

**AUGUST 20, 2020**

This document supersedes all previously published versions of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens including those dated March 23, 2007, April 18, 2007, June 5, 2007, October 16, 2007, June 13, 2008, July 10, 2009, January 29, 2010, August 4, 2010, July 22, 2011, January 20, 2012, August 31, 2012, August 2, 2013, January 29, 2016, August 10, 2017, September 28, 2018, April 19,2019 and October 24, 2019.

**Disclaimer:** Please note the definitions presented here are simplified, functional definitions that have been derived from various resources for specific use in this document and may differ from definitions used in relevant federal, state, and local regulations.

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| Glossary |
| **ACCREDITATION** | A rigorous assessment conducted by an independent science-based organization to assure the overall capability and competency of a laboratory and its quality management systems. |
| **ACTIVE COMPOST** | Compost feedstock that is in the process of being rapidly decomposed and is unstable. Active compost is generating temperatures of at least 50 degrees Celsius (122 degrees Fahrenheit) during decomposition; or is releasing carbon dioxide at a rate of at least 15 milligrams per gram of compost per day, or the equivalent of oxygen uptake. |
| **ADEQUATE / ADEQUATELY** | That which is needed to accomplish the intended purpose in keeping with good public health practice. |
| **AERIAL APPLICATION** | Any application administered from above leafy greens where water may come in contact with the edible portion of the crop; may be delivered via aircraft, sprayer, sprinkler, etc. |
| **AEROSOLIZED** | The dispersion or discharge of a substance under pressure that generates a suspension of fine particles in air or other gas. |
| **AGRICULTURAL / COMPOST TEA** | A water extract of biological materials (such as compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural / Compost teas are held for longer than one hour before application and are considered non-synthetic crop treatments for the purposes of this document. |
| **AGRICULTURAL TAILWATER** | Excess run off water which is generated and collected during the process of irrigation. |
| **ANCILLARY EQUIPMENT** | Temporary storage equipment for fertilizers such as third-party storage tanks, pony tanks, etc. |
| **AGRICULTURAL WATER** | Water used in activities covered in these guidelines where water is intended to, or is likely to, contact lettuce/leafy greens or food-contact surfaces, including water used in growing activities (including all irrigation water and water used for preparing crop sprays) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested lettuce/leafy greens and water used for preventing dehydration of lettuce/leafy greens). |
| **AGRICULTURAL WATER SYSTEM** | Each distinct , separate combination of water source, conveyance, storage used to carry water from its primary source to its point of use; includes wells, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, pipes, fittings, and sprinklers. |
| **AGRICULTURAL WATER TREATMENT SYSTEM** | An add-on to an agricultural water system that improves the quality (safety) of the water to make it more acceptable for a specific end- use. The agricultural water treatment system may treat multiple ranches, water sources or batches of water as defined by the water system description. |
| **ANIMAL BY-PRODUCT** | Most parts of an animal that do not include muscle meat including organ meat, nervous tissue, cartilage, bone, blood, and excrement. |
| **ANIMAL HAZARD** | Feeding, skin, feathers, fecal matter or signs of animal presence in an area to be harvested in sufficient number and quantity to suggest to a reasonable person the crop may be contaminated. |
| **ANTIMICROBIAL WATER TREATMENT** | A physical, energetic, or chemical agent, applied alone, in combination, or as a sequential process, to achieve and maintain a defined microbiological water quality standard. |
| **ADENOSINE TRI-PHOSPHATE (ATP)** | A high-energy phosphate molecule required to provide energy for cellular function. |
| **APPLICATION INTERVAL** | Means the time between application of an agricultural input (such as a soil amendment) to a growing area and harvest of leafy greens from the growing area where the agricultural input was applied. |
| **ATP TEST METHODS** | Exploits knowledge of the concentration of ATP as related to viable biomassor metabolic activity; provides an estimate of cleanliness. |
| **BIOFERTILIZERS** | Fertilizer materials/products that contain microorganisms such as bacteria, fungi, and cyanobacteria that shall promote soil biological activities. |
| **BIOSOLIDS** | Solid, semisolid, or liquid residues generated during primary, secondary, or advanced treatment of domestic sanitary sewage through one or more controlled processes. |
| **BLUE VALVE** | Pipes which are used as a closed conveyance system for moving agricultural surface water from water source to irrigation systems or reservoirs for agricultural use. |
| **BREAKPOINT** | The point at which the disinfection demand has been met. |
| **BUILDINGS** | Any fully or partially enclosed building on the farm that is used for storing of food-contact surfaces and packaging materials, including minimal structures that have a roof but no walls. |
| **CLOSED DELIVERY SYSTEM** | A water storage or conveyance system which is fully enclosed and protected such that water is not exposed to the environment from the water source to the point of use. |
| **COLONY FORMING UNITS (CFU)** | Viable microorganisms (bacteria, yeasts & mold) either consisting of single cells or groups of cells, capable of growth under the prescribed conditions (medium, atmosphere, time and temperature) to develop into visible colonies (colony forming units) which are counted. |
| **CONCENTRATED ANIMAL FEEDING OPERATION (CAFO)** | A lot or facility where animals have been, are or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12-month period and crops, vegetation forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility. In addition, there must be more than 1,000 'animal units' (as defined in 40 CFR 122.23) confined at the facility; or more than 300 animal units confined at the facility if either one of the following conditions are met: pollutants are discharged into navigable waters through a man-made ditch, flushing system or other similar man-made device; or pollutants are discharged directly into waters of the United States which originate outside of and pass over, across, or through the facility or otherwise come into direct contact with the animals confined in the operation. |
| **COLIFORMS** | Gram-negative, non-spore-forming, rod-shaped bacteria that ferment lactose to gas. They are frequently used as indicators of process control but exist broadly in nature. |
| **CO-MANAGEMENT** | An approach to conserving soil, water, air, wildlife, and other natural resources while simultaneously minimizing microbiological hazards associated with food production. |
| **COMPOSTING** | Means a process to produce compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated time period (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions. |
| **CROSS-CONTAMINATION** | The transfer of microorganisms, such as bacteria and viruses, from one place to another. |
| **CURING** | The final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions. |
| **DETECTION LIMIIT** | A detection limit is the lowest quantity of a substance or measurable target that can be distinguished from the absence of that substance or measurable target. Methods that estimate bacterial populations in serial dilutions are limited to a minimum level of <2.2 MPN/100 mL and methods that count bacterial colonies growing on media are limited to a minimum level of <1.0 CFU/100 mL. |
| **DIRECT WATER APPLICATION** | Using agricultural water in a manner whereby the water is intended to, or is likely to, contact leafy greens or food-contact surfaces during use of the water. |
| **ENTEROHEMORRHAGIC *E. COLI*** | Shiga toxin-producing *E. coli* clinically associated with bloody diarrhea. |
| ***ESCHERICHIA COLI* (*E. COLI*)** | *Escherichia coli* are common bacteria that live in the lower intestines of animals (including humans) and are generally not harmful. *E. coli* are frequently used as an indicator of fecal contamination but can be found in nature from non-fecal sources. |
| **FECAL COLIFORMS** | Coliform bacteria that grow at elevated temperatures and may or may not be of fecal origin. Useful to monitor effectiveness of composting processes. Also called “thermotolerant coliforms.” |
| **FIELD EQUIPMENT** | Equipment used to: prepare the production area and plant, cultivate, fertilize, treat or any other pre-harvest in-field activities. |
| **FLOODING** | The flowing or overflowing of a field with water outside a grower’s control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field.  |
| **FOOD-CONTACT SURFACE** | Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ‘‘Food-contact surfaces’’ includes food-contact surfaces of equipment and tools used during harvest, packing and holding. |
| **FOOD SAFETY ASSESSMENT** | A standardized procedure that predicts the likelihood of harm resulting from exposure to chemical, microbial and physical agents in the diet.  |
| **FOOD SAFETY PERSONNEL** | Person trained in basic food safety principals and/or working under the auspices of a food safety professional. |
| **FOOD SAFETY PROFESSIONAL** | Person entrusted with management level responsibility for conducting food safety assessments before food reaches consumers; requires documented training in scientific principles and a solid understanding of the principles of food safety as applied to agricultural production; in addition this individual must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration See appendix B for more details. |
| **GEOMETRIC MEAN** | Mathematical def.: the nth root of the product of n numbers, or:Geometric Mean = nth root of (X1)(X2)...(Xn), where X1, X2, etc. represent the individual data points, and n is the total number of data points used in the calculation.Practical def.: the average of the logarithmic values of a data set, converted back to a base 10 number.  |
| **GREEN WASTE** | Any plant material that is separated at the point of generation contains no greater than 1.0 percent of physical contaminants by weight. Green material includes, but is not limited to, yard trimmings ("Yard Trimmings" means any wastes generated from the maintenance or alteration of public, commercial or residential landscapes including, but not limited to, yard clippings, leaves, tree trimmings, prunings, brush, and weeds), untreated wood wastes, natural fiber products, and construction and demolition wood waste. Green material does not include food material, biosolids, mixed solid waste, material processed from commingled collection, wood containing lead-based paint or wood preservative, mixed construction or mixed demolition debris. "Separated At The Point of Generation" includes material separated from the solid waste stream by the generator of that material. It may also include material from a centralized facility as long as that material was kept separate from the waste stream prior to receipt by that facility and the material was not commingled with other materials during handling. 1 |
| **GROUND WATER** | The supply of fresh water found beneath the earth’s surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water. |
| **HARVESTING** | Activities that are traditionally performed on farms for the purpose of removing leafy greens from the field and preparing them for use as food; does not include activities that transform a raw agricultural commodity into a processed food. Examples of harvesting include cutting (or otherwise separating) the edible portion of the leafy greens from the crop plant and removing or trimming parts, cooling, field coring, gathering, hulling, removing stems, trimming of outer leaves of, and washing. |
| **HARVEST EQUIPMENT** | Any kind of equipment which is used during or to assist with the harvesting process including but not limited to harvesting machines, food-contact tables, belts, knives, etc. |
| **HAZARD** | Any biological, physical, or chemical agent that has the potential to cause illness or injury in the absence of its control. |
| **HOBBY FARM** | A noncommercial farming operation or a farm where the primary source of income is not obtained by the sale of its products. |
| **HOLDING** | Storage of leafy greens in warehouses, cold storage, etc. including activities performed incidental to storage (*e.g.,* activities performed for safe or effective leafy green storage) as well as activities performed as a practical necessity for leafy green distribution (such as blending and breaking down pallets) but does not include activities that transform the raw commodity into a processed food. |
| **HYDROPONIC** | The growing of plants in nutrient solutions with or without an inert medium (as soil) to provide mechanical support. |
| **INDICATOR MICROORGANISMS** | An organism that when present suggests the possibility of contamination or under processing. |
| **IRRIGATION WATER TREATMENT** | Any system used to treat agricultural water, so it makes the quality adequate for its intended use |
| **KNOWN OR REASONABLY FORESEEABLE HAZARD** | Known or reasonably foreseeable hazard means a biological, chemical, and physical hazard that is known to be, or has the potential to be, associated with the farm or the food. |
| **LEAFY GREENS** | Iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage (green, red and savoy), kale, arugula and chard. |
| **MANURE** | Animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment. |
| **MICROORGANISMS** | Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance and those subjecting leafy greens to decomposition or that otherwise may cause leafy greens to be adulterated. |
| **MONITOR** | To conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement. |
| **MONTHLY** | Because irrigation schedules and delivery of water is not always in a grower’s control “monthly” for purposes of water sampling means within 35 days of the previous sample.  |
| **MOST PROBABLE NUMBER (MPN)** | Estimated values that are statistical in nature; a method for enumeration of microbes in a sample, particularly when present in small numbers. |
| **MUNICIPAL WATER** | Water that is processed and treated by a municipality to meet USEPA drinking water standards. |
| **NON-SYNTHETIC CROP TREATMENTS** | Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens. Includes agricultural or compost teas for the purposes of these guidelines. |
| **OPEN DELIVERY SYSTEM** | A water storage or conveyance system which is partially or fully open and unprotected such that water is exposed to the environment at any point from the water source to the point of use. |
| **PACKING** | Placing leafy greens into a container other than packaging them and also includes activities performed incidental to packing (*e.g.,* activities performed for the safe or effective packing of leafy greens (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)). |
| **PARTS PER MILLION (PPM)** | Usually describes the concentration of something in water or soil; one particle of a given substance for every 999,999 other particles. |
| **PATHOGEN** | A disease-causing agent such as a virus, parasite, or bacteria. |
| **PEST** | Any objectionable animals or insects, including birds, rodents, flies, and larvae. |
| **POOLED WATER** | An accumulation of standing water; not free-flowing. |
| **POTABLE WATER** | Water that is safe to drink or to use for food preparation without risk of health problems. |
| **PROCESS AUTHORITY** | A regulatory body, person, or organization that has specific responsibility and knowledge regarding a particular process or method; these authorities publish standards, metrics, or guidance for these processes and/or methods. |
| **READY-TO-EAT (RTE) FOOD*****(EXCERPTED FROM USFDA 2005 MODEL FOOD CODE)*** | (1) "Ready-to-eat food" means FOOD that:       (a) Is in a form that is edible without additional preparation to achieve FOOD         safety, as specified under one of the following: 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in 3-401.11(C); or      (d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.(2) "Ready-to-eat food" includes:        (b) Raw fruits and vegetables that are washed as specified under § 3-302.15;        (c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;        (e) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD  safety, and from which rinds, peels, husks, or shells, if naturally present are removed. |
| **RISK MITIGATION** | Actions to reduce the severity/impact of a risk. |
| **SANITARY FACILITY** | Includes both toilet and hand-washing stations. |
| **SANITIZE** | To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.  |
| **SEDIMENT** | Undissolved organic and inorganic material transported or deposited by water. |
| **SHIGA-TOXIN PRODUCING *E. COLI*** | Bacteria found in the environment, foods, and animal and human intestines that produce a potent disease-causing toxin. The serogroup most commonly identified and associated with severe illness and hospitalization in the United States is *E. coli* O157; however, there are over 50 other serogroups that can also cause illness. |
| **SHIPPING UNIT/ EQUIPMENT** | Any cargo area used to transport leafy greens on the farm or from the farm to cooling, packing, or processing facilities. |
| **SOIL AMENDMENT** | Elements added to the soil, such as compost, peat moss, or fertilizer, to improve its capacity to support plant life. |
| **SURFACE WATER** | Water either stored or conveyed on the surface and open to the environment. (e.g. rivers, lakes, streams, reservoirs, etc.)  |
| **SYNTHETIC CROP TREATMENTS (CHEMICAL FERTILIZERS)** | Any crop inputs that may be refined, and/or chemically synthesized and/or transformed through a chemical process (e.g. gypsum, lime, sulfur, potash, ammonium sulfate etc.).  |
| **TOTAL COLIFORMS** | Total coliforms are a group of related bacteria that are (with few exceptions) not harmful to humans. This family of bacteria are found in soil and water. The EPA considers total coliforms to be a useful indicator of the possible presence of other pathogens for drinking water. Total coliforms are used to determine the adequacy of water treatment and the integrity of a water distribution system. |
| **TRANSPORTER** | The entity responsible for transporting product from the field; LGMA guidelines apply only to handlers and cover production through harvesting.  |
| **ULTRAVIOLET INDEX (UV INDEX)** | A measure of the solar ultraviolet intensity at the Earth's surface; indicates the day's exposure to ultraviolet rays. The UV index is measured around noon for a one-hour period and rated on a scale of 0-15. |
| **VALIDATED PROCESS** | A process that has been demonstrated to be effective though a statistically based study, literature, or regulatory guidance. |
| **VALIDATION** | The act of determining whether products or services conform to meet specific requirements. |
| **VERIFICATION** | The act of confirming a product or service meets the requirements for which it was intended. |
| **VISITOR** | Any person (other than personnel) who enters your field/operations with your permission. |
| **WATER DISTRIBUTION SYSTEM** | Distribution systems -- consisting of pipes, pumps, valves, storage tanks, reservoirs, meters, fittings, and other hydraulic appurtenances - to carry water from its primary source to a lettuce and leafy green crop. |
| **WATER SOURCE** | The location from which water originates; water sources can be municipal, well or surface water such as rivers, lakes, or streams. |
| **WATER TREATMENT** | Any process that improves the quality (safety) of the water to make it more acceptable for a specific end-use. |
| **WATER USE** | The method by which water is being used in the agricultural process. |
| **WELL** | An artificial excavation put down by any method for the purposes of withdrawing water from the underground aquifers. A bored, drilled, or driven shaft, or a dug hole whose depth is greater than the largest surface dimension and whose purpose is to reach underground water supplies |

Acronyms and Abbreviations

AOAC AOAC International (formerly the Association of Official Analytical Chemists)

CAFOs Concentrated animal feeding operations

CFU Colony forming units

cGMP Current good manufacturing practices

COA Certificate of analysis

DL Detection limit

FDA Food and Drug Administration

FSMA Food Safety Modernization Act

GAPs Good agricultural practices

GLPs Good laboratory practices

HACCP Hazard analysis critical control point

mL Milliliter

MPN Most probable number

NRCS Natural Resources Conservation Service

PPM Parts per million

SOP Standard operating procedure

SSOPs Sanitation standard operating procedures

STEC Shiga-toxin producing *E. coli*

TMECC Test methods for the examination of composting and compost US EPA

USDA United States Department of Agriculture

US EPA United States Environmental Protection Agency

UV Ultraviolet

WHO World Health Organization

# Issue: Soil Amendments

Soil amendments are commonly but not always incorporated prior to planting into agricultural soils used for lettuce/leafy greens production to add organic and inorganic nutrients to the soil as well as intended to improve the physical, chemical, or biological characteristics of soil. Human pathogens may persist in animal manures for weeks or even months (Fukushima et al. 1999; Gagliardi and Karns 2000). Proper composting of animal manures via thermal treatment will reduce the risk of potential human pathogen survival. However, the persistence of many human pathogens in agricultural soils depends on many factors (soil type, relative humidity, UV index, etc.) and the effects of these factors are under extensive investigation (Jiang et al. 2003; Islam et al. 2004).

Field soil contaminated with human pathogens may provide a means of lettuce and leafy greens contamination. Studies of human pathogens conducted in cultivated field vegetable production models point towards an initial rapid die-off from high pathogen populations, but a characteristic and prolonged low-level survival. Survival is typically less than 8 weeks following incorporation, but pathogens have still been detected at over 12 weeks (Jiang et al. 2002; Islam et al. 2004). Under some test conditions and using highly sensitive detection techniques, pathogen populations have been recovered demonstrating persistence beyond this period. Human pathogens do not persist for long periods of time in high UV index and low relative humidity conditions but may persist for longer periods of time within aged manure or inadequately composted soil amendments. Therefore, establishing suitably conservative pre-plant intervals, appropriate for specific regional and field conditions, is an effective step towards minimizing risk (Suslow et al. 2003).

## The Best Practices Are:

* Do not use biosolids as a soil amendment for production of lettuce or leafy greens.
* DO NOT USE raw manure or soil amendments containing untreated animal by-products, un-composted / incompletely composted animal manure and/or green waste, or non-thermally treated animal manure to fields, which will be used for lettuce and leafy green production.
* See Table 3 and Decision Trees (Figures 7A and 7B) for numerical criteria and guidance for compost and soil amendments used in lettuce and leafy greens production fields. The Technical Basis Document (Appendix B) describes the process used to develop these metrics.
* Implement management plans (e.g., timing of applications, storage location, source and quality, transport, etc.) that significantly reduce the likelihood that soil amendments being used contain human pathogens.
* Verify that the time and temperature process used during the composting process reduces, controls, or eliminates the potential for human pathogens being carried in the composted materials, as applicable to regulatory requirements.
* Maximize the time interval between soil amendment application and time to harvest.
* Implement practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields in close proximity to on-farm stacking of manure.
* Use soil amendment application techniques that control, reduce or eliminate likely contamination of surface agricultural water and/or edible crops being grown in adjacent fields.
* Segregate equipment used for soil amendment handling, preparation, distribution, applications or use effective means of equipment sanitation before subsequent use that effectively reduce the potential for cross-contamination.
* Minimize the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing lettuce/leafy greens or adjacent edible crops.
* Compost suppliers and on-farm composting operations shall have written sampling procedures as well as Standard Operating Procedures to prevent cross-contamination of in-process and finished compost with raw materials through equipment, runoff, or wind, including instructions for handling, conveying and storing in-process or finished compost like it is untreated if it becomes contaminated. Growers shall annually obtain proof that these documents exist.
* Temperature monitoring and turning records for compost applied to leafy greens crops shall be maintained for at least two years. Growers purchasing compost shall annually obtain proof from their supplier that this documentation exists. This applies to composting operations regulated under Title 14 CCR as well as smaller operations that do not fall under Title 14.
* Perform microbiological testing of composted soil amendments prior to application (Table 3.
* Any soil amendment that does not contain animal manure or other animal by-products must have a document (e.g., ingredient list, statement of identity, letter of guaranty, etc.) from the producer or seller confirming that the soil amendment is manure / animal by-product-free. This document must indicate in some way that manure is not an ingredient used in the production of the amendment or provide the ingredients of the product. A statement of identity or product is sufficient for single-chemical amendments (i.e., “calcium carbonate” or “gypsum”). If “inert ingredients” are listed as part of an amendment, then a document from the producer or seller is necessary indicating manure has not been added. The document confirming the soil amendment is manure-/animal by-product-free must be available for verification before harvest begins, and it must be saved and available for inspection for 2 years. A new document is required every two years unless there is a significant process or ingredient change.
* Retain documentation of all processes and test results by lot (at the supplier) and/or Certificates of Analysis available for inspection for a period of at least two years.

## TABLE 3. Soil Amendments

| **Amendment** | **Metric/Rationale** |
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| **Raw manure, untreated animal products/by-products, or not fully composted green waste and/or animal manure-containing soil amendments****(see composted manure process definition below)** | **DO NOT USE OR APPLY** soil amendments that contain un-composted, incompletely composted or non-thermally treated (e.g., heated) animal manure or animal product/by-products to fields which will be used for lettuce and leafy greens production. If these materials have been applied to a field, wait one year prior to producing leafy greens. |
| **Composted soil amendments (containing animal manure or animal products)**\*Composted soil amendments should not be applied after emergence of plants. | **Please see Figure 7A: Decision Tree for Use of Composted Soil Amendments.****Composting Process Validation:**Enclosed or within-vessel composting:Active compost must maintain a minimum of 131oF for 3 daysWindrow composting:Active compost must maintain aerobic conditions for a minimum of 131oF for 15 days or longer, with a minimum of five turnings during this period followed by adequate curing.Aerated static pile composting:Active compost must be covered with 6 to 12 inches of insulating materials and maintain a minimum of 131oF for 3 days followed by adequate curing.**Target Organisms:*** Fecal coliforms
* *Salmonella* spp.
* *E. coli* O157:H7

**Acceptance Criteria:*** Fecal coliforms: < 1,000 MPN / gram of total solids (dry weight basis)
* *Salmonella* spp.: Negative or < DL (< 1 MPN / 30 grams)
* *E. coli* O157:H7: Negative or < DL (< 1 MPN / 30 grams)

**Recommended Test Methods:*** Fecal coliforms: U.S. EPA Method 1680; multiple tube MPN
* *Salmonella* spp.: U.S. EPA Method 1682
* *E. coli* O157:H7: Any laboratory validated method for compost sampling.
* Other U.S. EPA, FDA, AOAC, TMECC or accredited methods may be used as appropriate.

**Sampling Plan:*** A composite sample shall be representative and random and obtained as described in the California state regulations.[[1]](#footnote-2) (See Appendix E)
* Sample may be taken by the supplier if trained by a testing laboratory or state authority
* Laboratory must be certified/accredited for microbial testing by a certification or accreditation body.[[2]](#footnote-3)

**Testing Frequency:*** Each lot before application to production fields. A lot is defined as a unit of production equal to or less than 5,000 cubic yards.

**Application Interval:*** Must be applied > 45 days before harvest.

**Documentation:*** All test results and/or Certificates of Analysis shall be documented annually and available for verification from the grower (the responsible party) for a period of two years. Records of process control monitoring for on-farm produced soil amendments must be reviewed, dated, and signed, within a week after the records are made, by a supervisor or responsible party.

**Rationale:*** The microbial metrics and validated processes are based on allowable levels from California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7), with the addition of testing for *E. coli* O157:H7 as microbe of particular concern. The 45-day application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure must be composted with an approved process and pass testing requirements before an application.
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| **Soil amendments containing animal manure that has been heat-treated or processed by other equivalent methods.** | **Please see Figure 7B: Decision Tree for Use of Heat-Treated Soil Amendments.****Heat Process Validation*** The heat treatment processes applied to the soil amendment-containing animal manure shall be done via a process validated to assure the process is capable of reducing pathogens of human health significance to acceptable levels.

**Target Organism:** * Fecal coliforms
* *Salmonella* spp.
* *E. coli* O157:H7
* *Listeria monocytogenes*

**Acceptance Criteria:*** Fecal coliforms Negative or <DL per gram
* *Salmonella:* Negative or <DL (<1/30 grams)
* *E. coli O*157:H7 Negative of <DL (<1/30 grams)
* *Listeria monocytogenes:* Not detected or < DL (<1 CFU/5 grams)

**Recommended Test Methods:** * Fecal coliforms: U.S. EPA Method 1680;multiple tube MPN
* *Salmonella* spp*.*: U.S. EPA Method 1682
* *E. coli* O157:H7 and *Listeria monocytogenes*: Any laboratory validated method for testing soil amendments
* U.S. EPA, FDA, AOACor other accredited methods may be used as appropriate.

**Sampling Plan:*** Extract at least 12 equivolume samples (identify 12 separate locations from which to collect the sub-sample, in case of bagged product 12 individual bags)
* Sample may be taken by the supplier if trained by a testing laboratory or state authority
* Laboratory must be certified / accredited by annual review of laboratory protocols based on GLPs by a certification or accreditation body.

**Testing Frequency:** * Each lot before application to production fields.
* In lieu of the above analysis requirement, a Certificate of Process Validity issued by a recognized process authority can be substituted. This certificate will attest to the process validity as determined by either a documented (included w/Certificate)) inoculated pack study of the standard process or microbial inactivation calculations of organisms of significant risk (included w/Certificate) as outlined in FDA CFSAN publication “Kinetics of Microbial Inactivation for Alternative Food Processing Technologies. Overarching Principles: Kinetics and Pathogens of Concern for All Technologies”(incorporated for reference in Appendix E - Thermal Process Overview).

**Application Interval:*** + If the heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments, is validated and meets the microbial acceptance criteria outlined above, then no time interval is needed between application and harvest.
	+ If the heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments is not validated but will likely significantly reduce microbial populations of human pathogens and meets microbial acceptance criteria outlined above, then a 45-day interval between application and harvest is required.

**Documentation:*** All test results and/or Certificates of Analysis and/or Certificates of Process Validation shall be documented and available for verification from the producer who is the responsible party for a period of two years. The soil amendment supplier’s operation should be validated by a process authority and a record maintained by the producer for a period of two years.

**Rationale:** * The microbial metrics are based on allowable levels from California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. A more stringent level of fecal coliform was also included to address the much more controlled nature of soil amendments produced in this manner. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure must be composted with an approved process and pass testing requirements before application.
* FDA has established the validity of D-values and Z-values for key pathogens of concern in foods. This method of process validation is currently acceptable to US regulators. Alternatively, results of an inoculated test pack utilizing the specific process is also an acceptable validation of the lethality of the process.
 |
| **Soil Amendments Not Containing Animal Manure** | * Any soil amendment that DOES NOT contain animal manure must have documentation that it is free.
* The documentation must be available for verification before harvest begins.
* If there is documentation that the amendment does not contain manure or animal products then no additional testing is required, and there is no application interval necessary
* Any test results and/or documentation shall be available for verification from the grower who is the responsible party for a period of two years.
 |

## FIGURE 7A. DECISION TREE FOR COMPOSTED SOIL AMENDMENTS (SA)

If raw manure has been directly applied to the field in the past, a one-year waiting period shall be observed before planting any variety of leafy green crops.

**YES**

*and* microbial levels are below action levels.

Keep records of certificate for at least two years.

Observe application time interval of
> 45 days before harvest.

**YES**

**DO NOT USE IN EDIBLE CROP PRODUCTION.**

For previously treated fields, a 1 year waiting period shall be observed before planting any variety of leafy green crops.

**NO**

A certificate of analysis is not available. Samples may be collected by grower or third-party consultant. Microbial testing must be performed by an accredited/ certified laboratory.

**NO**

SA does not contain animal manure.

Have the “manure-free” certification available for verification before harvest.

Keep records of certificate for at least two years (grower is responsible party).

**NO**

**DO NOT USE IN EDIBLE CROP PRODUCTION.**

**YES**

Observe application time interval of
> 45 days before harvest.

**YES**

*but* microbial levels are above action levels.

 **DO NOT USE IN EDIBLE CROP PRODUCTION.**

**DO CURRENT AND/OR PAST APPLICATIONS OF SA CONTAIN RAW OR INCOMPLETELY COMPOSTED ANIMAL MANURE AND/OR GREEN WASTE?**

**Microbial Testing:**

A composite sample shall be representative and random and obtained as described in the California state regulations. Combine samples & submit to a certified/accredited laboratory for testing of the following:

* Fecal coliforms – Action level: < 1,000 MPN per gram
* *Salmonella* spp. – Action level: Negative or < DL (< 1 per 30 grams)
* *E. coli* O157:H7 – Action level: Negative or < DL (< 1 per 30 grams)

**ARE THE MICROBE LEVELS BELOW THE CORRESPONDING ACTION LEVELS?**

**NO**

SA contains only fully composted animal manure. Verify with compost supplier that the active composting process follows the guidelines outlined below. Also adjust compost production process to comply with Title 14 CCR, Chapter 3.1, Article 7 guidelines. The compost supplier should be able to provide a certificate verifying their process.

**DOES THE COMPOST SUPPLIER PROVIDE A CERTIFICATE OF ANALYSIS?**

## FIGURE 7B. DECISION TREE FOR HEAT-TREATED ANIMAL MANURE-CONTAINING SOIL AMENDMENTS (SA)

**DOES SA CONTAIN HEAT-TREATED ANIMAL MANURE THAT
HAS BEEN VALIDATED BY A RECOGNIZED AUTHORITY?**

**YES**

*and* microbial levels are below action levels and/or process validation documentation is available. Keep records of certificate for at least two years. For non-validated process, observe application time interval of > 45 days before harvest. For validated process, no application time interval is required.

**NO**

Verify with supplier (and obtain documentation) that the process is either validated by a recognized authority or meets the following criteria:

* Fecal coliforms Not detected or < DL per gram
* *Salmonella*:Not detected or < DL (< 1 / 30 grams)
* *E. coli* O157:H7: Not detected or < DL (< 1 / 30 grams)
* *L. monocytogenes* – Action level: Not detected or < DL (< 1 CFU / 5 grams)

 **DOES THE SUPPLIER PROVIDE A CERTIFICATE OF ANALYSIS AND/OR CERTIFICATE OF PROCESS VALIDATION?**

**NO**

**DO NOT USE IN EDIBLE CROP PRODUCTION.**

**YES**

* For non-validated process, observe application time interval of > 45 days before harvest
* For validated process, no application time interval is required.

**Microbial Testing:**

Collect 12 equivolume samples (identify 12 separate locations from which to collect the sub-sample, in case of bagged product 12 individual bags). Combine samples & submit to a certified/accredited laboratory for testing of the following:

* Fecal coliforms – Action level: Negative or < DL per gram
* *Salmonella* spp. – Action level: Negative or < DL (< 1 per 30 grams)
* *E. coli* O157:H7 – Action level: Negative or < DL (< 1 per 30 grams)
* *Listeria monocytogenes* – Action level: Not detected or < DL (< 1 CFU per 5 grams)

**Are the microbe levels below the corresponding action levels?**

**YES**

*but* microbial levels are above action levels.

 **DO NOT USE IN EDIBLE CROP PRODUCTION.**

**YES**

Obtain documentation of validated process.

**DOES THE SUPPLIER PROVIDE A CERTIFICATE OF ANALYSIS AND/OR CERTIFICATE OF PROCESS VALIDATION?**

**NO**

A certificate of analysis is not available. Samples may be collected by grower or third-party consultant. Microbial testing must be performed by an accredited/certified laboratory.

# Issue: Non-synthetic Crop Treatments

Non-synthetic crop treatments are commonly applied post-emergence for pest and disease control, greening, and to provide organic and inorganic nutrients to the plant during the growth cycle. For the purposes of this document, they are defined as any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens. Due to the potential for human pathogen contamination, these treatments should only be used under conditions that minimize the risk for crop contamination.

## The Best Practices Are:

* Do not use crop treatments that contain raw manure or other untreated animal products or by-products for lettuce or leafy green produce.
* Do not apply untreated agricultural or compost teas containing added nutrients (e.g., molasses, yeast extract, algal powder, etc.) intended to increase microbial biomass directly to lettuce/leafy greens.
* Water used to make agricultural teas must meet the water quality requirements for post-harvest water use in Table 2G. Liquid crop treatments such as agricultural or compost teas may be used in water distribution systems provided all other requirements herein are met.
* Implement management plans (e.g. timing of applications, storage location, source and quality, transport, etc.) that assure to the greatest degree practicable that the use of crop treatments does not pose a significant pathogen contamination hazard.
* Verify that the time and temperature process used during crop treatment manufacture reduces, controls, or eliminates the potential for human pathogens being carried in the non-synthetic crop treatment materials, as applicable to regulatory requirements.
* Maximize the time interval between the crop treatment application and time to harvest.
* Implement practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields that may be in close proximity to on-farm storage of crop treatments (see Table 7 for additional metrics).
* Use crop treatment application techniques that control, reduce or eliminate the likely contamination of surface water and/or edible crops being grown in adjacent fields.
* Segregate equipment used for crop treatment applications or use effective means of equipment sanitation before subsequent use.
* See Table 4 and Decision Tree (Figure 8) for numerical criteria and guidance for non-synthetic crop treatments used in lettuce and leafy greens production fields. The *Technical Basis Document* (Appendix B) describes the process used to develop these metrics.
* Retain documentation of all test results available for inspection for a period of at least two years.

## TABLE 4. Non-synthetic Crop Treatments

| **Treatment** | **Metric/Rationale** |
| --- | --- |
| ***Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens.***Examples include but are not limited to: * Agricultural / Compost teas,
* Fish emulsions
* Fish meal
* Blood meal
* "Bio-fertilizers" commonly used for pest control, greening, disease control, fertilizing.

Suppliers of these products shall disclose on labels, certificates of analysis, or other companion paperwork whether the product contains any animal manure or products.  | **Non-synthetic crop treatments that contain animal products or animal manure that have not been heat-treated or processed by other equivalent methods shall NOT be directly applied to the edible portions of lettuce and leafy greens.** **Please see Figure 8: Decision Tree for Use of Non-Synthetic Crop Treatments.****Process Validation*** The physical, chemical and/or biological treatment process(es) used to render the crop input safe for application to edible crops must be validated.

**Target Organism:** * Fecal coliform
* *Salmonella* spp.
* *E. coli* O157:H7
* *Listeria monocytogenes*
* Other pathogens appropriate for the source material

**Acceptance Criteria (at point of use):** * Fecal coliform: Negative or <DL (< 1 / 30 grams or mL)
* *Salmonella* spp.:Negative or < DL (< 1 / 30 grams or mL)
* *E. coli* O157:H7: Negative or < DL (< 1 / 30 grams or mL)
* *Listeria monocytogenes*: Not detected or < DL (< 1 CFU / 5 grams or mL)

**Recommended Test Methods:** * Fecal coliform: U.S. EPA Method 1680; Multiple tube MPN
* *Salmonella* spp.: U.S. EPA Method 1682
* *E. coli* O157:H7 and *Listeria monocytogenes*: Any laboratory validated method for the non-synthetic material to be tested.
* Other U.S. EPA, FDA, AOAC, TMECC or accredited methods may be used as appropriate

**Sampling Plan:*** If solid, 12-point sampling plan composite sample, or if liquid, one sample per batch (if liquid-based, then water quality acceptance levels as described in Table 1 must be used).
* Sample may be taken by the supplier if trained by the testing laboratory

**Application Interval:*** + If the physical, chemical and/or biological treatment process used to render the crop input safe for application to edible crops is validated and meets that microbial acceptance criteria outlined above, no time interval is needed between application and harvest.
	+ If the physical, chemical and/or biological treatment process used to render the crop input safe for application to edible crops is not validated yet meets the microbial acceptance criteria outlined above, a 45-day time interval between application and harvest is required.

**Documentation:*** All test results and/or Certificates of Analysis shall be documented and available from the grower for verification for a period of 2 years. The grower is the responsible party for maintaining the appropriate records.

**Rationale:** The microbial metrics and validated processes are based on allowable levels from California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Any non-synthetic crop treatment that contains animal manure must use only fully composted manure in addition to a validated process and pass testing requirements before an application to soils or directly to edible portions of lettuce and leafy greens.  |

## FIGURE 8. DECISION TREE FOR NON-SYNTHETIC CROP TREATMENTS THAT CONTAIN ANIMAL PRODUCTS

**HAS THE NON-SYNTHETIC CROP TREATMENT BEEN PRODUCED USING A VALIDATED PROCESS?**

**YES**

*and* microbial levels are below action levels. Keep records of certificate for at least two years. For non-validated process, observe application time interval of > 45 days before harvest. For validated process, no application time interval is required.

**NO**

**DOES THE SUPPLIER PROVIDE A CERTIFICATE OF ANALYSIS?**

**NO**

A certificate of analysis is not available. Samples may be collected by grower or third-party consultant. Microbial testing must be performed by an accredited/certified laboratory.

**NO**

**DO NOT USE IN EDIBLE CROP PRODUCTION.**

**YES**

* For non-validated process, observe application time interval of > 45 days before harvest
* For validated process, no application time interval is required.

**Microbial Testing:** Divide each lot/pile into a 3 x 4 grid and extract 12 equivolume samples. Combine samples & submit to a certified/accredited laboratory for testing of the following:

* Fecal coliform – Action level: Negative or < DL (< 1 / 30 grams or mL)
* *Salmonella* spp. – Action level: Negative or < DL (< 1 / 30 grams or mL)
* *E. coli* O157:H7 – Action level: Negative or < DL (< 1 / 30 grams or mL)
* *Listeria monocytogenes* – Action level: Not detected or < DL (< 1 CFU per 5 grams)
* Other pathogens based on the source materials.

**ARE THE MICROBE LEVELS BELOW THE CORRESPONDING ACTION LEVELS?**

Divide each lot/pile into a 3 x 4 grid and extract 12 equivolume samples (or one per batch if a liquid amendment). Combine samples & submit to a certified/accredited laboratory for testing of the following:

* Test compost for *Salmonella* spp. – Action level: Negative or < DL (<1 per 30)
* Test compost for *E. coli* O157:H7 – Action level: Negative or < DL (<1 per 30)
* Other pathogens based on the source materials.

**Are the microbe levels below the corresponding action levels?**

**YES**

*but* microbial levels are above action levels.

 **DO NOT USE IN EDIBLE CROP PRODUCTION.**

**YES**

Obtain documentation of validated process.

**DOES THE SUPPLIER PROVIDE A CERTIFICATE OF ANALYSIS?**

**NOTE: MIXTURES OF SOIL AMENDMENT MATERIALS**For soil amendments that contain mixtures of materials, each component must meet the requirements of its respective class of materials. The usages allowed will conform to that of the most stringent class of materials utilized in the mixture.

For example, soil amendments containing animal manure that has been heat-treated or processed by other equivalent methods that are mixed with soil amendments not containing animal manure would require a process certification for the heat-treated (or processed by other equivalent methods) materials and the components from non-animal manure would require documentation attesting to its manure-free status. The resulting mixture could then be applied in accordance with the guidelines associated with the heated treated class of materials (most stringent limits).

1. CCR Title 14 - Chapter 3.1 - Article 7 - **Section 17868.1** <http://www.calrecycle.ca.gov/Laws/Regulations/Title14/ch31a5.htm#article7> [↑](#footnote-ref-2)
2. See FDA’s Guidance for Industry: Submission of laboratory packages by accredited laboratories (<https://www.fda.gov/RegulatoryInformation/Guidances/ucm125434.htm>) for information on the process of accreditation. [↑](#footnote-ref-3)