665.

#### **§ 205.507 Denial of accreditation.**

(a) If the Program Manager has reason to believe, based on a review of the information specified in §§ 205.503 through 205.505 or after a site evaluation as specified in § 205.508, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, the Program Manager shall provide a written notification of noncompliance to the applicant. Such notification shall provide:

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

(b) When each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application.

(c) If an applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal of the notification of noncompliance by the date specified, or is unsuccessful in its rebuttal, the Program Manager will provide the applicant with written notification of accreditation denial. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with § 205.502, or appeal the denial of accreditation in accordance with § 205.681 by the date specified in the notification of accreditation denial.

(d) If the certifying agent was accredited prior to the site evaluation and the certifying agent fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, or fails to file a rebuttal of the notification of noncompliance by the date specified, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation. A certifying agent who has had its accreditation suspended 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 noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

#### **§ 205.508 Site evaluations.**

(a) Site evaluations of accredited certifying agents shall be conducted for the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and the regulations of this part. Site evaluations shall include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. Site evaluations shall be conducted by a representative(s) of the Administrator.

(b) An initial site evaluation of an accreditation applicant shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." A site evaluation shall be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. One or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements set forth in § 205.501.

**§ 205.509 Peer review panel.**

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not less than 3 members who shall annually evaluate the National Organic Program's adherence to the accreditation procedures in this subpart F and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions. This shall be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the National Organic Program's Program Manager.

**§ 205.510 Annual report, recordkeeping, and renewal of accreditation.**

(a) *Annual report and fees.* An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees:

- (1) A complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504;
- (2) Information supporting any changes being requested in the areas of accreditation described in § 205.500;
- (3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation;
- (4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and
- (5) The fees required in § 205.640(a).

(b) *Recordkeeping.* Certifying agents must maintain records according to the following schedule:

- (1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt;
- (2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and
- (3) Records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by § 205.510(b)(2), must be maintained for not less than 5 years beyond their creation or receipt.

(c) *Renewal of accreditation.*

- (1) The Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration.
- (2) An accredited certifying agent's application for accreditation renewal must be received at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and the regulations of this part.
- (3) Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and the regulations of this part and should have its accreditation renewed.

(d) *Notice of renewal of accreditation.* Upon a determination that the certifying agent is in compliance with the Act and the regulations of this part, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.

(e) *Noncompliance.* Upon a determination that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation.

(f) *Amending accreditation.* Amendment to scope of an accreditation may be requested at any time. The application for amendment shall be sent to the Administrator and shall contain information applicable to the requested change in accreditation, a complete and accurate update of the information submitted pursuant to §§ 205.503 and 205.504, and the applicable fees required in § 205.640.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§§ 205.511-205.599 [Reserved]

## Subpart G—Administrative

### The National List of Allowed and Prohibited Substances

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

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

- (a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).
- (b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:
  - (1) The substance cannot be produced from a natural source and there are no organic substitutes;
  - (2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
  - (3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;
  - (4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during 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) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

#### § 205.601 Synthetic substances allowed for use in organic crop production.

**EC Requirement:** inputs for crop production: substances allowed as fertilizers and soil conditioners are listed in Annex I; substances allowed for pest, disease and weed management are listed in Annex II of EC 889/08. These lists are closed (if not listed is not allowed), and substances listed can be used only in compliance with *Article 16 EC 843/07*, and if measures specified in *Article 12(1) of EC 843/07* prove to be not sufficient.

*JAS Requirement:* similar to the European Regulation, lists of allowed substances or ingredients are 'closed', meaning that if not listed it is not allowed. *These lists of allowed substances can be found at the end of each JAS standard.*

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: *Provided*, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), and (l) of this section, may only be used when the provisions set forth in § 205.206(a) through (d) prove insufficient to prevent or control the target pest.

- (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
  - (1) Alcohols.
    - (i) Ethanol (Not allowed: EU).
    - (ii) Isopropanol (Not allowed: EU)
  - (2) Chlorine materials – For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit

under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions. (Not allowed: EU, JAS)

- (i) Calcium hypochlorite (Not allowed: EU)
- (ii) Chlorine dioxide (Not allowed: EU)
- (iii) Sodium hypochlorite (Not allowed: EU)

(3) Copper sulfate – for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

(EU: Restricted to 6 kg copper per ha per year, averaged over a period of 5 years; the amount may exceed the ceiling a specific year if the 5-year average doesn't exceed 6 kg) (JAS: Limited to the use for preparing Bordeaux mixture.)

(4) Hydrogen peroxide (Not allowed: EU, JAS)

(5) Ozone gas—for use as an irrigation system cleaner only. (Not allowed: EU, JAS)

(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.

(EU: only allowed for disinfecting livestock buildings installations and equipment or utensils)

(7) Soap-based algicide/demossers.

(8) Sodium carbonate peroxyhydrate (CAS #–15630–89–4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

(b) As herbicides, weed barriers, as applicable.

(1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops (Not allowed: EU, JAS).

(2) Mulches.

- (i) Newspaper or other recycled paper, without glossy or colored inks. (Not allowed: EU)
- (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)) (Not allowed: EU).
- (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.

(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks (Not allowed: EU).

(d) As animal repellents

—Soaps, ammonium—for use as a large animal repellent only, no contact with soil or edible portion of crop (Not allowed: EU).

(e) As insecticides (including acaricides or mite control).

(1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil (Not allowed: EU, JAS).

(2) Aqueous potassium silicate (CAS #–1312–76–1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

(3) Boric acid—structural pest control, no direct contact with organic food or crops (Not allowed: EU; JAS: limited to use in insect traps when processing food or feed).

(4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

(EU: Restricted to 6 kg copper per ha per year, averaged over a period of 5 years; the amount may exceed the ceiling a specific year if the 5-year average doesn't exceed 6 kg) (JAS: Limited to the use for preparing Bordeaux mixture.)

(5) Elemental sulfur.

(6) Lime sulfur—including calcium polysulfide.

- (7) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.
- (8) Soaps, insecticidal.
- (9) Sticky traps/barriers.
- (10) Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.
- (f) As insect management.
  - Pheromones.
- (g) As rodenticides.
  - Vitamin D3 (Not allowed: EU, JAS).
- (h) As slug or snail bait.
  - Ferric phosphate (CAS # 10045–86–0).
- (i) As plant disease control.
  - (1) Aqueous potassium silicate (CAS #—1312–76–1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
  - (2) Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided*, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.
    - (EU: Restricted to a ceiling starting at 8 kg copper per ha, and after a limited transitional period of four years be reduced to 6 kg copper per ha unless it would be demonstrated that for certain crops such lower ceiling is not efficacious.)
  - (3) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.
    - (EU: Restricted to 6 kg copper per ha per year, averaged over a period of 5 years; the amount may exceed the ceiling a specific year if the 5-year average doesn't exceed 6 kg.) (JAS: Limited to the use for preparing Bordeaux mixture.)
  - (4) Hydrated lime. (Not allowed: EU) (JAS: slake lime, allowed for soil improvement)
  - (5) Hydrogen peroxide (Not allowed: EU, JAS).
  - (6) Lime sulfur.
  - (7) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.
  - (8) Peracetic acid—for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.
    - (EU: only allowed for disinfecting livestock equipment)
  - (9) Potassium bicarbonate (Not allowed: EU).
  - (10) Elemental sulfur.
- (j) As plant or soil amendments.
  - (1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction. (Not allowed: JAS)
  - (2) Elemental sulfur.
  - (3) Humic acids—naturally occurring deposits, water and alkali extracts only (Not allowed: EU, JAS).
  - (4) Lignin sulfonate—chelating agent, dust suppressant (Not allowed: EU).
  - (5) Magnesium sulfate—allowed with a documented soil deficiency .
  - (6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.
    - (i) Soluble boron products.
    - (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.
  - (7) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5 (Not allowed: EU, JAS: fish products are allowed, but not synthetic chemicals like sulfuric acid used for lowering pH; need to find formulation that is allowed).
  - (8) Vitamins, B1, C, and E (Not allowed: JAS).

(9) Sulfurous acid (CAS # 7782-99-2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.

(k) As plant growth regulators.

Ethylene gas—for regulation of pineapple flowering (*JAS*: limited to be used for after-ripening of banana).

(l) As floating agents in postharvest handling. Sodium silicate—for tree fruit and fiber processing (Not allowed: EU, *JAS*).

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern (Not allowed: EU) [some inert ingredients from this list were revoked, for details see NOP letter dated Sept. 6, 2007].

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers. (Not allowed: EU)

(n) Seed preparations.

Hydrogen chloride (CAS # 7647-01-0)—for delinting cotton seed for planting.

(o) As production aids. Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)—for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

(p)-(z) [Reserved]

[65 FR 80637, Dec. 21, 2000, as amended at 68 FR 61992, Oct. 31, 2003; 71 FR 53302 Sept. 11, 2006; 72 FR 69572, Dec. 10, 2007; 75 FR 38696, July 6, 2010; 75 FR 77524, Dec. 13, 2010, 77 FR 8092, Feb. 14, 2012; 77 FR 33298, June 6, 2012; 77 FR 45907, Aug. 2, 2012; 78 FR 31821, May 28, 2013; 79 FR 586632, Sept. 30, 2014; 80 FR 77234, Dec. 12, 2015; 82 FR 31244, July 6, 2017]

#### § 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

(a) Ash from manure burning.

(b) Arsenic.

(c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

(d) Lead salts.

(e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

(f) Sodium fluoaluminate (mined).

(g) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005. (Not allowed: EU, *JAS*.) NOP-certified product entering Canada **must** come from fields free of sodium nitrate, per USCOEA.

(h) Strychnine.

(i) Tobacco dust (nicotine sulfate).

(j)–(z) [Reserved]

[68 FR 61992, Oct. 31, 2003]

#### § 205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols.

(i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive.

- (ii) Isopropanol—disinfectant only.
- (2) Aspirin—approved for health care use to reduce inflammation.
- (3) Atropine (CAS #–51–55–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under **7 CFR Part 205**, the NOP requires:
  - (i) Use by or on the lawful written order of a licensed veterinarian; and
  - (ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.
- (4) Biologics—Vaccines.
- (5) Butorphanol (CAS #–42408–82–2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:
  - (i) Use by or on the lawful written order of a licensed veterinarian; and
  - (ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.
- (6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
- (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
  - (i) Calcium hypochlorite.
  - (ii) Chlorine dioxide. (Not allowed: EU)
  - (iii) Sodium hypochlorite.
- (8) Electrolytes—without antibiotics.
- (9) Flunixin (CAS #–38677–85–9)—in accordance with approved labeling; except that for use under 7 CFR Part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.
- (10) Glucose.
- (11) Glycerin—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
- (12) Hydrogen peroxide.
- (13) Iodine.
- (14) Magnesium hydroxide (CAS #–1309–42–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.
- (15) Magnesium sulfate.
- (16) Oxytocin—use in postparturition therapeutic applications.
- (17) Parasiticides. Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
  - (i) Fenbendazole (CAS #43210–67–9)—only for use by or on the lawful written order of a licensed veterinarian.
  - (ii) Ivermectin (CAS #70288–86–7).
  - (iii) Moxidectin (CAS #113507–06–5)—for control of internal parasites only.
- (18) Peroxyacetic/peracetic acid (CAS #–79–21–0)—for sanitizing facility and processing equipment.
- (19) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.
- (20) Poloxalene (CAS #–9003–11–6)—for use under 7 CFR Part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.



(21) Tolazoline (CAS #–59–98–3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:

- (i) Use by or on the lawful written order of a licensed veterinarian;
- (ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and
- (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(22) Xylazine (CAS #–7361–61–7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:

- (i) Use by or on the lawful written order of a licensed veterinarian;
- (ii) The existence of an emergency; and
- (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

- (1) Copper sulfate.
- (2) Formic acid (CAS # 64–18–6)—for use as a pesticide solely within honeybee hives.
- (3) Iodine.
- (4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.
- (5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes. (Not allowed: EU)
- (6) Mineral oil—for topical use and as a lubricant.
- (7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.
- (8) Sucrose octanoate esters (CAS #s–42922–74–7; 58064–47–4)—in accordance with approved labeling.

(c) As feed supplements —None.

(d) As feed additives.

- (1) DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.
- (2) Trace minerals, used for enrichment or fortification when FDA approved.
- (3) Vitamins, used for enrichment or fortification when FDA approved.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (1) EPA List 4—Inerts of Minimal Concern. (Not allowed: EU)
- (2) [Reserved]

(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

(g)–(z) [Reserved]

[72 FR 70484, Dec. 12, 2007, as amended at 73 FR 54059, Sept. 18, 2008; 75 FR 51924, Aug. 24, 2010, 77 FR 28745, May 15, 2012; 77 FR 45907, Aug. 2, 2012, 77 FR 57989, Sept. 19, 2012; 82 FR 31244, July 6, 2017]

#### **§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production.**

The following nonsynthetic substances may not be used in organic livestock production:

- (a) Strychnine.

(b)-(z) [Reserved]

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

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

(a) *Nonsynthetics allowed:*

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

(JAS: Citric - Limited to be used as pH adjustment agent or used for vegetable processed products or fruit processed products. Lactic - Limited to be used for processed vegetable and dairy products.)

Agar-agar.

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

Attapulgate—as a processing aid in the handling of plant and animal oils.

Bentonite.

Calcium carbonate.

Calcium chloride.

Calcium sulfate—mined.

Carrageenan.

Dairy cultures.

Diatomaceous earth—food filtering aid only.

Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

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

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

Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited. (Not allowed: EU, JAS)

Kaolin.

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

Magnesium sulfate, nonsynthetic sources only. (Not allowed: EU)

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

Nitrogen—oil-free grades.

Oxygen—oil-free grades.

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

Potassium chloride.

Potassium iodide. (Not allowed: EU)

Sodium bicarbonate.

Sodium carbonate.

(JAS: Limited to be used for the confectionery, sugar, processed products of beans, noodles, and bread.)

Tartaric acid—made from grape wine.

Waxes—nonsynthetic (Carnauba wax; and Wood resin). (Wood resin - Not allowed: EU)

Yeast— When used as food or a fermentation agent in products labeled as “organic,” yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented. (EU: organic yeast)

(b) *Synthetics allowed:*

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

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

Alginates.

Ammonium bicarbonate—for use only as a leavening agent.

Ammonium carbonate—for use only as a leavening agent.

Ascorbic acid.

Calcium citrate.

Calcium hydroxide.

Calcium phosphates (monobasic, dibasic, and tribasic).

Carbon dioxide.

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

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

Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus. (JAS: limited to be used for after-ripening of banana)

Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization). (Not allowed: EU)

Glycerides (mono and di)—for use only in drum drying of food. (Not allowed: EU)

Glycerin—produced by hydrolysis of fats and oils.

Hydrogen peroxide. (Not allowed: EU, JAS)

Magnesium chloride—derived from sea water. (JAS: Limited to be used for coagulating agent or processed products of beans.)

Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))” prohibited in agricultural products labeled “organic”. (Not allowed: EU, JAS)

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

**EC Requirement:** The European Regulation specifies that minerals (trace elements included), vitamins, amino acids, and micronutrients, only authorized as far their use is legally required in the foodstuffs in which they are incorporated [EC 889/2008, Article 27(1)(f)].

Ozone. (Not allowed: EU, JAS)

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

Phosphoric acid—cleaning of food-contact surfaces and equipment only. (Not allowed: EU)

Potassium acid tartrate. (Not allowed: EU)

Potassium carbonate. (JAS: Limited to be used for drying the fruit processed products, or used for grains processed products, processed products of beans, noodles, bread, or the confectionery.)

Potassium carbonate.

Potassium citrate. (Not allowed: EU)

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches. (Not allowed: EU)

(JAS: Limited to be used for processing sugar as pH adjustment agent.)

Potassium phosphate—for use only in agricultural products labeled “made with organic (specific ingredients or food group(s))” prohibited in agricultural products labeled “organic”. (Not allowed: EU, JAS)

Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available. (JAS: Limited to be used as gel or colloidal solution in processed food of plant origin.)

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

Sodium citrate. (Not allowed: EU)

Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables. (Not allowed: EU)

(JAS: Limited to be used for processing sugar as pH adjustment agent or used for grains processed products.)

Sodium phosphates—for use only in dairy foods. (Not allowed: EU, JAS)

Sulfur dioxide—for use only in wine labeled “made with organic grapes,” *Provided*, That, total sulfite concentration does not exceed 100 ppm. (EU: In fruit wines without added sugar or in mead: 50 mg, its use will be re-examined before 31 December 2010; JAS: not allowed)

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

Xanthan gum.

(c)–(z) [Reserved]

[68 FR 61993, Oct. 31, 2003, as amended as 68 FR 62217, Nov. 3, 2003; 71 FR 53302, Sept. 11, 2006; 72 FR 58473, Oct. 16, 2007; 73 FR 59481, Oct. 9, 2008; 75 FR 77524, Dec. 13, 2010; 77 FR 8092, Feb. 14, 2012; 77 FR 33298, June 6, 2012; 77 FR 45907, Aug. 2, 2012; 78 FR 31821, May 28, 2013; 78 FR 61161, Oct. 3, 2013; 81 FR 51709, Aug. 3, 2016; 82 FR 31244, July 6, 2017]

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

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

**EC Requirement:** For EU (EC 889/Article 22: only organic feed materials of animal origin shall be used in EU organic feed.

(a) Casings, from processed intestines.

(b) Celery powder.

(c) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(1) Beet juice extract color (pigment CAS # 7659–95–2).

(2) Beta-carotene extract color, derived from carrots or algae (pigment CAS # 7235–40–7).

(3) Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(4) Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(5) Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(6) Carrot juice color (pigment CAS # 1393–63–1).

(7) Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(8) Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(9) Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(10) Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(11) Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(12) Paprika color (CAS # 68917–78–2)—dried, and oil extracted.

(13) Pumpkin juice color (pigment CAS # 127–40–2).

(14) Purple potato juice (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

- (15) Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (16) Red radish extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (17) Saffron extract color (pigment CAS # 1393–63–1).
- (18) Turmeric extract color (CAS # 458–37–7).
- (d) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.

**EC Requirement:** For EU restriction will be followed as; organic feed materials of animal origin are only allowed (EC 889/2008 Article 22).

- (e) Fructooligosaccharides (CAS # 308066–66–2).
- (f) Gelatin (CAS # 9000–70–8).
- (g) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
- (h) Inulin-oligofructose enriched (CAS # 9005–80–5).
- (i) Kelp—for use only as a thickener and dietary supplement.
- (j) Konjac flour (CAS # 37220–17–0).
- (k) Lecithin—de-oiled.
- (l) Orange pulp, dried.
- (m) Orange shellac-unbleached (CAS # 9000–59–3).
- (n) Pectin (non-amidated forms only).
- (o) Seaweed, Pacific kombu
- (p) Starches.
  - (1) Cornstarch (native).
  - (2) Sweet potato starch—for bean thread production only.
- (q) Tragacanth gum (CAS #–9000–65–1).
- (r) Turkish bay leaves.
- (s) Wakame seaweed ( *Undaria pinnatifida* ).
- (t) Whey protein concentrate.

**EC Requirement:** For EU restriction will be followed as; organic feed materials of animal origin are only allowed (EC 889/2008 Article 22).

[72 FR 35140, June 27, 2007, as amended at 75 FR 77524, Dec. 13, 2010, 77 FR 8092, Feb. 14, 2012; 77 FR 33299, June 6, 2012; 77 FR 44429, July 30, 2012; 78 FR 31821, May 28, 2013; 79 FR 58663, Sept. 30, 2014; 80 FR 77234, Dec. 12, 2015; 82 FR 31244, July 6, 2017]

#### § 205.607 Amending the National List.

- (a) Any person may petition the National Organic Standards Board for the purpose of having a substance evaluated by the Board for recommendation to 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-NOP, 1400 Independence Ave. SW., Room 2648 So. Bldg., Ag Stop 0268, Washington, DC 20250-0268.

[65 FR 80637, Dec. 21, 2000, as amended at 68 FR 61993, Oct. 31, 2003]

#### §§ 205.608-205.619 [Reserved]

## State Organic Programs

### § 205.620 Requirements of State organic programs.

- (a) A State may establish a State organic program for production and handling operations within the State which produce and handle organic agricultural products.
- (b) A State organic program must meet the requirements for organic programs specified in the Act.
- (c) A State organic program may contain more restrictive requirements because of environmental conditions or the necessity of specific production or handling practices particular to the State or region of the United States.
- (d) A State organic program must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements approved by the Secretary.
- (e) A State organic program and any amendments to such program must be approved by the Secretary prior to being implemented by the State.

### § 205.621 Submission and determination of proposed State organic programs and amendments to approved State organic programs.

- (a) A State organic program's governing State official must submit to the Secretary a proposed State organic program and any proposed amendments to such approved program.
  - (1) Such submission must contain supporting materials that include statutory authorities, program description, documentation of the environmental conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary.
  - (2) Submission of a request for amendment of an approved State organic program must contain supporting materials that include an explanation and documentation of the environmental conditions or specific production and handling practices particular to the State or region, which necessitates the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations of this part.
- (b) Within 6 months of receipt of submission, the Secretary will: Notify the State organic program's governing State official of approval or disapproval of the proposed program or amendment of an approved program and, if disapproved, the reasons for the disapproval.
- (c) After receipt of a notice of disapproval, the State organic program's governing State official may submit a revised State organic program or amendment of such a program at any time.

### § 205.622 Review of approved State organic programs.

The Secretary will review a State organic program not less than once during each 5-year period following the date of the initial program approval. The Secretary will notify the State organic program's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

### §§ 205.623-205.639 [Reserved]

## Fees

### § 205.640 Fees and other charges for accreditation.

Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions:

- (a) Fees-for-service.
  - (1) Except as otherwise provided in this section, fees-for-service shall be based on the time required to render the service provided calculated to the nearest 15-minute period, including the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service. The hourly rate shall be the same as that charged by the Agricultural Marketing Service, through its Quality Systems Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

(2) Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F of this part shall receive service without incurring an hourly charge for service.

(3) Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following February 20, 2001, a nonrefundable fee of \$500.00 which shall be applied to the applicant's fees-for-service account.

(b) Travel charges. When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and back to the headquarters or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service shall include a mileage charge administratively determined by the U.S. Department of Agriculture and travel tolls, if applicable, or such travel prorated among all the applicants and certifying agents furnished the service involved on an equitable basis or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. Travel charges shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

(c) Per diem charges. When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the U.S. Department of Agriculture. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

(d) Other costs. When costs, other than costs specified in paragraphs (a), (b), and (c) of this section, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the U.S. Department of Agriculture. Such costs shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001.

#### **§ 205.641 Payment of fees and other charges.**

(a) Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee, pursuant to § 205.640(a)(3), along with their application. Remittance must be made payable to the USDA, AMS Livestock Program, and mailed to: USDA-AMS Livestock, Poultry and Seed Program QAD, P.O. Box 790304 St. Louis, MO 63179-0304 or such other address as required by the Program Manager.

(b) Payments for fees and other charges not covered under paragraph (a) of this section must be:

- (1) Received by the due date shown on the bill for collection;
- (2) Made payable to the Agricultural Marketing Service, USDA; and
- (3) Mailed to the address provided on the bill for collection.

(c) The Administrator shall assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

#### **§ 205.642 Fees and other charges for certification.**

Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.

#### **§§ 205.643-205.649 [Reserved]**

## Compliance

### § 205.660 General.

- (a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.
- (b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:
  - (1) When the Program Manager has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part; or
  - (2) When a certifying agent or a State organic program's governing State official fails to take appropriate action to enforce the Act or regulations in this part.
- (c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part.
- (d) Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to § 205.662, § 205.663, and § 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.

### § 205.661 Investigation of certified operations.

- (a) A certifying agent may investigate complaints of noncompliance 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 noncompliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

### § 205.662 Noncompliance 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 noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:
  - (1) A description of each noncompliance;
  - (2) The facts upon which the notification of noncompliance is based; and
  - (3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.
- (b) *Resolution.* When a certified operation demonstrates that each noncompliance 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 noncompliance resolution.
- (c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official 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 noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance 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 willfully 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 noncompliance.



(e) *Suspension or revocation.*

(1) If the certified operation fails to correct the noncompliance, 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 demonstrating correction of each noncompliance 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 the amount specified in §3.91(b)(1) of this title 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.

[65 FR 80637, Dec. 21, 2000, as amended by 75 FR 17560, Apr. 7, 2010; 79 FR 6430, Feb. 5, 2015]

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

**§ 205.664 [Reserved]**

**§ 205.665 Noncompliance procedure for certifying agents.**

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

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

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

(c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance 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 noncompliance is not possible, the notification of noncompliance 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
- (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 noncompliance 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.

#### §§ 205.666-205.667 [Reserved]

#### § 205.668 Noncompliance procedures under State organic programs.

- (a) A State organic program's governing State official must promptly notify the Secretary of commencement of any noncompliance proceeding against a certified operation and forward to the Secretary a copy of each notice issued.
- (b) A noncompliance 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 noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the State organic program's governing State official shall send a written report of noncompliance to the Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based.

#### § 205.669 [Reserved]

## Inspection and Testing, Reporting, and Exclusion from Sale

### § 205.670 Inspection and testing of agricultural products to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

- (a) All agricultural products that are to be sold, labeled, 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, labeled, 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. Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. 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) A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.

(d) A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

(e) Sample collection pursuant to paragraphs (b) and (c) 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 International* or other current applicable validated methodology for determining the presence of contaminants in agricultural products.

(f) Results of all analyses and tests performed under this section will be available for public access, unless the testing is part of an ongoing compliance investigation.

(g) 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. Test results that exceed federal regulatory tolerances must also be reported to the appropriate State health agency or foreign equivalent.

**EC Requirement:** If pesticide residue(s) is detected in any certified product by OneCert under EU equivalent program, then OneCert will investigate the matter as per the OneCert International Policy for Responding to Results from Residue Testing for EU Certified Operations (OC-214). In any case OneCert International will not allow the product with positive residue to be exported to EU. [EC 834/2007 Article 30]

[77 FR 67251, Nov. 9, 2012]

#### § 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, labeled, 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.

**EC Requirement:** When residue testing detects prohibited substances, the agricultural product must not be sold, labeled, or represented as organically produced. Such products will be not be allowed for export to EU. [EC 834/2007 Article 30 and EC 396/2005 Article 18]

#### § 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, labeled, or represented as organically produced; and
- (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, labeled, or represented as organically produced: *Except*, That:
- (1) Milk or milk products may be sold, labeled, 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 noncompliance 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 noncompliance 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 noncompliance 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.

- (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, 7 CFR part 1, subpart H, 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 noncompliance 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 nonappealable unless the decision is appealed in a timely manner.

(d) *Where and what to file.*

(1) Appeals to the Administrator must be filed in writing and addressed to: Administrator, USDA, AMS, c/o NOP Appeals Team, 1400 Independence Avenue SW., Room 2648-So., Stop 0268, Washington, DC 20250-0268.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 71 FR 53303, Sept. 11, 2006; 80 FR 6430, Feb. 4, 2015]

§§ 205.682-205.689 [Reserved]

## Miscellaneous

### § 205.690 OMB control number.

The control number assigned to the information collection requirements in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB number 0581-0191

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7195, Feb. 17, 2010]

§§ 205.691-205.699 [Reserved]

## Additional Requirements and Guidelines

This section contains additional requirements and guidelines that are not specifically included in the NOP. These standards may be used as guidance if certifying to the NOP only. They are, by contrast, requirements of the program indicated. In any event, all NOP standards must be met.

### EC Requirement:

#### Labelling

##### Use of terms referring to organic production

[EC 834/2007 Article 23]

1. For the purposes of this Regulation a product shall be regarded as bearing terms referring to the organic production method where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials are described in terms suggesting to the purchaser that the product, its ingredients or feed materials have been obtained in accordance with the rules laid down in this Regulation. In particular, the terms listed in the Annex, their derivatives or diminutives, such as 'bio' and 'eco', alone or combined, may be used throughout the Community and in any Community language for the labelling and advertising of products which satisfy the requirements set out under or pursuant to this Regulation.

In the labelling and advertising of live or unprocessed agricultural products terms referring to the organic production method may be used only where, in addition, all the ingredients of that product have also been produced in accordance with the requirements laid down in this Regulation.

2. The terms referred to in paragraph 1 shall not be used anywhere in the Community and in any Community language for the labelling, advertising and commercial documents of a product which does not satisfy the requirements set out under this Regulation, unless they are not applied to agricultural products in food or feed or clearly have no connection with organic production.

Furthermore, any terms, including terms used in trademarks, or practices used in labelling or advertising liable to mislead the consumer or user by suggesting that a product or its ingredients satisfy the requirements set out

under this Regulation shall not be used.

3. The terms referred to in paragraph 1 shall not be used for a product for which it has to be indicated in the labelling or advertising that it contains GMOs, consists of GMOs or is produced from GMOs according to Community provisions.

4. As regards processed food, the terms referred to in paragraph 1 may be used:

(a) in the sales description, provided that:

(i) the processed food complies with Article 19;

(ii) at least 95 % by weight, of its ingredients of agricultural origin are organic;

(b) only in the list of ingredients, provided that the food complies with Article 19(1), 19(2)(a), 19(2)(b) and 19(2)(d);

(c) in the list of ingredients and in the same visual field as the sales description, provided that:

(i) the main ingredient is a product of hunting or fishing;

(ii) it contains other ingredients of agricultural origin that are all organic;

(iii) the food complies with Article 19(1), 19(2)(a), 19(2)(b) and 19(2)(d).

The list of ingredients shall indicate which ingredients are organic.

In the case where points (b) and (c) of this paragraph apply, the references to the organic production method may only appear in relation to the organic ingredients and the list of ingredients shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of ingredients of agricultural origin.

The terms and the indication of percentage referred to in the previous subparagraph shall appear in the same colour, identical size and style of lettering as the other indications in the list of ingredients.

5. Member States shall take the measures necessary to ensure compliance with this Article.

6. The Commission may in accordance with the procedure referred to in Article 37(2) adapt the list of terms set out in the Annex.

### Compulsory indications

*[EC 834/2007 Article 24]*

1. Where terms as referred to in Article 23(1) are used:

(a) the code number referred to in Article 27(10) of the control authority or control body to which the operator who has carried out the most recent production or preparation operation is subject, shall also appear in the labelling;

(b) the Community logo referred to in Article 25(1) as regards pre-packaged food shall also appear on the packaging;

(c) where the Community logo is used, an indication of the place where the agricultural raw materials of which the product is composed have been farmed, shall also appear in the same visual field as the logo and shall take one of the following forms, as appropriate:

- 'EU Agriculture', where the agricultural raw material has been farmed in the EU,

- 'non-EU Agriculture', where the agricultural raw material has been farmed in third countries,

- 'EU/non-EU Agriculture', where part of the agricultural raw materials has been farmed in the Community and a part of it has been farmed in a third country.

The abovementioned indication 'EU' or 'non-EU' may be replaced or supplemented by a country in the case where all agricultural raw materials of which the product is composed have been farmed in that country.

For the abovementioned 'EU' or 'non-EU' indication, small quantities by weight of ingredients may be disregarded provided that the total quantity of the disregarded ingredients does not exceed 2 % of the total quantity by weight of raw materials of agricultural origin.

The abovementioned 'EU' or 'non-EU' indication shall not appear in a colour, size and style of lettering more prominent than the sales description of the product.

The use of the Community logo as referred to in Article 25(1) and the indication referred to in the first subparagraph shall be optional for products imported from third countries. However, where the Community logo

as referred to in Article 25(1) appears in the labelling, the indication referred to in the first subparagraph shall also appear in the labelling.

2. The indications referred to in paragraph 1 shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.
3. The Commission shall, in accordance with the procedure referred to in Article 37(2), lay down specific criteria as regards the presentation, composition and size of the indications referred to in paragraph 1(a) and (c).

### Organic production logos

[EC 834/2007 Article 25]

1. The Community organic production logo may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation.

The Community logo shall not be used in the case of in-conversion products and food as referred to in Article 23(4)(b) and (c).

2. National and private logos may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation.
3. The Commission shall, in accordance with the procedure referred to in Article 37(2), lay down specific criteria as regards presentation, composition, size and design of the Community logo.

### Specific labelling requirements

[EC 834/2007 Article 26]

The Commission shall in accordance with the procedure referred to in Article 37(2) establish specific labeling and composition requirements applicable to:

- (a) organic feed;
- (b) in-conversion products of plant origin;
- (c) vegetative propagating material and seeds for cultivation.

### Community logo

[EC 889/2008 Article 57]

In accordance with Article 25(3) of Regulation (EC) No 834/2007, the Community logo shall follow the model in Annex XI to this Regulation.

The Community logo shall be used in accordance with the technical reproduction rules laid down in Annex XI to this Regulation.

### Conditions for the use of the code number and place of origin

[EC 889/2008 Article 58]

1. The indication of the code number of the control authority or control body referred to in Article 24(1)(a) of Regulation (EC) 834/2007 shall,
  - (a) start with the acronym identifying the Member State or the third country, as referred to in the international standard for the two letter country codes under ISO 3166 (*Codes for the representation of names of countries and their subdivisions*);
  - (b) include a term which establishes a link with the organic production method, as referred to in Article 23(1) of Regulation (EC) No 834/2007;
  - (c) include a reference number to be decided by the competent authority; and
  - (d) be placed immediately below the Community logo, where the Community logo is used in the labelling.
2. The indication of the place where the agricultural raw materials of which the products is composed have been farmed, as referred to in Article 24(1)(c) of Regulation (EC) 834/2007, shall be placed immediately below the code

number referred to in paragraph 1.

### Scope, use of trade marks and sales descriptions

*[EC 889/2008 Article 59]*

This Chapter shall not apply to pet food and feed for fur animals.

The trade marks and sales descriptions bearing an indication referred to in Article 23(1) of Regulation (EC)

No 834/2007 may be used only if at least 95 % of the product's dry matter is comprised of feed material from the organic production method.

### Indications on processed feed

*[EC 889/2008 Article 60]*

1. Without prejudice to Articles 61 and 59, second paragraph of this Regulation, the terms referred to in Article 23(1) of Regulation (EC) 834/2007 may be used on processed feed provided that:

- (a) the processed feed complies with the provisions of Regulation (EC) No 834/2007 and in particular with Article 14(1)(d)(iv) and (v) for livestock or with Article 15(1)(d) for aquaculture animals and Article 18 thereof;
- (b) the processed feed complies with the provisions of this Regulation and in particular with Articles 22 and 26 thereof;
- (c) at least 95 % of the product's dry matter is organic.

2. Subject to the requirements laid down in points (a) and (b) of paragraph 1, the following statement is permitted in the case of products comprising variable quantities of feed materials from the organic production method and/or feed materials from products in conversion to organic farming and/or non-organic materials: 'may be used in organic production in accordance with Regulations (EC) 834/2007 and (EC) 889/2008.

### Conditions for the use of indications on processed feed

*[EC 889/2008 Article 61]*

1. The indication provided for in Article 60 shall be:

- (a) separate from the wording referred to in Article 5 of Council Directive 79/373/EEC or in Article 5(1) of Council Directive 96/25/EC;
- (b) presented in a colour, format or character font that does not draw more attention to it than to the description or name of the animal feedingstuff referred to in Article 5(1)(a) of Directive 79/373/EEC or in Article 5(1)(b) of Directive 96/25/EC respectively;
- (c) accompanied, in the same field of vision, by an indication by weight of dry matter referring:
  - (i) to the percentage of feed material(s) from the organic production method;
  - (ii) to the percentage of feed material(s) from products in conversion to organic farming;
  - (iii) to the percentage of feed material(s) not covered by points (i) and (ii);
  - (iv) to the total percentage of animal feed of agricultural origin;
- (d) accompanied by a list of names of feed materials from the organic production method;
- (e) accompanied by a list of names of feed materials from products in conversion to organic production.

2. The indication provided for in Article 60 may be also accompanied by a reference to the requirement to use the feedingstuffs in accordance with Articles 21 and 22.

### In-conversion products of plant origin

*[EC 889/2008 Article 62]*

In-conversion products of plant origin may bear the indication 'product under conversion to organic farming'



provided that:

- (a) a conversion period of at least 12 months before the harvest has been complied with;
- (b) the indication shall appear in a colour, size and style of lettering which is not more prominent than the sales description of the product, the entire indication shall have the same size of letters;
- (c) the product contains only one crop ingredient of agricultural origin;
- (d) the indication is linked to the code number of the control body or control authority as referred to in Article 27(10) of Regulation 834/2007.

#### Use of certain products and substances in feed

For the purposes of Article 14(1)(d)(iv) of Regulation (EC) No 834/2007 only the following substances may be used in the processing of organic feed and feeding organic animals:

- (a) non-organic feed materials of plant or animal origin, or other feed materials that are listed in Section 2 of Annex V, provided that:
  - (i) they are produced or prepared without chemical solvents; and
  - (ii) the restrictions laid down in Article 43 or Article 47(c) are complied with;
- (b) non-organic spices, herbs, and molasses, provided that:
  - (i) their organic form is not available;
  - (ii) they are produced or prepared without chemical solvents; and
  - (iii) their use is limited to 1 % of the feed ration of a given species, calculated annually as a percentage of the dry matter of feed from agricultural origin;
- (c) organic feed materials of animal origin;
- (d) feed materials of mineral origin that are listed in Section 1 of Annex V;
- (e) products from sustainable fisheries, provided that:
  - (i) they are produced or prepared without chemical solvents;
  - (ii) their use is restricted to non-herbivores; and
  - (iii) the use of fish protein hydrolysate is restricted solely to young animals;
- (f) salt as sea salt, coarse rock salt;
- (g) feed additives listed in Annex VI.

## EC Requirement:

### Aquaculture

#### Production rules for aquaculture animals

*[EC 834/2007 Article 15]*

1. In addition to the general farm production rules laid down in Article 11, the following rules shall apply to aquaculture animal production:

- (a) with regard to the origin of the aquaculture animals:
  - (i) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock and organic holdings;
  - (ii) when young stock from organic broodstock or holdings are not available, non-organically produced animals may be brought onto a holding under specific conditions;
- (b) with regard to husbandry practices:

- (i) personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals;
- (ii) husbandry practices, including feeding, design of installations, stocking densities and water quality shall ensure that the developmental, physiological and behavioural needs of animals are met;
- (iii) husbandry practices shall minimise negative environmental impact from the holding, including the escape of farmed stock;
- (iv) organic animals shall be kept separate from other aquaculture animals;
- (v) transport shall ensure that the welfare of animals is maintained;
- (vi) any suffering of the animals including the time of slaughtering shall be kept to a minimum;
- (c) with regard to breeding: (i) artificial induction of polyploidy, artificial hybridisation, cloning and production of monosex strains, except by hand sorting, shall not be used;
- (ii) the appropriate strains shall be chosen;
- (iii) species-specific conditions for broodstock management, breeding and juvenile production shall be established;
- (d) with regard to feed for fish and crustaceans:
  - (i) animals shall be fed with feed that meets the animal's nutritional requirements at the various stages of its development;
  - (ii) the plant fraction of feed shall originate from organic production and the feed fraction derived from aquatic animals shall originate from sustainable exploitation of fisheries;
  - (iii) in the case of non-organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production under Article 16;
  - (iv) growth promoters and synthetic amino-acids shall not be used;
- (e) with regard to bivalve molluscs and other species which are not fed by man but feed on natural plankton:
  - (i) such filter-feeding animals shall receive all their nutritional requirements from nature except in the case of juveniles reared in hatcheries and nurseries;
  - (ii) they shall be grown in waters which meet the criteria for Class A or Class B areas as defined in Annex II of Regulation (EC) No 854/2004;
  - (iii) the growing areas shall be of high ecological quality as defined by Directive 2000/60/EC and, pending its implementation of a quality equivalent to designated waters under Directive 2006/113/EC;
- (f) with regard to disease prevention and veterinary treatment:
  - (i) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, optimal design of the holdings, the application of good husbandry and management practices, including regular cleaning and disinfection of premises, high quality feed, appropriate stocking density, and breed and strain selection;
  - (ii) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined;
  - (iii) the use of immunological veterinary medicines is allowed;
  - (iv) treatments related to the protection of human and animal health imposed on the basis of Community legislation shall be allowed.
- (g) With regard to cleaning and disinfection, products for cleaning and disinfection in ponds, cages, buildings and installations, shall be used only if they have been authorised for use in organic production under Article 16.

### **Aquaculture animal production**

*[EC 889/2008 Article 38a]*

1. The following conversion periods for aquaculture production units shall apply for the following types of aquaculture facilities including the existing aquaculture animals:

- (a) for facilities that cannot be drained, cleaned and disinfected, a conversion period of 24 months;

- (b) for facilities that have been drained, or fallowed, a conversion period of 12 months;
- (c) for facilities that have been drained, cleaned and disinfected a conversion period of six months;
- (d) for open water facilities including those farming bivalve molluscs, a three month conversion period.

2. The competent authority may decide to recognize retroactively as being part of the conversion period any previously documented period in which the facilities were not treated or exposed to products not authorized for organic production

### General rules

[EC 889/2008 Article 25]

#### a. Scope

This Chapter lays down detailed production rules for species of fish, crustaceans, echinoderms and molluscs as covered by Annex XIIIa. It applies mutatis mutandis to zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

#### b. Suitability of aquatic medium and sustainable management plan

1. The provisions of Article 6b(1) to (5) shall apply to this Chapter.
2. Defensive and preventive measures taken against predators under Council Directive 92/43/EEC and national rules shall be recorded in the sustainable management plan.
3. Verifiable coordination shall take place with the neighbouring operators in drawing up their management plans where applicable.
4. For aquaculture animal production in fishponds, tanks or raceways, farms shall be equipped with either natural-filter beds, settlement ponds, biological filters or mechanical filters to collect waste nutrients or use seaweeds and/or animals (bivalves and algae) which contribute to improving the quality of the effluent. Effluent monitoring shall be carried out at regular intervals where appropriate.

#### c. Simultaneous production of organic and non-organic aquaculture animals

1. The competent authority may permit hatcheries and nurseries to rear both organic and non-organic juveniles in the same holding provided there is clear physical separation between the units and a separate water distribution system exists.
2. In case of grow-out production, the competent authority may permit organic and non-organic aquaculture animal production units on the same holding provided Article 6b(2) of this Regulation is complied with and where different production phases and different handling periods of the aquaculture animals are involved.
3. Operators shall keep documentary evidence of the use of provisions referred to in this Article.

#### d. Origin of organic aquaculture animals

1. Locally grown species shall be used and breeding shall aim to give strains which are more adapted to farming conditions, good health and good utilisation of feed resources. Documentary evidence of their origin and treatment shall be provided for the control body or control authority.
2. Species shall be chosen which can be farmed without causing significant damage to wild stocks.

#### e. Origin and management of non-organic aquaculture animals

1. For breeding purposes or for improving genetic stock and when organic aquaculture animals are not available, wild caught or non-organic aquaculture animals may be brought into a holding. Such animals shall be kept under organic management for at least three months before they may be used for breeding.
2. For on-growing purposes and when organic aquaculture juvenile animals are not available non-organic aquaculture juveniles may be brought into a holding. At least the latter two thirds of the duration of the production cycle shall be managed under organic management.
3. The maximum percentage of non-organic aquaculture juveniles introduced to the farm shall be: 80 % by 31 December 2011, 50 % by 31 December 2013 and 0 % by 31 December 2015.
4. For on-growing purposes the collection of wild aquaculture juveniles is specifically restricted to the following cases:
  - (a) natural influx of fish or crustacean larvae and juveniles when filling ponds, containment systems and enclosures;
  - (b) European glass eel, provided that an approved eel management plan is in place for the location and artificial reproduction of eel remains unsolved.

#### f. General aquaculture husbandry rules

1. The husbandry environment of the aquaculture animals shall be designed in such a way that, in accordance with their

species specific needs, the aquaculture animals shall:

- (a) have sufficient space for their wellbeing;
- (b) be kept in water of good quality with sufficient oxygen levels, and
- (c) be kept in temperature and light conditions in accordance with the requirements of the species and having regard to the geographic location;
- (d) in the case of freshwater fish the bottom type shall be as close as possible to natural conditions;
- (e) in the case of carp the bottom shall be natural earth.

2. Stocking density is set out in Annex XIIIa by species or group of species. In considering the effects of stocking density on the welfare of farmed fish, the condition of the fish (such as fin damage, other injuries, growth rate, behaviour expressed and overall health) and the water quality shall be monitored.
3. The design and construction of aquatic containment systems shall provide flow rates and physiochemical parameters that safeguard the animals' health and welfare and provide for their behavioural needs.
4. Containment systems shall be designed, located and operated to minimize the risk of escape incidents.
5. If fish or crustaceans escape, appropriate action must be taken to reduce the impact on the local ecosystem, including recapture, where appropriate. Documentary evidence shall be maintained.

#### **g. Specific rules for aquatic containment systems**

1. Closed recirculation aquaculture animal production facilities are prohibited, with the exception of hatcheries and nurseries or for the production of species used for organic feed organisms.
2. Rearing units on land shall meet the following conditions:
  - (a) for flow-through systems it shall be possible to monitor and control the flow rate and water quality of both in-flowing and out-flowing water;
  - (b) at least five percent of the perimeter ("land-water interface") area shall have natural vegetation.
3. Containment systems at sea shall:
  - (a) be located where water flow, depth and water-body exchange rates are adequate to minimize the impact on the seabed and the surrounding water body;
  - (b) shall have suitable cage design, construction and maintenance with regard to their exposure to the operating environment.
4. Artificial heating or cooling of water shall only be permitted in hatcheries and nurseries. Natural borehole water may be used to heat or cool water at all stages of production.

#### **h. Management of aquaculture animals**

1. Handling of aquaculture animals shall be minimised, undertaken with the greatest care and proper equipment and protocols used to avoid stress and physical damage associated with handling procedures.

Broodstock shall be handled in a manner to minimize physical damage and stress and under anaesthesia where appropriate. Grading operations shall be kept to a minimum and as required to ensure fish welfare.
2. The following restrictions shall apply to the use of artificial light:
  - (a) for prolonging natural day-length it shall not exceed a maximum that respects the ethological needs, geographical conditions and general health of farmed animals, this maximum shall not exceed 16 hours per day, except for reproductive purposes;
  - (b) abrupt changes in light intensity shall be avoided at the changeover time by the use of dimmable lights or background lighting.
3. Aeration is permitted to ensure animal welfare and health, under the condition that mechanical aerators are preferably powered by renewable energy sources. All such use is to be recorded in the aquaculture production record.
4. The use of oxygen is only permitted for uses linked to animal health requirements and critical periods of production or transport, in the following cases:
  - (a) exceptional cases of temperature rise or drop in atmospheric pressure or accidental pollution,
  - (b) occasional stock management procedures such as sampling and sorting,
  - (c) in order to assure the survival of the farm stock.

Documentary evidence shall be maintained.

5. Slaughter techniques shall render fish immediately unconscious and insensible to pain. Differences in harvesting sizes,

species, and production sites must be taken into account when considering optimal slaughtering methods.

#### **i. Prohibition of hormones**

The use of hormones and hormone derivatives is prohibited.

#### **j. General rules on feeds**

Feeding regimes shall be designed with the following priorities:

- (a) animal health;
- (b) high product quality, including the nutritional composition which shall ensure high quality of the final edible product;
- (c) low environmental impact.

#### **k. Specific rules on feeds for carnivorous aquaculture animals**

1. Feed for carnivorous aquaculture animals shall be sourced with the following priorities:

- (a) organic feed products of aquaculture origin;
- (b) fish meal and fish oil from organic aquaculture trimmings;
- (c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish already caught for human consumption in sustainable fisheries;
- (d) organic feed materials of plant origin and of animal origin as listed in Annex V and the restriction laid down therein are complied with.

2. If feed mentioned under paragraph 1 is not available, fishmeal and fish oil from non-organic aquaculture trimmings, or trimmings of fish caught for human consumption may be used for a transitional period until 31 December 2014. Such feed material shall not exceed 30 % of the daily ration.

3. The feed ration may comprise a maximum of 60 % organic plant products.

4. Astaxanthin derived primarily from organic sources, such as organic crustacean shells may be used in the feed ration for salmon and trout within the limit of their physiological needs. If organic sources are not available natural sources of astaxanthin (such as Phaffia yeast) may be used.

#### **l. Specific rules on feeds for certain aquaculture animals**

1. Aquaculture animals as referred to in Annex XIIIa, Section 6, Section 7 and Section 9 shall be fed with feed naturally available in ponds and lakes.

2. Where natural feed resources are not available in sufficient quantities as referred to in paragraph 1, organic feed of plant origin, preferably grown on the farm itself or seaweed may be used. Operators shall keep documentary evidence of the need to use additional feed.

3. Where natural feed is supplemented according to paragraph 2 the feed ration of species as mentioned in section 7 and of siamese catfish (*Pangasius* spp.) as mentioned in section 9 may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries.

#### **m. Products and substances as referred to in Article 15(1)(d)(iii) of Regulation (EC) No 834/2007**

1. Feed materials of animal and mineral origin may be used in organic aquaculture, only if listed in Annex V.

2. Feed additives, certain products used in animal nutrition and processing aids may be used if listed in Annex VI and the restrictions laid down therein are complied with.

#### **n. Growing area**

1. Bivalve mollusc farming may be carried out in the same area of water as organic finfish and seaweed farming in a polyculture system to be documented in the sustainable management plan. Bivalve molluscs may also be grown together with gastropod molluscs, such as periwinkles, in polyculture.

2. Organic bivalve mollusc production shall take place within areas delimited by posts, floats or other clear markers and shall, as appropriate, be restrained by net bags, cages or other man made means.

3. Organic shellfish farms shall minimise risks to species of conservation interest. If predator nets are used their design shall not permit diving birds to be harmed.

#### **o. Sourcing of seed**

1. Provided that there is no significant damage to the environment and if permitted by local legislation, wild seed from outside the boundaries of the production unit can be used in the case of bivalve shellfish provided it comes from:

- (a) settlement beds which are unlikely to survive winter weather or are surplus to requirements, or

(b) natural settlement of shellfish seed on collectors.

Records shall be kept of how, where and when wild seed was collected to allow traceability back to the collection area. However, seed from non-organic bivalve shellfish hatcheries may be introduced to the organic production units with the following maximum percentages: 80 % by 31 December 2011, 50 % by 31 December 2013 and 0 % by 31 December 2015.

2. For the cupped oyster, *Crassostrea gigas*, preference shall be given to stock which is selectively bred to reduce spawning in the wild.

**p. Management**

1. Production shall use a stocking density not in excess of that used for non-organic shellfish in the locality. Sorting, thinning and stocking density adjustments shall be made according to the biomass and to ensure animal welfare and high product quality.
2. Biofouling organisms shall be removed by physical means or by hand and where appropriate returned to the sea away from shellfish farms. Shellfish may be treated once during the production cycle with a lime solution to control competing fouling organisms.

**q. Cultivation rules**

1. Cultivation on mussel ropes and other methods listed in Annex XIIIa, Section 8 may be eligible for organic production.
2. Bottom cultivation of molluscs is only permitted where no significant environmental impact is caused at the collection and growing sites. The evidence of minimal environmental impact shall be supported by a survey and report on the exploited area to be provided by the operator to the control body or control authority. The report shall be added as a separate chapter to the sustainable management plan.

**r. Specific cultivation rules for oysters**

Cultivation in bags on trestles is permitted. These or other structures in which the oysters are contained shall be set out so as to avoid the formation of a total barrier along the shoreline. Stock shall be positioned carefully on the beds in relation to tidal flow to optimise production. Production shall meet the criteria listed in the Annex XIIIa, Section 8.

**s. General rules on disease prevention**

1. The animal health management plan in conformity with Article 9 of Directive 2006/88/EC shall detail biosecurity and disease prevention practices including a written agreement for health counselling, proportionate to the production unit, with qualified aquaculture animal health services who shall visit the farm at a frequency of not less than once per year and not less than once every two years in the case of bivalve shellfish.
2. Holding systems, equipment and utensils shall be properly cleaned and disinfected. Only products listed in Annex VII, Sections 2.1 to 2.2 may be used.
3. With regard to fallowing:
  - (a) The competent authority shall determine whether fallowing is necessary and the appropriate duration which shall be applied and documented after each production cycle in open water containment systems at sea. Fallowing is also recommended for other production methods using tanks, fishponds, and cages;
  - (b) it shall not be mandatory for bivalve mollusc cultivation;
  - (c) during fallowing the cage or other structure used for aquaculture animal production is emptied, disinfected and left empty before being used again.
4. Where appropriate, uneaten fish-feed, faeces and dead animals shall be removed promptly to avoid any risk of significant environmental damage as regards water status quality, minimize disease risks, and to avoid attracting insects or rodents.
5. Ultraviolet light and ozone may be used only in hatcheries and nurseries.
6. For biological control of ectoparasites preference shall be given to the use of cleaner fish.

**t. Veterinary treatments**

1. When despite preventive measures to ensure animal health, according to Article 15(1)(f)(i) of Regulation (EC) No 834/2007, a health problem arises, veterinary treatments may be used in the following order of preference:
  - (a) substances from plants, animals or minerals in a homoeopathic dilution;
  - (b) plants and their extracts not having anaesthetic effects, and
  - (c) substances such as: trace elements, metals, natural immunostimulants or authorised probiotics.

2. The use of allopathic treatments is limited to two courses of treatment per year, with the exception of vaccinations and compulsory eradication schemes. However, in the cases of a production cycle of less than a year a limit of one allopathic treatment applies. If the mentioned limits for allopathic treatments are exceeded the concerned aquaculture animals can not be sold as organic products.
3. The use of parasite treatments, not including compulsory control schemes operated by Member States, shall be limited to twice per year or once per year where the production cycle is less than 18 months.
4. The withdrawal period for allopathic veterinary treatments and parasite treatments according to paragraph 3 including treatments under compulsory control and eradication schemes shall be twice the legal withdrawal period as referred to in Article 11 of Directive 2001/82/EC or in a case in which this period is not specified 48 hours.
5. Whenever veterinary medicinal products are used, such use is to be declared to the control body or the control authority before the animals are marketed as organic. Treated stock shall be clearly identifiable.

## EC Requirement:

### Beekeeping and Beekeeping Products

#### 1. General principles

- 1.2. The qualification of beekeeping products as being from European organic production regulations (EC-organic) is closely bound up both with the characteristic of the hives' treatments and the quality of the environment. This qualification also depends on the conditions for extraction, processing and storage of beekeeping products.
- 1.3. When an operator runs several beekeeping units in the same area all the units must comply with the requirements of this Regulation. By derogation from this principle, an operator can run units not complying with this Regulation provided that all the requirements of this Regulation are fulfilled with the exception of the provisions laid down in paragraph 4.2 for the siting of the apiaries. In that case, the product cannot be sold with references to organic production methods. Records of the separation must be maintained [EC 889/2008, Article 17(5)].

#### 2. Conversion period

- 2.1. It is expected that all existing hives within the production unit are simultaneously converted to organic management [EC 889/2008, Article 38(2)].
- 2.2. Beekeeping products can be sold as EC-organic only when the provisions laid down in this Regulation have been complied with for at least one year [EC 889/2008, Art 38(3)].
- 2.3. The bees wax for new foundations must come from organic production units [EC 889/2008, Art 13(4)], and during the conversion period the wax has to be replaced with wax coming from organic beekeeping [EC 889/2008, Art 38(5)]. However, in the case of new installations or during the conversion period, non-organic beeswax may be used only when non available on the market, comes from the cap, and proven it does not contain non allowed substances [EC 889/2008, Article 44].

When necessary for initiating or maintaining organic production facing climatic, geographical or structural constraints, for the purpose of pollination actions an operator may run organic and non-organic beekeeping units on the same holding, provided that all the requirements of the organic production rules are fulfilled, with the exception of the provisions for the siting of the apiaries. In that case the product cannot be sold as organic. [EC 889/2008, Article 41].

#### 3. Origin of the bees

- 3.1. In the choice of breeds, account must be taken of the capacity of animals to adapt to local conditions, their vitality and their resistance to disease. Preference [EC 889/2008, Art 8(2)] must be given to the use of European breeds of *Apis mellifera* and their local ecotypes.
- 3.2. Apiaries must be constituted by means of the division of colonies or the acquisition of swarms or hives from EC-organic units complying with the provisions laid down in this Regulation.
- 3.3. By way of a first derogation, subject to the prior approval by the inspection authority or body, apiaries existing in the production unit not complying with the rules of this Regulation can be converted.
- 3.4. By way of a second derogation, swarms on their own may be acquired from beekeepers not producing in accordance with this Regulation during a transitional period expiring on 24 August 2002 subject to the conversion period.
- 3.5. In the case of high mortality of animals caused by health or catastrophic circumstances, the reconstitution of the apiaries with non-organic bees, when organic apiaries are not available may be authorized by the control authority on a temporary basis, subject to the conversion period [EC 889/2008, Art 47 (a & b)].
- 3.6. By way of a fourth derogation, for the renovation of the apiaries 10 % per year of the queen bees and swarms not EC-organic can be incorporated into the organic-production unit provided that the queen bees and swarms are placed in hives with

combs or comb foundations coming from organic-production units. In the case, the conversion period does not apply. [EC 889/2008, Art 9(5)]

#### **4. Siting of the apiaries**

- 4.1. The Member States may designate regions or areas where beekeeping complying with this Regulation is not practicable [Art 13(2) 889/2008].
- 4.2. A map on an appropriate scale listing the location of hives must be provided to the inspection authority or body by the beekeeper. Where no such areas are identified, the beekeeper must provide the inspection authority or body with appropriate documentation and evidence, including suitable analyses if necessary, that the areas accessible to his colonies meet the conditions required in this Regulation [EC 889/2008, Art 78(1)]
- 4.3. The zone where the apiary is situated must be registered together with the identification of the hives. The control body or authority must be informed of the moving of apiaries by a deadline agreed on with the control authority or body [EC 889/2008, Art 78(4)]
- 4.4 The siting of the apiaries must:
- (a) ensure enough natural nectar, honeydew and pollen sources for bees and access to water;
  - (b) be such that, within a radius of 3 km from the apiary site, nectar and pollen sources consist essentially of organically produced crops and/or spontaneous vegetation and/or crops treated with low environmental impact methods which cannot significantly affect the qualification of beekeeping production as being organic; [EC 834/2007, Article 14(1b.ix); & EC 889/2008, Art 13(1)]
  - (c) maintain enough distance from any non-agricultural production sources possibly leading to contamination, for example: urban centres, motorways, industrial areas, waste dumps, waste incinerators, etc. The inspection authorities or bodies must establish measures to ensure this requirement.
  - (d) The above requirements do not apply to areas where flowering is not taking place, or when the hives are dormant [EC 889/2008, Art 13(1)].

#### **5. Feed**

- 5.1. At the end of the production season hives must be left with reserves of honey and pollen sufficiently abundant to survive the winter [EC 889/2008, Art 19(2)]
- 5.2. The feeding of colonies must only be authorized where the survival of the hives is endangered due to extreme climatic conditions and only between the last honey harvest and 15 days before the start of the next nectar or honeydew flow period. Artificial feeding must be made with organic honey, organic sugar syrup, or organic sugar [EC 889/2008, Art 19(3)]
- 5.3. In case of catastrophic circumstances, the competent authorities of the Member States can authorize the use of organically-produced sugar or sugar syrup, in case of long lasting exceptional weather conditions or catastrophic circumstances, which hamper the nectar or honeydew production [EC 889/2008, Art 47(d)]
- 5.5. The following information must be entered in the records of the apiaries with regard to the use of artificial feeding: type of product, dates, quantities and hives where it is used [EC 889/2008, Art 78(2)]
- 5.6. Other products different from those indicated in paragraphs 5.1 to 5.4 cannot be used in beekeeping which complies with this Regulation.

#### **6. Disease prevention and veterinary treatments [EC 889/2008, Art 25(3)]**

- 6.1. Disease prevention in beekeeping must be based on the following principles:
- (a) the selection of appropriate hardy breeds;
  - (b) the application of certain practices encouraging strong resistance to disease and the prevention of infections, such as: regular renewal of queen bees, systematic inspection of hives to detect any health anomalies, control of male broods in the hives, disinfecting of materials and equipment at regular intervals, destruction of contaminated material or sources, regular renewal of beeswax and sufficient reserves of pollen and honey in hives.
- 6.2. If despite all the above preventive measures, the colonies become sick or infested, they must be treated immediately and, if necessary, the colonies can be placed in isolation apiaries.
- 6.3. The use of veterinary medicinal products in beekeeping which complies with this Regulation must respect the following principles: [EC 889/2008, Art 25(5)]
- (a) they can be used in so far as the corresponding use is authorized in the Member State in accordance with the relevant Community provisions or national provisions in conformity with Community law; [EC 889/2008, Art 25(5)]
  - (b) phytotherapeutic and homeopathic products must be used in preference to allopathic products chemically synthesized, provided that their therapeutic effect is effective for the condition for which the treatment is intended; [EC 889/2008, Art 24(2)].
  - (c) if the use of the abovementioned products should prove or is unlikely to be effective to eradicate a disease or infestation which risks destroying colonies, allopathic chemically synthesized medicinal products may be used under



<p>the responsibility of a veterinarian without prejudice to the principles laid down in paragraphs (a) and (b) above [EC 889/2008, Art 24(3)];</p> <p>(d) the use of allopathic chemically synthesized medicinal products for preventive treatments is prohibited;</p> <p>(e) without prejudice to the principle in (a) above formic acid, lactic acid, acetic acid and oxalic acid and the following substances: menthol, thymol, eucalyptol or camphor can be used in cases of infestation with <i>Varroa destructor</i> [EC 889/2008, Art 25(6)].</p> <p>6.4. In addition to the above principles, veterinary treatments or treatments to hives, combs etc., which are compulsory under national or Community legislation, must be authorized.</p> <p>6.5. If a treatment is applied with chemically synthesized allopathic products, during such a period, the colonies treated must be placed in isolation apiaries and all the wax must be replaced with wax complying with the conditions laid down in this Regulation. Subsequently, the conversion period of one year will apply to those colonies [EC 889/2008, Article 25(7)].</p> <p>6.6. The requirements laid down in the previous paragraph do not apply to products mentioned in paragraph 6.3(e) [EC 889/2008, Art 25(8)].</p> <p>6.7. Whenever veterinary medicinal products are to be used, the type of product (including the indication of the active pharmacological substance) together with details of the diagnosis, the posology, the method of administration, the duration of the treatment and the legal withdrawal period must be recorded clearly and declared to the inspection body or authority before the products are marketed as organically produced [EC 889/2008, Article 76(e), 77 &amp; 78(3)].</p> <p><b>7. Husbandry management practices and identification</b></p> <p>7.1. The destruction of bees in the combs as a method associated with the harvesting of beekeeping products is prohibited [EC 834/2007, Article 14(1b.xi)].</p> <p>7.2. Mutilation such as clipping the wings of queen bees is prohibited [EC 889/2008, Article 18(3)].</p> <p>7.3. The replacement of the queen bees involving the killing of the old queen is permitted.</p> <p>7.4. The practice of destroying the male brood is permitted only to contain the infestation with <i>Varroa destructor</i> [EC 889/2008, Article 25(3)].</p> <p>7.5. The use of chemical synthetic repellents is prohibited during honey extractions operations [EC 889/2008, Art 13(6)]</p> <p>7.6. The zone where the apiary is situated must be registered together with the identification of the hives. The inspection body or authority must be informed of the moving of apiaries with a deadline agreed on with the inspection authority or body [EC 889/2008, Article 78(4)].</p> <p>7.7. Particular care must be taken to ensure adequate extraction, processing and storage of beekeeping products. All the measure to comply with these requirements must be recorded [EC 889/2008, Article 78(5)].</p> <p>7.8. The removals of the supers and the honey extraction operations must be part of the records of the apiary [EC 889/2008, Article 78(6)].</p> <p>7.9 The use of brood combs is prohibited for honey extraction [EC889/2008, Art 13(7)].</p> <p><b>8. Characteristics of hives and materials used in beekeeping</b></p> <p>8.1. The hives must be made basically of natural materials presenting no risk of contamination to the environment or the apiculture products [EC 889/2008, Article 13(3); EC 834/2007, Article 14(1b)(x)].</p> <p>8.2. With the exception of products mentioned in paragraph 6.3(e) in the hives can be used only natural products such as propolis, wax and plant oils.</p> <p>8.3. The beeswax for new foundations must come from organic production units (Art 13(4) 889/2008). By way of derogation, in particular in the case of new installations or during the conversion period, bees wax not coming from such units may be authorised by the inspection authority or body in exceptional circumstances where organically produced beeswax is not available on the market and provided that it comes from the cap.</p> <p>8.5. For the purposes of protecting materials (frames, hives and combs), in particular from pests, only rodenticides (to be used only in traps), only appropriate products from Annex II are permitted [EC 889/2008, Art 25(1)].</p> <p>8.6. Physical treatments such as steam or direct flame are permitted [EC 889/2008, Art 25(1)].</p> <p>8.7. For cleaning and disinfecting materials, buildings, equipment, or utensils used in beekeeping only the appropriate substances listed in Annex VII are permitted [EC 889/2008, Art 23(4)].</p>
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## EC Requirement:

### Mushrooms

*[EC 889/2008, Article 6]*

For production of mushrooms, substrates may be used, only if they are composed of the following components:

- a. farmyard manure and animal excrements from organic operations, or,
- b. farmyard manure and animal excrements referred to in Annex I of this Regulation, only when this organic product is not available, and up to 25% of the weight of total components (\*),
- c. products of agricultural origin( e.g. straw), other than those covered under point a, from holdings producing according to organic production method;
- d. peat not chemically treated;
- e. wood, not treated with chemical products after felling;
- f. mineral products of Annex I, of this Regulation, water and soil.

(\*) This percentage is calculated on weight of total components of the substrate (excluding the covering material and any added water) before composting.

## EC Requirement:

### Seaweed

#### Seaweed conversion period

*[EC 889/2008 Article 36a]*

1. The conversion period for a seaweed harvesting site shall be six months.
2. The conversion period for a seaweed cultivation unit shall be the longer of six months or one full production cycle.

#### Production rules for seaweed

*[EC 834/2007 Article 13]*

1. The collection of wild seaweeds and parts thereof, growing naturally in the sea, is considered as an organic production method provided that:
  - (a) the growing areas are of high ecological quality as defined by Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy and, pending its implementation, of a quality equivalent to designated waters under Directive 2006/113/EC of the European Parliament and of the Council of 12 December 2006 on the quality required of shellfish waters, and are not unsuitable from a health point of view. Pending more detailed rules to be introduced in implementing legislation, wild edible seaweeds shall not be collected in areas which would not meet the criteria for Class A or Class B areas as defined in Annex II of Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;
  - (b) the collection does not affect the long term stability of the natural habitat or the maintenance of the species in the collection area.
2. The farming of seaweeds shall take place in coastal areas with environmental and health characteristics at least equivalent to those outlined in paragraph 1 in order to be considered organic. In addition to this:
  - (a) sustainable practices shall be used in all stages of production, from collection of juvenile seaweed to harvesting;
  - (b) to ensure that a wide gene-pool is maintained, the collection of juvenile seaweed in the wild should take place on a regular basis to supplement indoor culture stock;
  - (c) fertilisers shall not be used except in indoor facilities and only if they have been authorised for use in organic production for this purpose under Article 16.
3. The measures necessary for the implementation of production rules contained in this Article shall be adopted in accordance with the procedure referred to in Article 37(2).

### Specific control requirements for seaweed

[EC 889/2008 Article 73a and b]

#### Control arrangements for seaweed

When the control system applying specifically to seaweed is first implemented, the full description of the site referred to in Article 63(1)(a) shall include:

- (a) a full description of the installations on land and at sea;
- (b) the environmental assessment as outlined in Article 6b(3) where applicable;
- (c) the sustainable management plan as outlined in Article 6b(4) where applicable;
- (d) for wild seaweed a full description and a map of shore and sea collection areas and land areas where post collection activities take place shall be drawn up.

#### Seaweed Production Records

1. Seaweed production records shall be compiled in the form of a register by the operator and kept available for the control authorities or control bodies at all times at the premises of the holding. It shall provide at least the following information:

- (a) list of species, date and quantity harvested;
- (b) date of application, type and amount of fertiliser used.

2. For collection of wild seaweeds the register shall also contain:

- (a) history of harvesting activity for each species in named beds;
- (b) harvest estimate (volumes) per season;
- (c) sources of possible pollution for harvest beds;
- (d) sustainable annual yield for each bed.

### Seaweed Production

[EC 889/2008 Article 6]

a. This Chapter lays down detailed production rules for the collection and farming of seaweed. It applies *mutatis mutandis* to the production of all multi-cellular marine algae or phytoplankton and micro-algae for further use as feed for aquaculture animals.

#### b. Suitability of aquatic medium and sustainable management plan

1. Operations shall be situated in locations that are not subject to contamination by products or substances not authorised for organic production, or pollutants that would compromise the organic nature of the products.
2. Organic and non-organic production units shall be separated adequately. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit. Member State authorities may designate locations or areas which they consider to be unsuitable for organic aquaculture or seaweed harvesting and may also set up minimum separation distances between organic and non-organic production units. Where minimum separation distances are set Member States shall provide this information to operators, other Member States and the Commission.
3. An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the control body or control authority. The content of the environmental assessment shall be based on Annex IV to Council Directive 85/337/EEC (\*). If the unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.
4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and seaweed harvesting. The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of

technical equipment.

5. Aquaculture and seaweed business operators shall by preference use renewable energy sources and re-cycle materials and shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy from renewable sources.
6. For seaweed harvesting a once-off biomass estimate shall be undertaken at the outset.

**c. Sustainable harvesting of wild seaweed**

1. Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild seaweed produced in accordance with Regulation (EC) No 834/2007.
2. Harvesting shall be carried out in such a way that the amounts harvested do not cause a significant impact on the state of the aquatic environment. Measures shall be taken to ensure that seaweed can regenerate, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining seaweed.
3. If seaweed is harvested from a shared or common harvest area, documentary evidence shall be available that the total harvest complies with this Regulation.
4. With respect to Article 73b(2)(b) and (c), these records must provide evidence of sustainable management and of no long-term impact on the harvesting areas.

**d. Seaweed Cultivation**

1. Seaweed culture at sea shall only utilise nutrients naturally occurring in the environment, or from organic aquaculture animal production, preferably located nearby as part of a polyculture system.
2. In facilities on land where external nutrient sources are used the nutrient levels in the effluent water shall be verifiably the same, or lower, than the inflowing water. Only nutrients of plant or mineral origin and as listed in Annex I may be used.
3. Culture density or operational intensity shall be recorded and shall maintain the integrity of the aquatic environment by ensuring that the maximum quantity of seaweed which can be supported without negative effects on the environment is not exceeded.
4. Ropes and other equipment used for growing seaweed shall be re-used or recycled where possible.

**e. Antifouling measures and cleaning of production equipment and facilities**

1. Bio-fouling organisms shall be removed only by physical means or by hand and where appropriate returned to the sea at a distance from the farm.
2. Cleaning of equipment and facilities shall be carried out by physical or mechanical measures. Where this is not satisfactory only substances as listed in Annex VII, Section 2 may be used.

## EC Requirement:

### Yeast

**General rules on the production of organic yeast**

*[EC 834/2007 Article 20]*

1. For the production of organic yeast only organically produced substrates shall be used. Other products and substances may only be used in so far as they have been authorised for use in organic production in accordance with Article 21.
2. Organic yeast shall not be present in organic food or feed together with non-organic yeast.
3. Detailed production rules may be laid down in accordance with the procedure referred to in Article 37(2).

**Allowed substances**

*[EC 889/2008 Article 27a]*

For the purpose of the application of Article 20 (1) of Regulation (EC) No 834/2007, the following substances may be

used in the production, confection and formulation of yeast:

- (a) substances listed in Annex VIII, Section C to this Regulation;
- (b) products and substances referred to in Article 27 (1) (b) and (e) of this Regulation.

#### **Addition of non-organic yeast extract**

[EC 889/2008 Article 46a]

Where the conditions laid down in Article 22 (2) (e) of Regulation (EC) No 834/2007 apply, the addition of up to 5 % non-organic yeast extract or autolysate to the substrate (calculated in dry matter) is allowed for the production of organic yeast, where operators are unable to obtain yeast extract or autolysate from organic production.

The availability of organic yeast extract or autolysate shall be re-examined by 31 December 2013 with a view to withdrawing this provision.

#### **Calculation of agricultural origin**

[EC 889/2008 Article 27c]

Yeast and yeast products shall be calculated as ingredients of agricultural origin as of 31 December 2013.

## **Lists of Substances**

The following lists from EC 899/2008 and JAS are provided as a reference. Items listed here may not be acceptable under the NOP or other programs. The NOP list has been annotated to reflect the combined limitations of the following lists. The full text of the regulations and/or standards of each program are available from the OneCert web site, which contains links to each of the programs.

### **EC Requirement:**

#### **ANNEX I. Fertilizers, soil conditioners and nutrients referred to in Article 3(1) and Article 6d(2)**

*Note:*

*A: authorised under Regulation (EEC) No 2092/91 and carried over by Article 16(3)(c) of Regulation (EC) No 834/2007*

*B: authorised under Regulation (EC) No 834/2007*

<b>Authorisation</b>	<b>Name Compound products or products containing only material listed hereunder</b>	<b>Description, compositional requirements, conditions for use</b>
A	Farmyard manure	Product comprising a mixture of animal excrements and vegetable matter (animal bedding). Factory farming origin forbidden
A	Dried farmyard manure and dehydrated poultry manure	Factory farming origin forbidden
A	Composted animal excrements, including poultry manure and composted farmyard manure included	Factory farming origin forbidden
A	Liquid animal excrements	Use after controlled fermentation and/or appropriate dilution Factory farming origin forbidden

B	Composted or fermented mixture of household waste	Product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production Only vegetable and animal household waste Only when produced in a closed and monitored collection system, accepted by the Member State Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable
A	Peat	Use limited to horticulture (market gardening, floriculture, arboriculture, nursery)
A	Mushroom culture wastes	The initial composition of the substrate shall be limited to products of this Annex
A	Dejecta of worms (vermicompost) and insects	
A	Guano	
A	Composted or fermented mixture of vegetable matter	Product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production
<b>Authorisation</b>	<b>Name Compound products or products containing only material listed hereunder</b>	<b>Description, compositional requirements, conditions for use</b>
B	Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	Animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories 2 and 3 as defined in Regulation (EC) No 1069/2009 of the European Parliament and of the Council (1) must not be from factory farming origin. The Processes have to be in accordance with Commission Regulation (EU) No 142/2011 (2). Not to be applied to edible parts of the crop
B	Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	Animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories 2 and 3 as defined in Regulation (EC) No 1069/2009 of the European Parliament and of the Council (1) must not be from factory farming origin. The Processes have to be in accordance with Commission Regulation (EU) No 142/2011 (2). Not to be applied to edible parts of the crop

B	Products or by-products of animal origin as below: Blood meal Hoof meal Horn meal Bone meal or degelatinised bone meal Fish meal Meat meal Feather, hair and "chiquette" meal Wool Fur (1) Hair Dairy products Hydrolysed proteins (2)	(1) Maximum concentration in mg/kg of dry matter of chromium (VI): not detectable (2) Not to be applied to edible parts of the crop
A	Products and by-products of plant origin for fertilisers	Examples: oilseed cake meal, cocoa husks, malt culms
B	Hydrolysed proteins of plant origin	
A	Seaweeds and seaweed products	As far as directly obtained by: (i) physical processes including dehydration, freezing and grinding (ii) extraction with water or aqueous acid and/or alkaline solution (iii) fermentation
<b>Authorisation</b>	<b>Name Compound products or products containing only material listed hereunder</b>	<b>Description, compositional requirements, conditions for use</b>
A	Sawdust and wood chips	Wood not chemically treated after felling
A	Composted bark	Wood not chemically treated after felling
A	Wood ash	From wood not chemically treated after felling
A	Soft ground rock phosphate	Product as specified in point 7 of Annex IA.2. to Regulation (EC) No 2003/2003 of the European Parliament and of the Council (3) relating to fertilisers Cadmium content less than or equal to 90 mg/kg of P205
A	Aluminium-calcium phosphate	Product as specified in point 6 of Annex IA.2. of Regulation (EC) No 2003/2003, Cadmium content less than or equal to 90 mg/kg of P205 Use limited to basic soils (pH > 7,5)
A	Basic slag	Products as specified in point 1 of Annex IA.2. of Regulation 2003/2003
A	Crude potassium salt or kainit	Products as specified in point 1 of Annex IA.3. of Regulation 2003/2003
A	Potassium sulphate, possibly containing magnesium salt	Product obtained from crude potassium salt by a physical extraction process, containing possibly also magnesium salts

A	Stillage and stillage extract	Ammonium stillage excluded
A	Calcium carbonate (chalk, marl, ground limestone, Breton ameliorant, (maerl), phosphate chalk)	Only of natural origin
A	Magnesium and calcium carbonate	Only of natural origin e.g. magnesian chalk, ground magnesium, limestone
A	Magnesium sulphate (kieserite)	Only of natural origin
A	Calcium chloride solution	Foliar treatment of apple trees, after identification of deficit of calcium
A	Calcium sulphate (gypsum)	Products as specified in point 1 of Annex ID. of Regulation (EC) No 2003/2003 Only of natural origin
A, B	Industrial lime from sugar production	By-product of sugar production from sugar beet and sugar cane
A	Industrial lime from vacuum salt production	By-product of the vacuum salt production from brine found in mountains
A	Elemental sulphur	Products as specified in Annex ID.3 of Regulation 2003/2003
A	Trace elements	Inorganic micronutrients listed in part E of Annex I to Regulation 2003/2003
A	Sodium chloride	Only mined salt
A	Stone meal and clays	
<b>Authorisation</b>	<b>Name Compound products or products containing only material listed hereunder</b>	<b>Description, compositional requirements, conditions for use</b>
B	Leonardite (Raw organic sediment rich in humic acids)	Only if obtained as a by-product of mining activities
B	Xylite	Only if obtained as a by-product of mining activities (e.g. by-product of brown coal mining)
B	Chitin (Polysaccharide obtained from the shell of crustaceans)	Only if obtained from sustainable fisheries, as defined in Article 3(e) of Council Regulation (EC) No 2371/2002 (4) or organic aquaculture
B	Organic rich sediment from fresh water bodies formed under exclusion of oxygen (e.g. sapropel)	Only organic sediments that are by-products of fresh water body management or extracted from former freshwater areas When applicable, extraction should be done in a way to cause minimal impact on the aquatic system Only sediments derived from sources free from contaminations of pesticides, persistent organic pollutants and petrol like substances Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable

(1) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

(2) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not



intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

(3) OJ L 304, 21.11.2003, p. 1.

(4) Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy (OJ L 358, 31.12.2002, p. 59).

Use of micro-organisms is allowed as the following:

1. Appropriate preparations of micro-organisms may be used to improve the overall condition of the soil or the availability of nutrients in the soil or in the crops.
2. For compost activation appropriate plant-based preparations or preparations of micro-organisms may be used.

The use of biodynamic preparations is allowed. [EC 834/2007 Article 12 (1)(c)]

## ANNEX II Pesticides — Plant protection products referred to in Article 5(1)

All the substances listed in this Annex have to comply at least with the conditions for use as specified in the Annex to Implementing Regulation (EU) No 540/2011 <sup>(1)</sup>. More restrictive conditions for use for organic production are specified in the second column of each table

### 1. Substances of plant or animal origin

Name	Description, compositional requirement, conditions for use
Allium sativum (Garlic extract)	
Azadirachtin extracted from <i>Azadirachta indica</i> (Neem tree)	
Basic substances (including: Lecithins, sucrose, fructose, vinegar, whey, chitosan hydrochloride <sup>(1)</sup> , and Equisetum arvense etc.)	Only those basic substances as defined by Article 23 of Regulation (EC) No 1107/2009 <sup>(2)</sup> which are food as defined in Article 2 of Regulation (EC) No 178/2002 and have plant or animal origin Substances not to be used as herbicides, but only for the control of pests and diseases.
Beeswax	Only as pruning agent/wound protectant
COS-OGA	
Hydrolysed proteins excluding gelatine	
Laminarin	Kelp shall be either grown organically in accordance with Article 6d or harvested in a sustainable way in accordance with Article 6c
Pheromones	Only in traps and dispensers.
Plant oils	All uses authorised, except herbicide.
Pyrethrins extracted from <i>Chrysanthemum cinerariaefolium</i>	

Pyrethroids (only deltamethrin or lambdacyhalothrin)	Only in traps with specific attractants; only against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i> Wied
Quassia extracted from <i>Quassia amara</i>	Only as Insecticide, repellent
Repellents by smell of animal or plant origin/sheep fat	Only on non-edible parts of the crop and where crop material is not ingested by sheep or goats
<i>Salix spp.</i> Cortex (aka willow bark extract)	

(1) Obtained from sustainable fisheries or organic aquaculture

(2) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).

## 2. Micro-organisms or substances produced by micro-organisms

Name	Description, compositional requirement, conditions for use
Micro-organisms	Not from GMO origin
Spinosad	

(1) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

## 3. Substances other than those mentioned in Sections 1 and 2

Name	Description, compositional requirement, conditions or restrictions to use
Aluminium silicate (Kaolin)	
Calcium hydroxide	When used as Fungicide, only in fruit trees, including nurseries, to control <i>Nectria galligena</i>
Carbon dioxide	
Copper compounds in the form of: copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture, and tribasic copper sulphate	Up to 6 kg copper per ha per year. For perennial crops, Member States may, by derogation from the previous paragraph, provide that the 6 kg copper limit can be exceeded in a given year provided that the average quantity actually used over a 5-year period consisting of that year and of the four preceding years does not exceed 6 kg.
Diammonium phosphate	Only as attractant in traps
Ethylene	Only indoor uses as plant growth regulator may be authorised. Authorisations shall be limited to professional users.
Fatty acids	All uses authorised, except herbicide
Ferric phosphate (iron (III) orthophosphate)	Preparations to be surface-spread between cultivated plants
Kieselgur (diatomaceous earth)	

Lime sulphur (calcium polysulphide)	
Paraffin oil	
Potassium and sodium hydrogen carbonate (aka potassium/sodium bicarbonate)	
Quartz sand	
Sulphur	

### EC Requirement:

## ANNEX III. Minimum surface areas indoors and outdoors and other characteristics of housing in the different species and types of production referred to in Article 10(4)

### 1. Bovines, equidae, ovine, caprine and porcine

	Indoors area (net area available to animals)		Outdoor area (exercise area, excluding pasturage)
	Light weight minimum (kg)	M <sup>2</sup> /head	M <sup>2</sup> /head
Breeding and fattening bovine and equidae	Up to 100	1,5	1,1
	Up to 200	2,5	1,9
	Up to 350	4,0	3
	Over 350	5 with a minimum of 1 m <sup>2</sup> /100kg	3,7 with a minimum of 0,75 m <sup>2</sup> /100kg
Dairy cows		6	4,5
Bulls for breeding		10	30
Sheep and goats		1,5 sheep/goat	2,5
		0,35 lamb/kid	0,5
Farrowing sows with piglets up to 40 days		7,5 sow	2,5
Fattening pigs	Up to 50	0,8	0,6
	Up to 85	1,1	0,8
	Up to 110	1,3	1
	Over 110 kg	1,5	1,2
Piglets	Over 40 days and up to 30 kg	0,6	0,4
Brood pigs		2,5 female	1,9
		6 male if pens are used for natural service: 10 m <sup>2</sup> /boar	8,0

### 2. Poultry

	Indoors area (net area available to animals)			Outdoors area (m <sup>2</sup> of area available in rotation/head)
	No animals/m <sup>2</sup>	Cm perch/animal	nest	
Laying hens	6	18	7 laying hens per nest or in case of common nest 120 cm <sup>2</sup> /bird	4, provided that the limit of 170 kg of N/ha/year is not exceeded
Fattening poultry (in fixed housing)	10 with a maximum of 21 kg live- weight/m <sup>2</sup>	20 (for guinea fowl only)		4 broilers and guinea fowl 4,5 ducks 10 turkey 15 geese In all the species mentions

				above the limit of 170 kg of N/ha/year is not exceeded
Fattening poultry in mobile housing	16 <sup>(1)</sup> in mobile poultry houses with a maximum of 30 kg live-weight/m <sup>2</sup>			2,5, provided that the limit of 170 kg of N/ha/year is not exceeded
<sup>(1)</sup> Only in the case of mobile houses not exceeding 150 m <sup>2</sup> floor space.				

**EC Requirement:****ANNEX IV. Maximum number of animals per hectare referred to in Article 15(2)**

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Equines over six months old	2
Calves for fattening	5
Other bovine animals less than one year old	5
Male bovine animals from one to less than two years old	3,3
Female bovine animals from one to less than two years old	3,3
Male bovine animals two years old or over	2
Breeding heifers	2,5
Heifers for fattening	2,5
Dairy cows	2
Cull dairy cows	2
Other cows	2,5
Female breeding rabbits	100
Ewes	13,3
Goats	13,3
Piglets	74
Breeding sows	6,5
Pigs for fattening	14
Other pigs	14
Table chickens	580
Laying hens	230

**EC Requirement:****ANNEX V. Feed materials referred to in Article 22(d), Article 24(2) and Article 25m(1)****1. FEED MATERIALS OF MINERAL ORIGIN**

A	Calcareous marine shells
A	Maerl
A	Lithotamn
A	Calcium gluconate
A	Calcium carbonate
A	Defluorinated monocalciumphosphate
A	Defluorinated dicalciumphosphate
A	Magnesium oxide (anhydrous magnesia)
A	Magnesium sulphate

A	Magnesium chloride
A	Magnesium carbonate
A	Calcium magnesium phosphate
A	Magnesium phosphate
A	Calcium sodium phosphate
A	Sodium chloride
A	Sodium bicarbonate
A	Sodium carbonate
A	Sodium sulphate
A	Potassium chloride

## 2. OTHER FEED MATERIALS

Fermentation (by-)products from microorganisms the cells of which have been inactivated or killed:

A	Saccharomyces cerevisiae
A	Saccharomyces carlsbergiensis

## EC Requirement:

### ANNEX VI. Feed additives used in animal nutrition referred to in Article 22(g), Article 24(2) and Article 25m(2)

Feed additives listed in this Annex must be authorised under Regulation (EC) No 1831/2003 of the European Parliament and of the Council <sup>(1)</sup>.

#### 1. TECHNOLOGICAL ADDITIVES

##### (a) Preservatives

ID numbers or Functional groups	Substance	Description, conditions for use
E 200	Sorbic acid	
E 236	Formic acid	
E 237	Sodium formate	
E 260	Acetic acid	
E 270	Lactic acid	
E 280	Propionic acid	
E 330	Citric acid	

<sup>(1)</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

##### (b) Antioxidants

ID number or Functional groups	Substance	Description, conditions for use
1b306(i)	Tocopherol extracts from vegetable oils	
1b306(ii)	Tocopherol-rich extracts from vegetable oils (delta rich)	

##### (c) Emulsifying and stabilizing agents, thickeners and gelling agents.

ID numbers or Functional groups	Substance	Description, conditions for use
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	E 322	Lecithins	Only when derived from organic raw material. Use restricted to aquaculture animal feed.
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(d) *Binders, anti-caking agents and coagulants*

ID number or Functional groups	Substance	Description, conditions for use
E 535	Sodium ferrocyanide	Maximum dose rate of 20 mg/kg NaCl calculated as ferrocyanide anion.
E 551b	Colloidal silica	
E 551c	Kieselgur (diatomaceous earth, purified)	
1m558i	Bentonite	
E 559	Kaolinitic clays, free of asbestos	
E 560	Natural mixtures of stearites and chlorite	
E 561	Vermiculite	
E 562	Sepiolite	
E 566	Natrolite-Phonolite	
1g568	Clinoptilolite of sedimentary origin	
E 599	Perlite	

(e) *Silage additives*

ID number or Functional groups	Substance	Description, conditions for use
1k	Enzymes and micro-organisms	Use restricted to production of silage when weather conditions do not allow for adequate fermentation.

## 2. SENSORY ADDITIVES

ID number or Functional groups	Substance	Description, conditions for use
2b	Flavouring compounds	Only extracts from agricultural products.

## 3. NUTRITIONAL ADDITIVES

(a) *Vitamins, pro-vitamins and chemically well-defined substances having similar effect*

ID number or Functional groups	Substance	Description, conditions for use
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3a	Vitamins and provitamins	<ul style="list-style-type: none"> <li>– Derived from agricultural products.</li> <li>– If derived synthetically, only those identical to vitamins derived from agricultural products may be used for monogastric animals and aquaculture animals.</li> <li>– If derived synthetically, only vitamins A, D and E identical to vitamins derived from agricultural products may be used for ruminants; the use is subject to prior authorisation of the Member States based on the assessment of the possibility for organic ruminants to obtain the necessary quantities of the said vitamins through their feed rations.</li> </ul>
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(b) *Compounds of trace elements*

ID numbers or Functional groups	Substance	Description, conditions for use
E1 Iron	Ferric oxide Ferrous carbonate Ferrous sulphate, heptahydrate Ferrous sulphate, monohydrate	
3b201 3b202 3b203	Potassium iodide Calcium iodate, anhydrous Coated granulated calcium iodate anhydrous	
3b301 3b302 3b303  3b304  3b305	Cobalt(II) acetate tetrahydrate Cobalt(II) carbonate Cobalt(II) carbonate hydroxide (2:3) monohydrate Coated granulated cobalt(II) carbonate Cobalt(II) sulphate heptahydrate	
E4 Copper   3b409	Basic cupric carbonate, monohydrate Cupric oxide Cupric sulphate, pentahydrate Dicopper chloride trihydroxide (TBCC)	
E5 Manganese	Manganous oxide Manganous sulfate, monohydrate Manganous carbonate	
E6 Zinc   3b609	Zinc oxide Zinc sulphate monohydrate Zinc sulphate heptahydrate Zinc chloride hydroxide monohydrate (TBZC)	
E7 Molybdenum	Sodium molybdate	
E8 Selenium  3b8.10, 3b8.11, 3b8.12, 3b813 and 3b817	Sodium selenite Sodium selenate Selenised yeast inactivated	

ID number or Functional groups	Substance	Description, conditions for use
4a, 4b, 4c and 4d	Enzymes and microorganism in the category of "Zootechnical additives"	

## EC Requirement:

### ANNEX VII. Products for cleaning and disinfection

1. Products for cleaning and disinfection of buildings and installations for livestock production referred to in Article 23(4):
  - Potassium and sodium soap
  - Water and steam
  - Milk of lime
  - Lime
  - Quicklime
  - Sodium hypochlorite (e.g. as liquid bleach)
  - Caustic soda
  - Caustic potash
  - Hydrogen peroxide
  - Natural essences of plants
  - Citric, peracetic acid, formic, lactic, oxalic and acetic acid
  - Alcohol
  - Nitric acid (dairy equipment)
  - Phosphoric acid (dairy equipment)
  - Formaldehyde
  - Cleaning and disinfection products for teats and milking facilities
  - Sodium carbonate
2. Products for cleaning and disinfection for aquaculture animals and seaweed production referred to in Articles 6e(2), 25s(2), and 29a.
  - 2.1 Substances for cleaning and disinfection of equipment and facilities, in the absence of aquaculture animals:
    - ozone
    - sodium chloride
    - sodium hypochlorite
    - calcium hypochlorite
    - lime (CaO, calcium oxide)
    - caustic soda
    - alcohol
    - hydrogen peroxide
    - organic acids (acetic acid, lactic acid, citric acid)
    - humic acid
    - peroxyacetic acids
    - iodophores
    - copper sulphate: only until 31 December 2015
    - potassium permanganate
    - peracetic and peroctanoic acids
    - tea seed cake made of natural camellia seed (use restricted to shrimp production)
  - 2.2 Limited list of substances for use in the presence of aquaculture animals:
    - limestone (calcium carbonate) for pH control
    - dolomite for pH correction (use restricted to shrimp production)

## EC Requirement:

### ANNEX VIII. Certain products and substances for use in production of processed organic food, yeast and yeast products referred to in Article 27(1)(a) and Article 27a(a).

#### Section A-Food Additives, Including Carriers



For the purpose of calculation referred to in Article 23(4)(a)(ii) of Regulation (EC) No 834/2007, food additives marked with an asterisk in the column of the cod number, shall be calculated as ingredients of agricultural origin.

Code	Name	Preparation of foodstuffs of		Specific conditions
		plant origin	animal origin	
E 153	Vegetable carbon		X	Ashy goat cheese Mobier cheese
E 160b*	Annatto, Bixin, Norbixin		X	Red Leicester cheese Double Gloucester cheese Cheddar Mimolette cheese
E 170	Calcium carbonate	X	X	Shall not be used for colouring or calcium enrichment of products
E 220 Or	Sulphur dioxide	X	X (Only for mead)	In fruit wines (*) and mead with and without added sugar):100 mg (**)
E 224	Potassium metabisulphite	X	X (Only for mead)	In fruit wines (*) and mead with and without added sugar):100 mg (**).  (* In this context, "fruit wine" is defined as wine made from fruits other than grapes (including cider and perry). (**) Maximum levels available from all sources, expressed as SO <sub>2</sub> in mg/l.
E 223	Sodium Metabisulphite		X	Crustaceans (2)
E 250 Or	Sodium nitrite		X	For meat products (1)
E 252	Potassium nitrate		X	For E 250: indicative ingoing amount expressed as NaNO <sub>2</sub> : 80 mg/kg  For E 252: indicative ingoing amount expressed as NaNO <sub>3</sub> : 80 mg/kg  For E 250: maximum residual amount expressed as NaNO <sub>2</sub> : 50 mg/kg  For E 252: maximum residual amount expressed as NaNO <sub>3</sub> : 50 mg/kg
E 270	Lactic acid	X	X	
E 290	Carbon dioxide	X	X	
E 296	Malic acid	X		
E 300	Ascorbic acid	X	X	Meat products (2)
E 301	Sodium ascorbate		X	Meat products (2) in connection with nitrates and nitrites
E 306 (*)	Tocopherol-rich extract	X	X	Anti-oxidant
E 322 (*)	Lecithins	X	X	Milk products (2) Only when derived from organic raw material (***) In this context, (***) As from 1 January 2019.'
E 325	Sodium lactate		X	Milk-based and meat products
E 330	Citric acid	X	X	
E 330	Citric acid		X	Crustaceans and molluscs (2)
E 331	Sodium citrate	X	X	

E 333	Calcium citrates	X		
E 334	Tartaric acid (L(+)-)	X	X (Only for mead)	
E 335	Sodium tartrates	X		
E 336	Potassium tartrates	X		
E 341 (i)	Monocalcium-phosphate	X		Raising agent for self raising flour
E 392*	Extracts of rosemary	X	X	Only when derived from organic production
E 400	Alginic acid	X	X	Milk-based products (2)
E 401	Sodium alginate	X	X	Milk-based products (2)
E 402	Potassium alginate	X	X	Milk-based products (2)
E 406	Agar	X	X	Milk-based and meat products (2)
E 407	Carrageenan	X	X	Milk-based products (2)
E 410*	Locust bean gum	X	X	
E 412*	Guar gum	X	X	
E 414*	Arabic gum	X	X	
E 415	Xanthan gum	X	X	
E 418	Gellan gum	X	X	High-acyl form only
E 422	Glycerol	X		From plant origin. For plant extracts and flavourings
E 440 (i)*	Pectin	X	X	Milk-based products (2)
E 464	Hydroxypropyl methyl cellulose	X	X	Encapsulation material for capsules
E 500	Sodium carbonate	X	X	E 500
E 501	Potassium carbonates	X		
E 503	Ammonium carbonates	X		
E 504	Magnesium carbonates	X		
E 509	Calcium chloride		X	Milk coagulation
E 516	Calcium sulphate	X		Carrier
E 524	Sodium hydroxide	X		Surface treatment of "Laugengebäck" and regulation of acidity in organic flavourings
E 551	Silicon dioxide gel or colloidal solution	X	X	For herbs and spices in dried powdered form Flavourings and propolis
E 553b	Talc	X	X	Coating agent for meat products
E 901	Beeswax	X		As a glazing agent for confectionary only. Beeswax from organic beekeeping
E 903	Carnauba wax	X		As a glazing agent for confectionary only. Only when derived from organic raw material'
E 938	Argon	X	X	
E 939	Helium	X	X	
E 941	Nitrogen	X	X	
E 948	Oxygen	X	X	
E 968	Erythritol	X	X	Only when derived from organic production without using ion exchange technology'

(1) This additive can only be used, if it has been demonstrated to the satisfaction of the competent authority that no technological alternative, giving the same guarantees and/or allowing to maintain the specific features of the product, is available.

(2) The restriction concerns only animal products.

(3) 'Dulce de leche' or 'Confiture de lait' refers to a soft, luscious, brown cream, made of sweetened, thickened milk.

### Section B- Processing Aids and other products, which may be used for processing of ingredients of agricultural origin from organic production

Name	Preparation of foodstuffs of	Specific conditions
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	Plant origin	Animal origin	
Water	X	X	Drinking water within the meaning of Council Directive 98/83/EC
Calcium chloride	X		Coagulation agent
Calcium carbonate	X		
Calcium hydroxide	X		
Calcium sulphate	X		Coagulation agent
Magnesium chloride (or nigari)	X		Coagulation agent
Potassium carbonate	X		Drying of grapes
'Sodium carbonate	X	X	
Lactic acid		X	For the regulation of the pH of the brine bath in cheese production (1)
Citric acid	X	X	
Sodium hydroxide	X		For sugar(s) production. For oil production excluding olive oil production
Sulphuric acid	X	X	Gelatine production (1) Sugar(s) production (2)
Hydrochloric acid		X	Gelatine production For the regulation of the pH of the brine bath in the processing of Gouda, Edam, and Maasdammer cheeses, Boerenkaas, Friese, and Leidse Nagelkaas
Ammonium hydroxide		X	Gelatine production
Hydrogen peroxide		X	Gelatine production
Carbon dioxide	X	X	
Nitrogen	X	X	
Ethanol	X	X	Solvent
Tannic acid	X		Filtration aid
Egg white albumen	X		
Casein	X		
Gelatin	X		
Isinglass	X		
Vegetable oils	X	X	Greasing, releasing or anti foaming agent. Only when derived from organic production
Silicon dioxide gel or colloidal solution	X		
Activated carbon	X		
Talc	X		In compliance with the specific purity criteria for food additive E 553b
Bentonite	X	X	Sticking agent for mead (1)
Cellulose	X	X	Gelatine production (1)
Diatomaceous earth	X	X	Gelatine production (1)
Perlite	X	X	Gelatine production (1)
Hazelnut shells	X		
Rice Meal	X		
Beeswax	X		Releasing agent. Beeswax from organic beekeeping
Carnauba wax	X		Releasing agent. Only when derived from organic raw material'
'Acetic acid/vinegar		X	Only when derived from organic production. For fish processing, only from biotechnological source, except if produced by or from GMO
Thiamin hydrochloride	X	X	Only for use in processing of fruit wines, including cider and perry and mead
Diammonium phosphate	X	X	Only for use in processing of fruit wines, including cider and perry and mead

Wood fibre	X	X	The source of timber should be restricted to certified, sustainably harvested wood. Wood used must not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from micro-or-ganisms) <sup>1</sup>
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<sup>(1)</sup> The restriction concerns only animal products.

<sup>(2)</sup> The restriction concerns only plant products.

### Section C- Processing Aids for the Production of Yeast and Yeast Products referred to in Article 27(1)(a) and Article 27a(a).

Name	Primary Yeast	Yeast confections/ formulations	Specific conditions
Calcium chloride	X		
Carbon dioxide	X	X	
Citric acid	X		For the regulation of the pH in east production
Lactic acid	X		For the regulation of the pH in yeast production
Nitrogen	X	X	
Oxygen	X	X	
Potato starch	X	X	For filtering Only when derived from organic production
Sodium carbonate	X	X	For the regulation of the pH
Vegetable oils	X	X	Greasing, releasing or anti-foaming agent Only when derived from organic production <sup>2</sup>

### EC Requirement:

### ANNEX IX. Ingredients of agricultural origin which have not been produced organically referred to in Article 28

#### 1. UNPROCESSED VEGETABLE PRODUCTS AS WELL AS PRODUCTS DERIVED THEREFROM BY PROCESSES

##### 1.1 Edible fruits, nuts and seeds:

- Acorns *Quercus spp.*
- Cola nuts *Cola acuminata*
- Gooseberries *Ribes uva-crispa*
- Maracujas (passion fruit) *Passiflora edulis*
- Raspberries (dried) *Rubus idaeus*
- Red currants (dried) *Ribes rubrum*

##### 1.2 Edible spices and herbs:

- Pepper (Peruvian) *Schinus molle L.*
- Horseradish seeds *Armoracia rusticana*
- Lesser galanga *Alpinia officinarum*
- Safflower flowers *Carthamus tinctorius*
- Watercress herb *Nasturtium officinale*

##### 1.3 Miscellaneous:

Algae, including seaweed, permitted in non-organic foodstuffs preparation

#### 2. VEGETABLE PRODUCTS

##### 2.1 Fats and oils whether or not refined, but not chemically modified, derived from plants other than:

- Cocoa *Theobroma cacao*
- Coconut *Cocos nucifera*

– olive	<i>Olea europaea</i>
– Sunflower	<i>Helianthus annuus</i>
– Palm	<i>Elaeis guineensis</i>
– Rape	<i>Brassica napus, rapa</i>
– Safflower	<i>Carthamus tinctorious</i>
– Sesame	<i>Sesamum indicum</i>
– soya	<i>Glycine max</i>

## 2.2 The following sugars, starches and other products from cereals and tubers:

Fructose, rice paper, unleavened bread paper, starch from rice and waxy maize, not chemically modified.

## 2.3 Miscellaneous:

Pea protein (*Pisum* spp.); rum, only obtained from cane sugar juice; kirsch prepared on the basis of fruits and flavorings as referred to in Article 27(1)(c).

## 3. ANIMAL PRODUCTS

Aquatic organisms, not originating from aquaculture, and permitted in no-organic foodstuffs preparation: Gelatin; whey powder 'herasoula'; casings.

## EC Requirement:

### ANNEX XI. (Organic logo and code numbers)

#### A. Organic logo of the EU, referred to in Article 57

1. The Organic logo of the EU shall comply with the model below:



2. The reference colour in Pantone is Green Pantone No 376 and Green (50 % Cyan + 100 % Yellow), when a four-colour process is used.
3. The Organic logo of the EU can also be used in black and white as shown, only where it is not practicable to apply it in colour:



4. If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.
5. If a symbol is used in colour on a coloured background, which makes it difficult to see, a delimiting outer line around the symbol can be used to improve contrast with the background colours.
6. In certain specific situations where there are indications in a single colour on the packaging, the Organic logo of the EU may be used in the same colour.

7. The Organic logo of the EU must have a height of at least 9 mm and a width of at least 13,5 mm; the proportion ratio height/width shall always be 1:1,5. Exceptionally the minimum size may be reduced to a height of 6 mm for very small packages.
8. The Organic logo of the EU may be associated with graphical or textual elements referring to organic farming, under the condition that they do not modify or change the nature of the Organic logo of the EU, nor any of the indications mentioned at Article 58. When associated to national or private logos using a green colour different from the reference colour mentioned in point 2, the Organic logo of the EU may be used in that non-reference colour.

### B. Code numbers referred to in Article 58

The general format of the code numbers is as follows:

AB-CDE-999

Where:

1. 'AB' is the ISO code as specified in Article 58(1)(a) for the country where the controls take place; and
2. 'CDE' is a term, indicated in three letters to be decided by the Commission or each Member State, like 'bio' or 'öko' or 'org' or 'eko' establishing a link with the organic production method as specified in Article 58(1)(b); and
3. '999' is the reference number, indicated in maximum three digits, to be attributed, as specified in Article 58(1)(c) by:
  - (a) each Member State's competent authority to the Control Authorities or Control Bodies to which they have delegated control tasks in accordance with Article 27 of Regulation (EC) No 834/2007;
  - (b) the Commission, to:
    - (i) the Control Authorities and Control Bodies referred to in Article 3(2)(a) of Commission Regulation (EC) No 1235/2008 ( 1 ) and listed in Annex I to that Regulation;
    - (ii) the third countries' competent authorities or Control Bodies referred to in Article 7(2)(f) of Regulation (EC) No 1235/2008 and listed in Annex III to that Regulation;
    - (iii) the Control Authorities and Control Bodies referred to in Article 10(2)(a) of Regulation (EC) No 1235/2008, and listed in Annex IV to that Regulation;
  - (c) each Member State's competent authority to the Control Authority or Control Body which has been authorised until 31 December 2012 for issuing the certificate of inspection in accordance with Article 19(1) fourth subparagraph of Regulation (EC) No 1235/2008 (import authorisations), upon proposal of the Commission.

The Commission shall make the code numbers available to the public by any appropriate technical means, including publication on the Internet.

### EC Requirement:

#### Annex XIIIa. (Organic Production of Aquaculture)

##### Section 1 Organic production of salmonids in fresh water:

Brown trout (*Salmo trutta*) – Rainbow trout (*Oncorhynchus mykiss*) – American brook trout (*Salvelinus fontinalis*) – Salmon (*Salmo salar*) – Charr (*Salvelinus alpinus*) – Grayling (*Thymallus thymallus*) – American lake trout (*Salvelinus namaycush*) – Huchen (*Hucho hucho*)

Production system	Ongrowing farm systems must be fed from open systems. The flow rate must ensure a minimum of 60% oxygen saturation for stock and must ensure their comfort and the elimination of farming effluent.
Maximum stocking density	Salmonid species not listed below 15 kg/m <sup>3</sup> Salmon 20 kg/m <sup>3</sup> Brown trout and Rainbow trout 25 kg/m <sup>3</sup> Arctic charr 20 kg/m <sup>3</sup>

##### Section 2 Organic production of salmonids in sea water:

Salmon (*Salmo salar*), Brown trout (*Salmo trutta*) – Rainbow trout (*Oncorhynchus mykiss*)

Maximum stocking density	10 kg/m <sup>3</sup> in net pens
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**Section 3 Organic production of cod (*Gadus morhua*) and other Gadidae, sea bass (*Dicentrarchus labrax*), sea bream (*Sparus aurata*), meager (*Argyrosomus regius*), turbot (*Psetta maxima* [= *Scophthalmus maximus*]), red porgy (*Pagrus pagrus* [= *Sparus pagrus*]), red drum (*Sciaenops ocellatus*) and other Sparidae, and spinefeet (*Siganus* spp.)**

Production system	In open water containment systems (net pens/cages) with minimum sea current speed to provide optimum fish welfare or in open systems on land.
Maximum stocking density	For fish other than turbot: 15kg/m <sup>3</sup> For turbot: 25 kf/m <sup>2</sup>

**Section 4 Organic production of sea bass, sea bream, meager, mullets (*Liza*, *Mugi*) and eel (*Anguilla* spp.) in earth ponds of tidal areas and costal lagoons**

Containment system	Traditional salt pans transformed into aquaculture production units and similar earth ponds in tidal areas
Production system	There shall be adequate renewal of water to ensure the welfare of the species, At least 50% of the dikes must have plant cover Wetland based depuration ponds required
Maximum stocking density	4 kg/m <sup>3</sup>

**Section 5 Organic production of Sturgeon in fresh water:**

Species concerned: *Acipenser* family

Production system	Water flow in each rearing unit shall be sufficient to ensure animal welfare Effluent water to be of equivalent quality to incoming water
Maximum stocking density	30 kg/m <sup>3</sup>

**Section 6 Organic production of fish in inland waters:**

Species concerned: Carp family (*Cyprinidae*) and other associated species in the context of polyculture, including perch, pick, catfish, coregonids, sturgeon.

Production System	<p>In fishponds which shall periodically be fully drained and in lakes. Lakes must be devoted exclusively to organic production, including the growing of crops on dry areas.</p> <p>The fishery capture area must be equipped with a clean water inlet and of a size to provide optimal comfort for the fish. The fish must be stored in clean water after harvest.</p> <p>Organic and mineral fertilisation of the ponds and lakes shall be carried out in compliance with Annex I to Regulation (EC) No 889/2008 with a maximum application of 20 kg Nitrogen/ha.</p> <p>Treatments involving synthetic chemicals for the control of hydrophytes and plant coverage present in production waters are prohibited.</p> <p>Areas of natural vegetation shall be maintained around inland water units as a buffer zone for external land areas not involved in the farming operation in accordance with the rules of organic aquaculture.</p> <p>For grow-out “polyculture” shall be used on condition that the criteria laid down in the present specifications for the other species of lakes fish are duly adhered to.</p>
Farming yield	The total production of species is limited to 1500 kg of fish per hectare per year.

**Section 7 Organic production of penaeid shrimps and freshwater prawns (*Macrobrachium* spp.):**

Establishment of production unit/s	Location to be In sterile clay areas to minimize environmental impact of pond construction. Ponds to be built with the natural pre-existing clay. Mangrove destruction is not permitted.
Conversion time	Six months per pond, corresponding to the normal lifespan of a farmed shrimp.
Broodstock origin	A minimum of half the broodstock shall be domesticated after three years operating. The remainder is to be pathogen free wild broodstock originating from sustainable fisheries. A compulsory screening to be implemented on the first and second generation prior to introducing to the farm.
Eystalk ablation	Is prohibited.
Maximum on farm stocking densities and production limits.	Seeding: maximum 22 post larvae/m <sup>2</sup> Maximum instantaneous biomass: 240 g/m <sup>2</sup>

**Section 8 Molluscs and echinoderms:**

Production systems	Long-lines, rafts, bottom culture, net bags, cages, trays, lantern nets, bouchot poles and other containment systems.  For mussel cultivation on rafts the number of drop-ropes shall not exceed one per square meter of surface area. The maximum drop-rope length shall not exceed 20 metres. Thinning-out of drop-ropes shall not take place during the production cycle, however sub-division of drop ropes shall be permitted without increasing stocking density at the outset.
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**Section 9 Tropical fresh water fish: milkfish (*Chanos chanos*), tilapia (*Oreochromis* spp.), Siamese catfish (*Pangasius* spp.)**

Production systems	Ponds and net cages
Maximum stocking density	Pangasius: 10 kg/m <sup>3</sup> Oreochromis: 20 kg/m <sup>3</sup>

**Section 10 Other aquaculture animal species: none**

## JAS Lists of Substances

The following list from JAS is provided as a reference. Items listed here may not be acceptable under the NOP or other programs. The NOP list has been annotated to reflect the combined limitations of the lists. The full text of the regulations and/or standards of each program are available from OneCert. The web site, , contains links to each of the programs.

## JAS FOR ORGANIC PLANTS [FARMS] . Notif. 1605, MAFF.

### Fertilizers and Soil Improvement Substances

Fertilizers and soil improvement substances	Criteria
Materials derived from plants and plant residues	



Materials derived from fermented, dried or baked excrements	Those derived from livestock and poultry excrements.
By-products of food & textile industries of plant, animal and fish origin	Those derived from natural sources, or natural sources without the use of chemical treatment (except for organic solvent extraction of oil).
Processed animal products from slaughterhouses or fish industries	Those derived from natural sources, or natural sources without the use of chemical treatment.
Materials derived from fermented leftover food	Those prevented from mixing other material than leftover food.
Bark compost	Those derived from natural sources, or natural sources without the use of chemical treatment.
Guano	
Dried algae, including powdered form	
Vegetation ash	Those derived from natural sources, or natural sources without the use of chemical treatment.
Calcium carbonate	Those derived from natural sources, or natural sources without the use of chemical treatment (including calcium magnesium carbonate).
Potassium chloride	Those formed by pulverizing or washing and refining the natural ore or those recovered from the natural brackish water.
Potassium sulfate	Those derived from natural sources, or natural sources without the use of chemical treatment.
Potassium magnesium sulfate	Those formed by washing and refining the natural ore.
Natural rock phosphate	Cadmium should not exceed 90 mg/kg P <sub>2</sub> O <sub>5</sub> .
Magnesium sulfate	Those derived from natural sources, or natural sources without the use of chemical treatment.
Magnesium hydroxide	Those formed by pulverizing the natural ore.
Gypsum (calcium sulfate)	Those derived from natural sources, or natural sources without the use of chemical treatment.
Sulfur	
Calcium oxide (including unslaked lime)	Those derived from natural sources, or natural sources without the use of chemical treatment.
Calcium hydroxide (Slaked lime)	Those derived from Calcium oxide written above.
Trace elements (manganese, boron, iron, copper, zinc, molybdenum and chlorine)	Limited to the case that the crop is unable to grow normally because of shortage of trace elements.
Stone meal	Those derived from natural sources, or natural sources without the use of chemical treatment and not contaminating soil with harmful heavy metal or other substances included in sources.
Charcoal	Those derived from natural sources, or natural sources without the use of chemical treatment.
Peat	Those derived from natural sources, or natural sources without the use of chemical treatment. As for soil improvement substances, peat shall be only used for soil for raising seedling.
Bentonite	Those derived from natural sources, or natural sources without the use of chemical treatment.
Perlite	Those derived from natural sources, or natural sources without the use of chemical treatment.

Zeolite	Those derived from natural sources, or natural sources without the use of chemical treatment.
Vermiculite	Those derived from natural sources, or natural sources without the use of chemical treatment.
Calcined diatomaceous earth	Those derived from natural sources, or natural sources without the use of chemical treatment.
Basic slag	
Slag silicate fertilizer	Those derived from natural sources, or natural sources without the use of chemical treatment.
Fused magnesium phosphate	Those derived from natural sources, or natural sources without the use of chemical treatment. Cadmium should not exceed 90 mg/kg P <sub>2</sub> O <sub>5</sub> .
Sodium chloride	Mined, or produced from seawater or lake water without the use of chemical treatment.
Aluminum calcium phosphate	Cadmium should not exceed 90 mg/kg P <sub>2</sub> O <sub>5</sub> .
Calcium chloride	
Vinegar	
Lactic acid	Those obtained by fermenting plants and limited to be used as pH adjusting agent in soil for raising seedling.
By-products of sugar industries	
Granulating agent and anticaking agent for fertilizer	Those derived from natural sources, or natural sources without the use of chemical treatment. In case of a difficulty to manufacture granulating agent and anticaking agent from these substances, lignin sulfonic acid may be used.
Other fertilizers and soil improvement substances	<p>Those including living organisms;</p> <p>a. applied to soil for providing plants with nutrition or improving the soil property;</p> <p>b. applied to plants for providing with nutrition;</p> <p>c. derived from natural sources, or natural sources without the use of chemical treatment (those produced by burning, calcining, melting, dry distilling, and saponifying the natural resources and those produced from natural resources without using any chemical methods and recombinant DNA technology); and</p> <p>d. shall not be effective as pest and disease control.</p> <p>Those satisfying a. through d. may be used only in the cases where soil fertility cannot be maintained and enhanced by the use of fertilizers and soil improvement substances in this Table.</p>

### Substances for Plant Pest and Disease Control [Notif. 1605, MAFF]

Substances for plant pest and disease control	Criteria
Pyrethrum emulsion	Those extracted from <i>Chrysanthemum cinerariaefolium</i> , and without piperonyl butoxide as synergist.
Canola oil emulsion	
Petroleum oil aerosol	

Petroleum oil emulsion	
Soybean lecithin/petroleum oil	
Starch wettable powder	
Fatty glyceride emulsion	
Metaldehyde (granular formulation)	Limited to the use in insect traps.
Sulfur smoking agent	
Sulfur powdered agent	
Sulfur/copper wettable powder	
Wettable sulfur powder	
Sulfur/soybean lecithin wettable powder	
Lime sulfur powder	
<i>Lentinus edodes</i> mycelium extract liquid	
Sodium hydrogencarbonate wettable powder and sodium bicarbonate	
Sodium hydrogencarbonate/ copper wettable powder	
Copper wettable powder	
Copper powdered agent	
Copper sulfate	Limited to the use for preparing Bordeaux mixture.
Calcium oxide	Limited to the use for preparing Bordeaux mixture.
Biopesticide formulation	
Sex pheromone agent	Limited to the agent containing sex pheromone activity for pest as active ingredient.
Chlorella extract liquid	
Mixed crude medical plant extract liquid	
Wax wettable powder	
Spreader	Limited to agent containing casein and paraffin as active ingredient.
Carbon dioxide fumigant	Limited to the use in storage facilities.
Diatomaceous earth powder	Limited to the use in storage facilities.
Vinegar	

### Substances for Post-Harvest Preparation; [Notif. 1605, MAFF]

Substances for preparation	Criteria
Calcium carbonate	
Calcium hydroxide	
Carbon dioxide	
Nitrogen	
Ethanol	
Casein	

Gelatin	
Active carbon	
Talc	
Bentonite	
Kaolin	
Diatomaceous earth	
Perlite	
DL- tartaric acid	
L- tartaric acid	
DL- potassium hydrogen tartrate	
L- potassium hydrogen tartrate	
DL-sodium tartrate	
L-sodium tartrate	
Citric acid	
Substances for preparation derived from microorganisms	
Enzyme	
Albumen albumin	
Isinglass	
Vegetable fat and oil	
Preparations of bark components	
Hazelnut shell	
Ethylene	Limited to be used for after-ripening banana.

## JAS FOR ORGANIC PROCESSED FOODS. [Notif. 1606, MAFF]

### Food Additives

Food additives	Criteria
Citric acid	Limited to be used as pH adjuster agent or used for processed vegetable products or processed fruit products.
Sodium citrate	Limited to be used for dairy products or used for albumen and sausage as low temperature pasteurization.
DL- malic acid	Limited to be used for processed foods of plant origin.
Lactic acid	Limited to be used for processed vegetable products, for sausage as casing, for dairy products as coagulating agent, and for cheese in salting as pH adjuster.
L- ascorbic acid	Limited to be used for processed foods of plant origin.
Sodium L-ascorbate	Limited to be used for processed meat.
Tannin (Tanmic acid)	Limited to be used for processed foods of plant origin as filter aid.

Food additives	Criteria
Sulfuric acid	Limited to be used for extracted water in producing sugar as pH adjustment agent.
Sodium carbonate and sodium acid carbonate	Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, or for dairy products as neutralizing substance.
Potassium carbonate	Limited to be used for drying processed fruit products, or used for grain processed foods, processed beans products, noodles, bread or confectionary.
Calcium carbonate	In case for livestock products, limited to be used for dairy products (except for coloring) and for cheese as coagulating agent.
Ammonium carbonate and ammonium acid carbonate	Limited to be used for processed foods of plant origin.
Magnesium carbonate	Limited to be used for processed foods of plant origin.
Potassium chloride	Limited to be used for processed vegetable products, fruits processed products, seasonings, or soup.
Calcium chloride	Limited to be used for processed foods of plant origin and cheese as coagulating agent, or used for edible fat and oil, processed vegetable products, processed fruit products, processed beans products, dairy products or processed meat.
Magnesium chloride	Limited to be used for processed foods of plant origin as coagulating agent or used for processed beans products.
Crude sea water magnesium chloride	Limited to be used for processed foods of plant origin as coagulating agent or used for processed beans products.
Sodium hydroxide	Limited to be used for processing sugar as pH adjustment agent or used for grain processed foods.
Potassium hydroxide	Limited to be used for processing sugar as pH adjustment agent.
Calcium hydroxide	Limited to be used for processed foods of plant origin.
DL- tartaric acid	Limited to be used for processed foods of plant origin.
L- tartaric acid	Limited to be used for processed foods of plant origin.
DL-sodium tartrate	Limited to be used for the confectionary.
L-sodium tartrate	Limited to be used for the confectionary.
DL- potassium hydrogen tartrate	Limited to be used for grain processed foods or confectionary.
L- potassium hydrogen tartrate	Limited to be used for grain processed foods or confectionary.
Mono calcium phosphate	Limited to be used for powders as expanding agent.
Calcium sulfate	Limited to be used as coagulating agent or used for the confectionary, the processed products of beans, or bread yeast
Alginic acid	Limited to be used for processed foods of plant origin.
Sodium alginate	Limited to be used for processed foods of plant origin.
Carrageenan	In case for processed foods of animal origin, limited to be used for dairy products.
Carob bean gum (Locust bean gum)	In case used for processed foods of animal origin, limited to be used for dairy products or processed meat.
Guar gum	In case used for processed foods of animal origin, limited to be used for dairy products, canned meat or egg products.
Tragacanth gum	
Arabian gum	Limited to be used for dairy products, edible fat and oil or confectionary.
Xanthan gum	In case used for processed foods of animal origin, limited to be used for dairy products or confectionary.

Food additives	Criteria
Karaya gum	In case used for processed foods of animal origin, limited to be used for dairy products or confectionary.
Casein	Limited to be used for processed foods of plant origin.
Gelatin	Limited to be used for processed foods of plant origin.
Pectin	In case used for processed foods of plant origin, limited to be used for dairy products. Limited to be used for processed foods of plant origin.
Ethanol	In case used for processed foods of animal origin, limited to be used for processed meat. In case used for processed foods of animal origin, limited to be used for dairy products.
Mix tocopherol	In case used for processed foods of animal origin, limited to be used for processed meat. In case used for processed foods of animal origin, limited to be used for processed meat.
Enzyme treated lecithin	Limited to those obtained without any bleaching or organic solvent treatment and in case used for processed foods of animal origin, limited to be used for dairy products, baby foods derived from milk, fat and oil products or mayonnaise. In case used for processed foods of animal origin, limited to be used for processed meat.
Enzymatic degraded lecithin	Limited to those obtained without any bleaching or organic solvent treatment and in case used for processed foods of animal origin, limited to be used for dairy products, baby foods derived from milk, fat and oil products or mayonnaise.
Plant lecithin	Limited to those obtained without any bleaching or organic solvent treatment and in case used for processed foods of animal origin, limited to be used for dairy products, baby foods derived from milk, fat and oil products or mayonnaise.
Egg yolk lecithin	Limited to those obtained without any bleaching or organic solvent treatment and in case used for processed foods of animal origin, limited to be used for dairy products, baby foods derived from milk, fat and oil products or mayonnaise.
Talc	Limited to be used for processed foods of plant origin. Limited to those obtained without any bleaching or organic solvent treatment and in case used for processed foods of animal origin, limited to be used for dairy products, baby foods derived from milk, fat and oil products or mayonnaise.
Bentonite	Limited to be used for processed foods of plant origin.
Kaolin	Limited to be used for processed foods of plant origin.
Diatomaceous earth	Limited to be used for processed foods of plant origin.
Perlite	Limited to be used for processed foods of plant origin.
Silicon dioxide	Limited to be used for processed foods of plant origin as gel or colloidal solution.
Active carbon	Limited to be used for processed foods of plant origin.
Beeswax	Limited to be used for processed foods of plant origin as separating agent.
Carnaiba wax	Limited to be used for processed foods of plant origin as separating agent.
Wood ash	Limited to those derived or produced from natural sources without chemical treatment. Limited to be used for traditional cheese production, alimentary konjac product production or removing harshness of wild vegetable.
Flavorings	Except those chemically synthesized.
Nitrogen	
Oxygen	

Food additives	Criteria
Carbon dioxide	
Enzyme	
Sodium hypochlorite	
Substances which are generally provided for eating or drinking as foods and which are used as food additives	
Hypochlorite solution	Limited to be used for animal intestine as disinfection and used for egg as cleansing.
Boletic acid	Limited to be used for animal intestine as disinfection and used for egg as cleansing.
Fumaric acid	Limited to be used for animal intestine as disinfection and used for egg as cleansing.
Sodium fumarate	Limited to be used for animal intestine as disinfection and used for egg as cleansing.

### Substances Allowed for Pest Control in Processing Facilities. [Notif. 1606, MAFF]

Chemical agents	Criteria
Pyrethrum emulsion	Those without piperonyl butoxide as synergist.
Plant and animal oils	Except for the purpose of pests control for plants.
Gelatin	Except for the purpose of pests control for plants.
Casein	Except for the purpose of pests control for plants.
Fermented products from aspergillus	Except for the purpose of pests control for plants.
Extract from mushroom (shiitake fungus)	Except for the purpose of pests control for plants.
Extract from chlorella	Except for the purpose of pests control for plants.
Chitin	Except for the purpose of pests control and limited to those derived from natural source.
Beewax	Except for the purpose of pests control for plants.
Silicate mineral	Except for the purpose of pests control for plants.
Diatomaceous earth	
Bentonite	Except for the purpose of pests control for plants.
Sodium silicate	Except for the purpose of pests control for plants.
Sodium bicarbonate	
Carbon dioxide	
Potassium soap	Except for the purpose of pests control for plants.
Ethyl alcohol	Except for the purpose of pests control for plants.
Boric acid	Limited to the use of insect trap.
Pheromone agent	Limited to those containing sex pheromone activity of insects as an active ingredient, and except for the purpose of pests control for plants.
Edible plants extract	Limited to those derived from natural sources without the use of chemical treatment and not used for the purpose of pest control.

(Notes) The use of chemical agents shall be in accordance with the prescribed usage.