

COMMODITY SPECIFIC FOOD SAFETY GUIDELINES

FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS



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.

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Disclaimer: Please note the definitions presented here are simplified, functional definitions that have been derived 18 from various resources for specific use in this document and may differ from definitions used in relevant federal,

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19 state, and local regulations. 20

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.
AERATED STATIC PILE	Composting process where active ingredients are covered with an insulating material and air is forced through the product. The product is maintained at a minimum of 131 degrees Fahrenheit for 3 days.
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 inputs for the purposes of this document.
AGRICULTURAL MATERIAL	Agricultural Material means waste material of plant or animal origin, which results directly from the conduct of agriculture, animal husbandry, horticulture, aquaculture, silviculture, vermiculture, viticulture and similar activities undertaken for the production of food or fiber for human or animal consumption or use, which is separated at the point of generation, and which contains no other solid waste. With the exception of grape pomace or material generated during nut or grain hulling, shelling, and processing, agricultural material has not been processed except at

Commented [G1]: #1 New glossary term added because ASP is reviewed in Table 3

Commented [G2]: #2 Crop treatment changed to crop input in alignment with proposed changes to Issue 7 and Issue 8

	its point of generation and has not been processed in a way that alters its essential character as a waste resulting from the production of food or fiber for human or animal consumption or use. Agricultural material includes, but is not limited to, manures, orchard and vineyard prunings, grape pomace, and crop residues.
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 <mark>/PRODUCT</mark>	Most pParts of an animal that do not include muscle meat-including organ meat, nervous tissue, cartilage, bone, blood, feathers, and excrement. This also include worm castings, guano, and other animal-based products and excrements.
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.

Commented [G3]: #3 New glossary term because agricultural material is referenced as a compost feedstock

Commented [G4]: #4 Added the word **product** to the glossary term and updated the glossary definition. Product was added because both by-products and products of animal origin could be used to create soil amendments and crop inputs. The word "not" was removed because the types of by-products and products originally listed (organ meat, nervous tissue, cartilage, bone, blood, etc) are used in the production of soil amendments and crop inputs but there are possible restrictions as related to mortality composting. To address mortality composting a new glossary term is being proposed and a new best practice is also being proposed.

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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 biomass or 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.	
BIOLOGICALS	Biologicals are products that contain beneficial, naturally occurring microorganisms or microbial derivatives as active ingredients.	Commented [G5]: #5
BIORATIONALS	Biorationals are non-synthetic input materials in agriculture that are derived from natural sources such as microorganisms, biochemicals, minerals, organic materials, and plant extracts	New glossary term because this term is referenced in Table 3 section 7b.
	Solid, semisolid, or liquid residues generated during primary, secondary, or advanced treatment of domestic sanitary sewage through one or more controlled processes.	New glossary term because this term is referenced in Table 3 section 7b.
	Class A: Class A biosolids undergo a "Process to Further Reduce Pathogens (PFRP)." Pathogens are reduced to a level similar to the native soil and environment. Class A biosolids products can be used on hand golf courses, and other places where public	
BIOSOLIDS	contact is likely. Class A biosolids products include composted biosolids, lime pasteurized biosolids, and fertilizer pellets. Class A biosolids products are soil	Commonded (07), #7
	amendments, potting soils, and slow-release fertilizers.	Commented [G7]: #7 New wording because new requirements, regarding Class A biosolids, have been proposed to Table 3
	Class B: Class B biosolids undergo a "Process to Significantly Reduce Pathogens (PSRP)." This means that while pathogens are significantly reduced to levels which are often below those found in animal manure, management practices (BMPs) are required at the site where they are used. Class B biosolids are used in bulk as fertilizers in agriculture and forestry and to reclaim	
	barren lands. Site permits are required	Commented [G8]: #8 New wording because new requirements, regarding Class B
BLUE VALVE	Pipes which are used as a closed conveyance system for moving agricultural surface water from water	biosolids, have been proposed to Table 3

	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.
<u>CARBOHYDRATE</u>	Ingredient for soil amendments and crop inputs that could improve growth of bacteria.
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.

Commented [G9]: #9 New glossary term because carbohydrate was added to the area of best practices for soil amendments and crop inputs. A **carbohydrate** is a naturally occurring compound, or a derivative of such a compound, with the general chemical formula C_x(H₂O)_x, made up of molecules of carbon (C), hydrogen (H), and oxygen (O). **Carbohydrates** are the most widespread organic substances and play a vital role in all life. We are adding it to best practices because the use of different carbohydrates, during the application of soil amendments and crop inputs can significantly increase microbial populations including human pathogens if they are present in the soil amendment or crop input.

<u>COMPOST/MATURE COMPOST</u>	Compost is the product manufactured through the controlled aerobic, biological decomposition of biodegradable materials. The product has undergone mesophilic and thermophilic temperatures, which significantly reduces the viability of pathogens and weed seeds and stabilizes the carbon such that it is beneficial to plant growth. Compost is typically used as a soil amendment but may also contribute plant nutrients.	Commented [G10]: #10 New glossary term because a major part of Issue 7 deals with compost but there was not a glossary term for compost
COMPOST FEEDSTOCK	<u>"Feedstock" means any compostable material used in</u> <u>the production of compost or chipped and ground</u> <u>material including, but not limited to, agricultural</u> <u>material, green material, vegetative food material,</u> <u>food material, biosolids, digestate, and mixed material.</u> <u>Feedstocks shall not be considered as either additives</u> <u>or amendments</u> .	Commented [G11]: #11 New glossary term because feedstock is part of a new proposed best practices in issue 7.
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.	
COVERED PRODUCE	Commodities that FDA has identified as typically consumed raw. For our purposes this is for lettuce and leafy greens.	Commented [G12]: #12 New glossary term because Covered Produce is used in the
CROSS-CONTAMINATION	The transfer of microorganisms, such as bacteria and viruses, from one place to another.	best practices section of issue 7
<u>CROP INPUT</u>	Crop inputs are materials that 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.	Commented [G13]: #13
CURING	The secondary phase of the composting process. As the active phase slows down and the temperature drops, mesophilic microorganisms recolonize and continue to breakdown the remaining organic matter. This process is also known as or referred to as the maturation step. The final stage of composting, which is conducted after much of the readily metabolized	New glossary term because a main proposal is to change the term crop treatment to crop input. While both are considered closely related crop input was determined to be the more universally acceptable term over crop treatment.
	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.	Updated for clarification and simplification. Commented [S14]: LGSC would like to see this process better defined, including metrics defining what "adequate curing" would include

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 <i>E. COLI</i> (<u>EHEC)</u>	Shiga toxin-producing <i>E. coli</i> clinically associated with bloody diarrhea.
ESCHERICHIA COLI (E. COLI)	<i>Escherichia coli</i> are common bacteria that live in the lower intestines of animals (including humans) and are generally not harmful. <i>E. coli</i> 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.

Commented [DS16]: #15 These limits are dependent on the set up and are not inherent to the methodologies in general. It is possible to have a detection limit of <1 MPN/100 ml (e.g., the popular Quantitray 2000 setup for Idexx Colilert) and it is possible to count bacterial colonies from more than 100 mL of water (detection limit <1/volume filtered or plated). Minor editorial changes could address this potential source of confusion.

Susan: Based on Don's comment, I deleted the last sentence specifying minimum detection levels since these change based on improved techniques and methods.

FOOD MATERIAL	Food Material means a waste material of plant or animal origin that results from the preparation or processing of food for animal or human consumption and that is separated from the municipal solid waste stream. Food material includes, but is not limited to, food waste from food facilities, food processing establishments, grocery stores, institutional cafeterias (such as prisons, schools and hospitals), and residential food scrap collection. Material that is defined as "food material" is not agricultural material.
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 n th root of the product of n numbers, or: Geometric Mean = n th root of $(X_1)(X_2)(X_n)$, where X_1 , X_2 , 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

Commented [G17]: #16 New glossary term because food material is referenced in other glossary terms, including compost feed stock

	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.
HEAT TREATED SOIL AMENDMENTS AND CROP INPUTS	Soil amendments and crop inputs that have been physically heat treated and dried in accordance to standards issued by the USDA
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 (<i>e.g.</i> , 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.

Commented [G18]: #17 New glossary term because treatment is referenced in Table 3 section 7c

According to the U.S. Food and Drug Administration Food Safety Modernization Act, alternative treatments are recommended for reducing or eliminating human pathogens in raw animal manure. Physical heat treatments can be considered an effective method to inactivate pathogens in animal wastes.

Processed manure products must be treated so that all portions of the product, reach a minimum temperature of either 1500 F (660 C) for at least one hour or 1650 F (740 C), and are dried to a maximum moisture level of 12%; or an equivalent heating and drying process could be used. <u>https://www.ams.usda.gov/sites/default/files/media/5006.pdf</u> - amended Aug 31 2018

HYDROPONIC	The growing of plants in nutrient solutions with or without an inert medium (as soil) to provide mechanical support.
INCOMPLETELY COMPOSTED MANURE /IMMATURE COMPOST	Any form of compost that has not gone through a complete, validated, composting process approved by the LGMA and does not have tests showing that Fecal Coliforms, <i>E. coli</i> , <i>E.coli</i> 0157:H7, Listeria, and Salmonella have been eliminated.
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.
LETTUCE AND 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.
<u>LISTERIA</u>	Any of a genus (<i>Listeria</i>) of small, gram-positive, rod- shaped bacteria that do not form spores and have a tendency to grow in chains and that include one (<i>Listeria monocytogenes</i>) that causes isteriosis.
LOT (Pertaining to Soil Amendments and Crop Inputs other than compost)	Lot means a specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
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.

Commented [G19]: #18 New glossary term because the term incompletely composted manure and immature compost are referenced but there is no glossary term

Commented [G20]: #19 New glossary term because listeria is referenced in the metrics document

Commented [G21]: #20 New glossary term because new requirements for lot information, for products other than compost, are being proposed in Table 3

 $\label{eq:https://www.ifsqn.com/forum/index.php/topic/25737-lot-definition-for-recall-24-hour-bakery-operation/#:~:text=(iv)%20%C2%A9%20%22Batch%20or,the%20same%20cycle%20of%20manufacture.$

MONTHLY MORTALITY COMPOST	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. <u>Mortality Compost is compost created through a</u> process to manage livestock mortalities. The use of crop inputs, made from mortality composting processes, shall follow all local, state and federal regulations.	Commented [G22]: #21 New glossary term because new best practice language for mortality compost is being proposed in Issue 7
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.	
<u>NON-DETECT</u>	Non-detect means not present but consideration should be given to the limit of detection of the approved laboratory method used for biological or chemical analysis.	Commented [G23]: #22
NON-SYNTHETIC <u>SOIL AMENDMENTS AND</u> CROP INPUTS OF ANIMAL ORIGINTREATMENTS	Any <u>soil amendment and/or</u> 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.	New glossary term because non-detect is referenced in Table 3 Commented [G24]: #23 Glossary term updated to stay in harmony with proposed changes to issue 7 and 8
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 (<i>e.g.</i> , 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.	
POST-CONSUMER WASTE	Post-consumer waste is a waste type produced by the end consumer of a material stream. Generally, this is	

	POTABLE WATER PRE-CONSUMER WASTE PROCESS AUTHORITY	discarded materials after something has been used.Post-consumer waste can include items such aspackaging and unconsumed food.Water that is safe to drink or to use for foodpreparation without risk of health problems.A food item that was produced for consumption butthat was never purchased, consumed or used.A regulatory body, person, or organization that hasspecific responsibility and knowledge regarding aparticular process or method; these authorities publish	Commented [G25]: #24 New glossary term because post-consumer waste is referenced as new proposed best practices in Issue 7 Commented [G26]: #25 New glossary term because pre-consumer waste is referenced in the agricultural/compost tea glossary term.
	READY-TO-EAT (RTE) FOOD (EXCERPTED FROM USFDA 2005 MODEL FOOD CODE)	 standards, metrics, or guidance for these processes and/or methods. (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. 	
	RECONDITIONED/RE-PROCESSED	Finished product that is added to a new production lot and goes through the entire validated production process. The old, finished product is now part of the new lot and testing of the new lot must follow all current requirements for LGMA testing before the product is used.	Commented [G27]: #26 New glossary term because reconditioning and reprocessing are referenced in new processor arguirements in Table 2
	RISK MITIGATION	Actions to reduce the severity/impact of a risk. <u>Salmonella</u> is a Gram-negative facultative rod-shaped bacterium in the same proteobacterial family as <u>Escherichia coli</u> , the family Enterobacteriaceae, trivially known as "enteric" bacteria. Salmonellae live in the intestinal tracts of warm, and cold blooded, animals. In humans, Salmonella is the cause of two diseases called salmonellosis: enteric fever (typhoid), resulting from bacterial invasion of the bloodstream, and acute gastroenteritis, resulting from a foodborne infection/intoxication.	are referenced in new proposed requirements in Table 3 Commented [G28]: #27 New glossary term because salmonella is referenced in multiple areas of the metrics and in Issue 7

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 <i>E. COLI</i>	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 <i>E. coli</i> 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 <u>SOIL AMENDMENTS AND</u> CROP <u>INPUTSTREATMENTS</u> (CHEMICAL FERTILIZERS)	Any <u>soil amendments and/or</u> 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			

Commented [G29]: #28 Glossary term updated to assure harmonization with the other proposed changes to the metrics.

	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.
VEGETATIVE MATERIAL	<u>Vegetative material</u> means food material resulting from the production or processing of food for animal or human consumption, but is no longer intended for such consumption, that is derived solely from plants and is separated from the municipal solid waste stream.
VERIFICATION	The act of confirming a product or service meets the requirements for which it was intended.
VESSEL COMPOST PROCESS	Enclosed composting process where ingredients are maintained at a minimum of 131 degrees Fahrenheit for at least 3 days.
VISITOR Any person (other than personnel) who enter 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

Commented [G30]: #29 New glossary term because the term is in other glossary terms and is also referenced in new proposed language in Table 3

Commented [G31]: #30 New glossary term because vessel compost process has been in the metrics, in Issue 7, but there is no glossary term for the activity.

	S 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	
ISO	International Organization for Standardization	Commented [G32]: #31 Acronym added because ISO is being proposed to be add
mL	Milliliter	the general requirements section under the proposed
MPN	Most probable number	laboratory requirements.
NRCS	Natural Resources Conservation Service	
PPM	Parts per million	
SOP	Standard operating procedure	
SSOPs	Sanitation standard operating procedures	
STEC	Shiga-toxin producing <i>E. coli</i>	
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	
UVT	Ultraviolet transmittance	
WHO	World Health Organization	

24 LIST OF APPENDICES

Appendix A: Agricultural Water System Assessment

<u>Appendix B</u>: Technical Basis Document

Appendix C: Crop Sampling Protocol

Appendix D: Kinetics of Microbial Inactivation for Alternative Food Processing Technologies

Appendix E: Environmental Health Standards for Composting Operations (California Code of Regulations)

Appendix F: Considerations for Assessing Environmental Weather Conditions

Appendix G: Consideration for Growing Leafy Greens near CAFOs

Appendix R: Root Cause Analysis

Appendix X: Guidance for Soil Collection for Cadmium Analysis

Appendix Y: Guidance for Developing Best Management Practices to Reduce Cadmium Uptake by Spinach

Appendix Z: CA Resource Agency Contacts

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LETTUCE/LEAFY GREENS COMMODITY SPECIFIC GUIDANCE PRODUCTION & HARVEST UNIT OPERATIONS

27 **1. PURPOSE**

The issues identified in this document are based on the core elements of Good Agricultural Practices. The specific recommendations contained herein are intended for lettuce and leafy greens only. If these specific recommendations are effectively implemented this would constitute the best practices for a GAP program for the production and harvest unit operations of lettuce and leafy greens.

2. GENERAL REQUIREMENTS

In addition to the area-specific requirements discussed in latter sections, there are several general requirements
 that are part of an effective best practices program. These requirements are outlined below.

35 The Best Practices Are:

- A written Leafy Greens Compliance Plan shall be prepared that specifically addresses the Best Practices listed in this document. This plan shall address at least for the following areas: water, soil amendments, environmental factors, work practices, and field sanitation.
- Handlers shall have an up-to-date growers list with contact and location information on file.
- The handler shall comply with the requirements of The Public Health Security and Bioterrorism Preparedness
 and Response Act of 2002 (farms are exempt from the Act) including those requirements for recordkeeping
 (traceability) and registration...
- Designate an individual responsible for their operation's food safety program. Twenty-four-hour contact
 information shall be available for this individual in case of food safety emergencies.
- Pre-harvest testing is required when risk assessments deem it is necessary (i.e., in proximity to animal
 operations per guidance.).
- Laboratories used for any analytical parameters (microbial, chemical, etc.) required in the metrics must be
 certified and/or accredited for the analytical methods being reported and the matrices being analyzed (water,
 soil, soil amendment, product, etc.). Certification and accreditation must be recognized by State, Federal, or
 internationally bodies (ISO).
- 51 o Note: It may be appropriate for proprietary or modified methods to be used but there must be assurances
 52 that the results are consistent with accredited methodologies.
- Perform root cause analysis after any incident that has a high likelihood of causing a foodborne illness or injury
 (i.e., high risk adjacent land concern, positive pre-harvest pathogen test, water system non-compliance, high
- 55 risk health or hygiene incident, soil amendment concern, traceability failure, field fecal contamination, etc.).
- 56

Commented [SS33]: POLL QUESTION: Are you currently performing pre-harvest testing?

Commented [G34]: #32

Added in response to the CA LGMA Advisory Board's recommendation to add a risk based pre-harvest testing requirement to the LGMA metrics.

Commented [G35]: #33

This lab requirement is being proposed to be added to the General Requirements section as a blanket requirement for all labs being used for LGMA required testing and analysis. See FDA's Guidance for Industry: Submission of laboratory packages by accredited laboratories (https://www.fda.gov/RegulatoryInformation/Guidances/ucm1

25434.htm) for information on the process of accreditation.

Commented [SS36]: POLL QUESTION: What do you need to perform Root Cause Analysis?

Commented [G37]: #34

Added in response to the CA LGMA Advisory Board's recommendation to add a requirement to conduct Root Cause Analysis when a high risk incident has occurred.

3. ISSUE: SOIL AMENDMENTS AND CROP INPUTS

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.

- 66 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,
- 70 pathogen populations have been recovered demonstrating persistence beyond this period. Human pathogens do 71 not persist for long periods of time in high UV index and low relative humidity conditions but may persist for
- Interpretative infinitive 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).
- 75 Non-synthetic Crop treatments inputs are commonly applied post-emergence for pest and disease control,
- 76 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, these treatments should only be used under conditions that minimize the risk for crop
 contamination. One type of crop input is known as Biological Products. Biological Products are used to manage
- plant diseases; enhance nutrient uptake and improve crop growth; manage insects and related pests; and manage
- 82 weeds. For the purposes of this document, soil amendment and crop inputs will be categorized as follows:
- 83 7a Biological of animal origin
- <u>7b Biological of non-animal origin (fungal/bacterial extracts, green/plant waste, plant extracts, vegetative</u>
 material, algae, yeast extract, pre/post-consumer waste not containing products of animal origin, etc)
- 86 <u>7c Processed products</u>

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- 87 <u>7d Synthetic and inorganic</u>
- 88 **<u>7e Mixed components** (blending categories 7a, 7b, 7c, and 7d)</u>

89 The Best Practices Soil Amendment Are:

- 90 When using soil amendments, a risk assessment shall be performed considering the supplier, delivery, storage,
 91 and application of the product. Additionally, weather and climactic conditions (wind, rain, and water runoff),
- 92 animal intrusion, visitor/ employee movements, vehicle traffic, or other applicable hazards should be part of
- 93 the risk assessment.
- 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 areas.
- Do not use biosolids as a soil amendment for production of lettuce and leafy greens or as an ingredient for soil
 amendments and crop inputs used for lettuce and leafy greens production.

Commented [SS38]: CHAT QUESTION Do you have any comments about the inclusion of both soil amendments and crop inputs?

Commented [GK39]: #35 Preamble changed for clarification regarding crop input use and for new risk categorization.

Original language from Issue 8 - Non-synthetic crop treatments are included here.

Commented [GK40]: #36

The committee work has expanded the categories to include a larger variety of amendments and inputs. The most significant update is regarding section 7b as a majority of the section is new proposed language.

Commented [SS41]: POLL QUESTION (END OF SECTION, after comment #54)

•Overall, do the proposed revisions to current best practices for the use of soil amendments both enhance food safety and are feasible to implement?

•If any, what is a top concern associated with these proposed revisions? And why? CHAT QUESTION

Commented [G42]: #37

New proposed language taking into consideration the possible risks associated with the entire product life cycle from creation until application of soil amendments.

Commented [G43]: #38

Added "or as an ingredient" per discussions with M Jay Russell from WCFS. Review of compost production practices showed that biosolids may be used as a feedstock.

103	use materials that are not verified to be safe for food production (i.e., green waste from processing facilities).
104	 Post-consumer waste materials shall be used according to all local, state, and federal regulations.
105 106 107 108 109	Implement management plans (e.g., timing of applications, storage location, source and quality, transport, etc.) a SOP regarding storage and application controls that significantly reduce the likelihood that soil amendments being used may contain human pathogens. Consider timing of applications, application processes, surplus/unconsumed inventory, length of storage, storage location, source and quality, transport, weather, or any other potential controls that may impact the safety of the soil amendments being used.
110 111 112	If soil amendments may have become contaminated, the product must be segregated and prevented from being used until it is determined to be safe for food production. If a product can be re-conditioned there must be verification that it is free of pathogens such as a COA.
113 114 115	 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. Consider the moisture content of the finished product.
116 117 118	 Maximize the time interval between soil amendment application and time to harvest. When applying materials that may contact the edible portion of the crop consider the type of product being grown, the stage of the product growth, and the application process.
119	←
120 121 122 123	 Implement practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields in close proximity to on-farm stacking of manure. <u>Consider potential Minimize the proximity of</u> wind dispersed and aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing lettuce/leafy greens or adjacent edible crops.
124 125	 Use soil amendment application techniques that control, reduce or eliminate likely contamination of surface agricultural water and/or edible crops-portion of covered produce being grown in adjacent fields.
126 127 128	• Do not stockpile compost and/or other soil amendments near open system irrigation sources, including on- farm sources and those that serve multiple users, unless best management practices have been employed to prevent cross-contamination of common water sources (e.g. run-off protection such as berms, covering

• The use of soil amendments, made from mortality composting processes, shall follow all local, state, and

When creating compost and/or soil amendments, use feedstocks and ingredients that will minimize the

amount of biological, physical, and chemical food safety hazards that will be introduced to the process. Do not

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federal regulations

compost)

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Perform a risk assessment based on the type and stage of crop prior to stockpiling compost and/or other soil
 amendments adjacent to covered produce/lettuce and leafy greens production areas.

Segregate equipment, or use dedicated 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. Efforts should be made to assure proper flow of
 equipment to maintain segregation of raw and finished product. Site maps should be used to ensure that the
 necessary traffic flow is in place.

<u>Compost Soil amendment</u> suppliers and on-farm composting operations shall have written sampling
 procedures.

Commented [G44]: #39

New proposed language per LGMA subcommittee discussions about mortality composted products.

Commented [G45]: #40

New proposed language reflects that soil amendment risk is not only associated with biological contaminants. Physical and chemical risks should also be considered when approving feedstocks.

Commented [G46]: #41

New proposed language reflecting new CA regulations minimizing waste materials from entering landfills.

Commented [G47]: #42

Additional language reflects best practices from published composting resources (i.e. Best Management Practices Guidelines for Pathogen Control at Organic Material Processing Facilities Washington Organic Recycling Council, Original Language 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.

Commented [G48]: #43

New proposed language reflecting corrective action best practices if a soil amendment is potentially contaminated or is contaminated.

Commented [G49]: #44

Proposed language regarding moisture. The moisture level of compost can impact the safety of the product.

Commented [G50]: #45

There is evidence that contamination of romaine is more prevalent at the bottom 1/3 of the head due to contamination getting into the pre-cupped romaine. Applications of any products that might contact the edible portion of the plant should consider this possible risk.

Commented [S51]: LGSC supports the elimination of storage on/application to immediately adjacent fields until after the final leafy greens harvest

Commented [DS52]: Content, add "the application field and any adjacent fields"? Seems unlikely that would ever be a practice (application of untreated while leafy greens are growing) but it would be parallel with Subpart F (reduce likelihood of contact during application).

Sonia:

Add "on the application or adjacent fields"

Commented [G53]: #46 Added the term covered produce to align with FSMA language.

Commented [G54]: #47

New proposed language to address practices to reduce contamination of water sources.

Commented [G55]: #48

New proposed language to address potential cross contamination of leafy greens and leafy greens production areas when soil amendments are stockpiled

Commented [G56]: #49

Added the term dedicated equipment and added a sentence regarding soil amendment production process flow to prevent

	139 140 141 142 143	 <u>Soil amendment suppliers shall have</u> Standard Operating Procedures to prevent cross-contamination of in- process and finished <u>soil amendments</u> with raw materials. <u>SOPs should consider through</u> equipment, runoff, and wind. <u>Additionally, the SOPs shall</u> include instructions for the handling, conveyance and storage of in- process and finished <u>soil amendments that have become contaminated</u>. Growers shall annually obtain proof that these documents exist. 	
	144 145 146	 Temperature monitoring and turning records for compost applied to <u>lettuce and</u> leafy greens crops shall be maintained for at least two years. Growers purchasing compost shall annually obtain proof from their supplie that this documentation exists. This applies to composting operations regulated under Title 14 CCR as well as 	
	147 148 149 150	 smaller operations that do not fall under Title 14. When insulation materials are used during aerated static pile compost production, the insulation materials must be used in a way to minimize cross contamination. All air equipment should be maintained to minimize recontamination of the compost. 	
1	151	 Perform microbiological testing of composted soil amendments prior to application (Table 3). 	

- 152 Any soil amendment that does not contain animal manure or other animal by-products must have a document (e.g., COAs, ingredient list, statement of identity, letter of guaranty, etc.) from the producer or seller 153 confirming that the soil amendment is manure / animal by-product-free. This document must indicate in some 154
- 155 way that manure is not an ingredient used in the production of the amendment or provide the ingredients of the product. 156
 - o A statement of identity is sufficient for single-chemical amendments (i.e., "calcium carbonate" or "gypsum").
 - o_____If "inert ingredients" are listed as part of an amendment, then a document from the producer or seller is necessary indicating manure, products of animal origin, or other non-synthetic products (of animal or non-animal origin) has have not been added.
 - The document confirming the soil amendment is manure/animal by-product/ and non-syntheticfree must be available for verification before harvest beginsand 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.
 - Assure product is handled properly from production to delivery.
- <u>Retain</u> Documentation of all <u>ingredients</u>, processes and test results by lot (at the supplier) and/or Certificates 167 of Analysis is required to be available for inspection for a period of at least every two years. If there is a 168 169 significant process or ingredient change the results must be updated.
- See Table 3 and Decision Trees (Figures 7A and 7B) for numerical criteria and guidance for compost and soil 170 171 amendments used in lettuce and leafy greens production fields. The Technical Basis Document (Appendix B)
- describes the process used to develop these metrics. 172

The Best Practices Crop Inputs Are: 173

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- 174 When using crop inputs, a risk assessment shall be performed considering the supplier, delivery, storage, and 175 application of the product.
- 176 Do not use crop inputs that contain raw manure or other untreated animal products or by-products for lettuce 177 or leafy green produce.

Commented [DS57]: Editorial, since the nonBSAAO bullet specifies the form the relevant documentation may take consider doing the same here and including the Produce Safety Rule term "certificate of conformance" per 112.60(b)(1). The focus on COA doesn't address handling after treatment.

Sonia: Consider the use the term "certificate of conformance" moving forward

Commented [G58]: #50 Language was simplified

Commented [G59]: #51 New proposed language to assure insulation and air equipment are managed to prevent re-contamination of finished compost.

Commented [GK60]: #52

Adding additional language for clarification. The original language was broken up to allow for clarity and simplification. Additional language to assure product is handled properly from production to delivery was added.

Commented [G61]: #53

Language was amended to include ingredients and to update information if a significant process or ingredient change occurs.

Commented [S62]: #54 This bullet was deleted by the CALGMA subcommittee.

Commented [SS63]: RUN POLL

Commented [SS64]: POLL QUESTION (END OF SECTION, after comment #71) •Overall, do proposed best practices for the use of crop inputs enhance food safety and are feasible to implement?

If any, what is a top concern associated with these proposed revisions? And why? CHAT QUESTION

Commented [GK65]: #55 Copied from soil amendment best practices

Commented [G66]: #56 Similar to soil amendment language for consistency.

178	•	When creating crop inputs, use ingredients that will minimize the amount of biological, physical, and chemical		
179		food safety hazards that will be introduced to the process.		Commen
180	•	Post-consumer waste materials shall be used according to all local, state, and federal regulations		New prop practices.
181 182	•	_Do not apply untreated agricultural or compost teas containing added nutrients (e.g., <u>carbohydrates</u> , molasses, yeast extract, algal powder, etc.) intended to increase microbial biomass directly to lettuce and		Commen New prop practices.
183		leafy greens <u>.</u>		Commen New langu
184 185	•	All crop inputs, in their final composition/end product, that will have contact with the edible portion of the crop need to have proof that they are free of pathogens of concern.		Commen The word
186 187	•	Crop inputs that are biologically active must have assurances that they are pathogen free. A COA shall be available showing the input is free of pathogens of concerner.		adding ca growth of crop input
188 189	•	The use of crop inputs, made from mortality composting processes, shall follow all local, state and federal regulations.		Commen New prop inputs are
190	•	Water used to make agricultural teas must <u>minimally</u> meet <u>Type A</u> water quality requirements for post-	$\setminus \setminus$	requireme
191 192		harvest water use in Table 26. Liquid crop treatmentsinputs such as agricultural or compost teas may be used in water distribution systems provided all other requirements herein are met.		Commen New prop inputs, that
193	•	Implement a SOP that establishes management controls that significantly reduce the likelihood that crop	$\langle \rangle$	concern p
194 195		inputs being used may contain human pathogens. Controls could include the timing of applications, application processes, surplus/unconsumed inventory, length of storage, storage location, source and quality,		Commen New prop
196		transport, weather, and any other control that could reduce the likelihood of contamination.		practice la
197	•	If a crop input may have become contaminated, the product must be segregated and prevented from being		Proposed classificat
198 199		used until it is determined to be safe for food production. If a product can be re-conditioned there must be verification that it is free of pathogens such as a COA.		
200	•	Verify that the time and temperature during crop input manufacture reduces, controls, or eliminates the		Commen New prop
200	•	potential for human pathogens being carried in the non-synthetic crop input materials as applicable to		is similar t
202		regulatory requirements.		New prop practices.
203	•	Maximize the time interval between crop input application and time to harvest. When applying materials that		proceess
204		may contact the edible portion of the crop consider the type of product being grown, the stage of the product		
205		growth, and the application process.		Commen This is ne
206 207	•	_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 <u>inputs treatments</u> (see Table 7 for additional metrics).		contamina the head romaine.
208 209	•	_Use crop treatment_input application techniques that control, reduce or eliminate the likely contamination of surface water and/or edible crops being grown in adjacent fields.		
210	•	When mixing multiple partial lots of materials, ensure there is lot integrity.		Commen
211	•	Do not mix and use materials that are not verified to be safe for food production or do not have a labeled use.		New prop capture lo
212		(i.e., the production process has verified pathogen reduction, pathogens are tested, heavy metal analysis,		are mixed
213		etc.)		Commen New prop
214 215	•	Segregate equipment, or use dedicated equipment, for crop input applications or use effective means of equipment sanitation before subsequent use. <u>All sanitation events must be documented.</u>		uncharact
216	•	Retain all_documentation_of all test results available for inspection for a period of at least two years		Commen New prop retained f

ommented [G67]: #57 ew proposed language similar to soil amendment best actices. ommented [G68]: #58

New proposed language similar to soil amendment best practices.

Commented [G69]: #59 New language (similar to soil amendments)

Commented [G70]: #60

The word carbohydrate was added based on evidence that adding carbohydrate food sources can cause significant growth of bacteria, including pathogens of concern, in the rop input.

mmented [G71]: #61

lew proposed language asking for assurance that all crop nputs are free of pathogens of concern per Table 3 equirements.

ommented [G72]: #62

we proposed language asking for assurance that all crop buts, that are biologically active, are free of pathogens of ncern per Table 3 requirements.

ommented [G73]: #63 ew proposed language similar to soil amendment best ractice language

Commented [G74]: #64 Proposed language to harmonize language regarding water lassification. Current language uses Type A water quality.

Commented [GK75]: #65 New proposed language. A majority of this proposed language is similar to soil amendment best practices.

Commented [G76]: #66 New proposed language that is similar to soil amendment best practices.

Commented [G77]: #67 This is new proposed language. There is evidence that contamination of romaine is more prevalent at the bottom of the head due to contamination getting into the pre-cupped romaine.

Commented [G78]: #68 New proposed language to ensure there is a mechanism to capture lot information when partial amounts of different lots are mixed.

Commented [G79]: #69 New proposed language to reduce the potential of uncharacterized crop inputs from being used.

Commented [G80]: #70 New proposed language requires all documentation to be retained for at least 2 years - not just test results.

- •—See Table 3 and Decision Trees (Figures) for numerical criteria and guidance for soil amendments and crop
- inputs used in lettuce and leafy greens production fields The Technical Basis Document (Appendix B)
 describes the process used to develop these metrics.

Commented [G81]: #71 New proposed language to align with soil amendment best practices.

Commented [SS82]: RUN POLL

TABLE 3. Soil Amendments and Crop Inputs

220

Amendment	Metric/Rationale		
Raw manure, untreated	DO NOT USE OR APPLY soil amendments, or crop inputs, that contain un-composted,		
animal products/by-	mal products/by- incompletely composted or non-thermally treated (e.g., heated) animal manure		
products, or not fully	and/or animal product/by-products, or biosolids* to fields which will be used for	/	
composted green	lettuce and leafy greens production or to lettuce and leafy greens crops. If these		
waste, biosolids, and/or	materials have been applied to a field, wait one year prior to producing lettuce and		
animal manure-	leafy greens.		
containing soil	, ,		
amendments and crop	Applications include, but are not limited to, the intentional use of an untreated soil		
nputs	amendment or crop input, the use of animals for field management of weeds and crop		
see composted manure	residue, the unintentional application due to drift from an adjacent area.		
orocess definition			
below)	If applied to the crop the crop cannot be harvested for the fresh market.		
	*For Class A Biosolids use the one calendar year guidance. For Class B Biosolids the		
	field cannot be replanted for a minimum of 38 months from discontinued use of Class		
	B Biosolids. Soil testing must also be conducted demonstrating the soil meets the		
	standard for compost.		
		1	
Fime interval and	 Minimum (1) one calendar year after application of the product. 		
mitigations before			
planting can commence			
following the application ofperiods (or unusual amounts) of rain or moisture, and increased humidity can cause pathogens of concern to persist for longer periods of time or to re-grow after being			
unallowed materials.	shown to be nondetectable. Also, the type, and amount of the soil amendment and		
crop input can also impact the persistence of pathogens which may char			
	minimum time required before replanting.		
	When deemed acceptable, and guided through a proper risk assessment, appropriate		
	soil testing can be used to shorten this period to no less than 270 days prior to	~	
	planting		
	• Suitable representative samples shall be collected for the entire area suspected to	7	
	have been exposed to the applied products. This testing must be performed in a		
	manner that accurately represents the production field.		
	 Results must indicate that soil levels of microorganisms meet the recommended 		
	standards for processed compost.		
	 For additional guidance on appropriate soil sampling techniques, use the Soil 		
	Screening Guidance: Technical Background Document (US EPA 1996).		
	Specifically, Part 4 provides guidance for site investigations. Reputable third-		
	party environmental consultants or lanoratories provide sampling services		
	party environmental consultants or laboratories provide sampling services		
	 consistent with this guidance. Appropriate mitigation and mitigation strategies are included in the text 	-	

Commented [DS83]: Clarification, same as narrative, what the risk-based issue with green waste? lot addressed in rationale

Definition of green waste does not seem to include anything hat generally would be associated with an elevated risk

Sonia: Addressed by Greg below (rationale may be good to add to the LGMA Technical Basis document)

Commented [G84]: Dr. Paula Rivendeira (previously of the J of Arizona) did a fly study that showed post-processed green waste (from salad production) was positive for athogens. Additionally, testimony from compost producers, during our committee meetings, suggested that green waste had a high likelihood of harboring fecal contamination from omestic pets and other animals.

Commented [S85]: LGSC supports the elimination of torage on/application to immediately adjacent fields until fter the final leafy greens harvest.

commented [G86]: #72 lew proposed language to clarify when the prohibition pplies.

commented [G87]: #73

lew proposed language based on federal restrictions. Commented [SS88]: POLL QUESTION (after comment #

- Do time intervals enhance both food safety and are feasible?
 - A 1 calendar year after application does
 - A1 calendar year after application doesn't
 - With soil testing 270 days prior planting does
 With soil testing 270 days prior planting doesn't

commented [G89]: #74 lew proposed language to clarify the requirement.

commented [G90]: #75

Bardsley CA, Weller DL, Ingram DT, Chen Y, Oryang D, Rideout SL and Strawn LK (2021) Strain, Soil-Type, Irrigation Regimen, and Poultry Litter Influence Salmonella Survival and Die-off in Agricultural Soils. Front. Microbiol. 12:590303. oi: 10.3389/fmicb.2021.590303

Commented [SS91]: POLL QUESTION (after comment

- Do time intervals enhance both food safety and are feasible?
 - $_{\odot}$ A 1 calendar year after application does
 - A1 calendar year after application doesn't
 With soil testing 270 days prior planting does
 - With soil testing 270 days prior planting doesn't

commented [G92]: #76

270 days based on original FDA language regarding use of intreated BSAAO and discussions with leading researchers -. Ingram FDA, M. Russell WCFS

commented [G93]: #77 This information is not new language but was taken from the flood mitigation section.

Amendment	Metric/Rationale		omment ombining	
7a Composted	Please see Figure 7A: Decision Tree for Use of Composted Biological Soil			
Soil Amendments and	Amendments and Crop inputs of Animal Origin.			
Crop Inputs (containing	Composting Process Validation:		ommen	
animal manure or	Enclosed or within-vessel composting:		ecessary he sectio	
animal <mark>products</mark>)	Active compost must maintain a minimum of 131°F for <mark>3 days <u>or longer</u>.</mark>			
*Composted soil	Windrow composting:		onia: Ad ommen	
amendments should not	Active compost must maintain aerobic conditions for a minimum of 131°F for 15 days			
be applied after	or longer, with a minimum of five turnings during this period followed by adequate			
emergence of plants.	curing.	pr	omment	
	Aerated static pile composting:		ne goal as	
	Active compost must be covered with 6 to 12 inches of insulating materials per		omment roposed la	
	federal, state, and local regulation and maintain a minimum of 131°F for 3 days or		re being u	
	longer with proper management to ensure elevated temperatures throughout all	to	achieve a	
	materials followed by adequate curing.		omment	
	Target Organisms:	82	 Does t 	
	Fecal coliforms		feasible	
	• Salmonella spp.	w l	/hat is yo	
	 E. coli 0157:H7 E. coli 0157:H7STEC 		arget orga	
	Acceptance Criteria:		omment	
	• Fecal coliforms: (AZ: 1,000) 100 MPN / gram of total solids (dry weight basis)		cluded	
	• Salmonella spp.: Negative or < DL (< 1 MPN / 30 grams)	C	omment	
	 <u>E. coli O157:H7STEC</u>: Negative or < DL (< 1 MPN / 30 grams) 		roposed t r STEC of	
	Recommended Test Methods:		omment	
	Fecal coliforms: U.S. EPA Method 1680; multiple tube MPN		•Is the	
	• Salmonella spp.: U.S. EPA Method 1682	\mathbb{N}	100 MPI	
	• E. coli O157:H7STEC: Any laboratory validated method for compost sampling.		/hat is yo	
	• Other U.S. EPA, FDA, AOAC, TMECC or validated/accredited methods may be	ta	arget orga	
	used as appropriate.		omment rotocol fo	
	Sampling Plan:		nd the in	
 A composite sample shall be representative and random. and obtained as described in the California state regulations.¹ (See Appendix E) 			omment	
		11 11	esearch is ne risks as:	
	 Verification and COA testing should have statistically relevant sample units 		omment	
	(minimum n=60) to provide high probability of detection.		see that t	
			4/27/202	

¹-CCR Title 14 Chapter 3.1 Article 7 Section 17868.1 <u>http://www.cakrecycle.ca.gov/Laws/Regulations/Title14/ch31a5.htm#article7</u>

Commented [GK95]: #78 Combining for simplicity

Commented [G94]: #79

Proposed name changed to soil amendments and crop inputs.

Commented [DS96]: Clarification, Is 'adequate curing' not necessary for vessel composting? The section does not fully describe what is vessel composting

Sonia: Addressed by Greg

Commented [G97]: There is a glossary term for vessel composting

Commented [S98]: LGSC would like to see a better-defined process for curing. Establishing time/temp metrics would be the goal as compared to defining the intended results

Commented [G99]: #80

Proposed language to address that different insulation materials are being used and that ASP composting must be managed in order to achieve a hygienic finished product.

Commented [SS100]: POLL QUESTION (after comment

Does the addition of STEC enhance food safety and is feasible?

What is your top concern with proposed revisions to the target organisms and acceptance criteria? And why? CHAT

Commented [S101]: LGSC would like to understand if L mono needs to be added if there are non-animal components included

Commented [G102]: #81

Proposed to expand target as O157:H7 is not the only EHEC or STEC of concern.

•Is the modification of the acceptance criteria from 1,000 to 100 MPN/gr enhance food safety and is feasible?

What is your top concern with proposed revisions to the target organisms and acceptance criteria? And why? CHAT

Commented [S104]: LGSC would like to see established protocol for what to do if unacceptable results are returned and the inputs need to be further processed

Commented [S105]: #82A AZLGMA: Research is ongoing through FDA and other entities with regards to the risks associated with fecal coliforms in

Commented [S106]: #82B John Massa I see that the current link here on the web site, as of 04/27/2021, doesn't show the current proposed changes to

Commented [S107]: LGSC would like to explore tighter limits up to <100MPN. Would like to understand what historical values look like

Commented [G108]: #83 FDA's language = PSR 112.55 What microbial standards apply to the treatment process.

Commented [S109]: LGSC would like to revisit this sampling plan to determine efficacy. N=60 is the standard

Commented [S110]: #84 AZLGMA:

Maintain sampling protocols aligned with the CA Code of Regulations regarding composting (n=12). Compost

Amendment	Metric/Rationale	Commented [G111]: #86 Proposed to simplify the training requirement. Generaly consensus
	 Sample may be taken by <u>a trained representative</u> the supplier if trained by a 	that it is not necessary to have training by a lab.
	testing laboratory or state authority.	Commented [G112]: Note: Appendix E needs updating
	Laboratory must be certified/accredited for microbial testing by a certification	Commented [G112]. Note: Appendix E needs updating
	or accreditation body. ²	Commented [S113]: #85 AZLGMA does not support this bullet point as proposed by CALGMA
	Testing Frequency:	Commented [SS114]: POLL QUESTION (after comment #
	Each lot before application to production fields. A <u>sampling</u> lot is defined as a	 90) Do proposed revisions to the testing frequency enhance
	unit of production equal to or less than 5,000 cubic yards.	food safety and are feasible to implement?
	A unit of production is meant to be physically unique. Some	Do you have any concerns? And Why? CHAT
	characteristics could include the same ingredients, same time of production, same production conditions, same equipment, etc. (i.e.,	Commented [S115]: LGSC supporting efforts to establish a
	for each production lot, take one sample per each 5,000 cu vards).	recommended lot size for composted soil amendments that is in line with a new sampling proposal
	 Reconditioned/re-processed product suspected of being contaminated. 	Commented [DS116]: Clarification, why is it OK to have a
	 Bulk finished product, not enclosed or packaged, must be re-tested at 	Certification of Process Validity for thermal processes, but no
	minimum annually if it is stored for greater than one calendar year and none	for biological/composting processes?
	of the product has been distributed.	Sonia: Question to considered in the process
	• E	Commented [S117]: LGSC supporting efforts to establish a
	Application Interval:	recommended lot size for composted soil amendments that is in line with a new sampling proposal
	 Must be applied > 45 days before harvest. 	
	Note: See best practices regarding what to consider when applying materials that	Commented [G118]: #87 Sampling lot has been proposed to be added in reference to STA
	may contact the edible portion of the crop.	sampling protocols which are a system approach to testing vs
	Documentation:	individual wind row samples.
	All products must have documentation that demonstrates they are free of	Commented [G119]: #88
	pathogens of <mark>concern</mark> .	New proposed language to assure lot description is based on
	 All test results, and/or Certificates of Analysis, and documentation shall be 	lot definition per a production run and not an overall time period similar to STA definitions.
	documented annually current, reviewed before use, and available for	Commented [G120]: #89
	verification from the grower (the responsible party) for a period of two years.	New proposed corrective action language to assure if re-
	Policies, procedures, letters of guarantee, and similar types of documents,	testing is conducted it is of reconditioned product.
	must be updated annually.	Commented [G121]: The second bullet could be a sub-
	Records of process control monitoring for on-farm produced soil amendments	bullet. But the third bullet is a stand alone and should be a primary bullet (reconditioning bullet)
	must be reviewed, dated, and signed, within a week after the records are	Commented [G122]: #90
	made, by a supervisor or responsible party.	Commented [G123]: #91
	Rationale:	Additional language for consideration.
	• The microbial metrics and validated processes are based on allowable levels	Commented [DS124]: Is this consistent with the statement
	from California state regulations for compost (CCR Title 14 - Chapter 3.1 -	in asterisk, that composted product should not be applied
	Article 7), with the addition of testing for STEC-E. coli O157:H7 as microbe of	Commented [G125]: That astericked statement is being proposed to be removed.
	particular concern. The 45-day application interval was deemed appropriate	
	due to the specified multiple hurdle risk reduction approach outlined. Raw	Commented [S126]: LGSC does not want composted soil amendments applied post-emergence
		Commented [G127]: #92

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Commented [S128]: LGSC would like to understand traceability for composted soil amendments, including

Commented [S130]: LGSC supports COA's submitted per established lot on composted soil amendments, based on

Commented [GK129]: #93

Commented [G131]: #94

^aSee FDA's Guidance for Industry: Submission of laboratory packages by accredited laboratories (<u>https://www.fda.gov/RegulatoryInformation/Guidances/ucm125434.htm</u>) for information on th ditati

	Amendment	Metric/Rationale		
Ī		manure must be composted with an approved process and pass testing		
		requirements before an application.	/	Commented [G132]: #95 New proposed language to assure the legal use of compost
		 All products must be used in accordance with all local, state, and federal 		Commented [SS133]: POLL QUESTION (after comment #
		regulations.		106)
			/	 Do proposed metrics for composted not containing product of animal origin enhance food safety and are
	<u>7b – Composted Not</u>	Please see Figure 7B: Decision Tree for Use of Biological Soil Amendments and Crop		feasible to implement?
	Containing products	Inputs of Non-Animal Origin.		If any, do you have a top concern? And Why? CHAT
	of Animal origin	Composting Process Validation:		Commented [G134]: #96 This proposed language is similar to 7a.
	(green/plant waste,	Enclosed or within-vessel composting:		This proposed language is similar to 7a.
	vegetative material,	Active compost must maintain a minimum of 131°F for 3 days or longer.		Commented [SS135]: POLL QUESTION (after comment #
	pre/post-consumer	Windrow composting:		 Boes the addition of STEC enhance food safety and is
	waste not containing	Active compost must maintain aerobic conditions for a minimum of 131°F for 15 days		• Does the addition of STEC enhance rood safety and is feasible?
	products of animal	or longer, with a minimum of five turnings during this period followed by adequate		What is your top concern with proposed revisions to the
	origin, <mark>etc)</mark>	curing.		target organisms and acceptance criteria? And why? CHAT
		Aerated static pile composting:	$\ $	
		Active compost must be covered with 6 to 12 inches of insulating materials per		•Is the modification of the acceptance criteria from 1,000 to
		federal, state, and local regulation and maintain a minimum of 131°F for 3 days or		100 MPN/gr enhance food safety and is feasible?
		longer with proper management to ensure elevated temperatures throughout all		What is your top concern with proposed revisions to the
		materials followed by adequate curing		target organisms and acceptance criteria? And why? CHAT
		Target Organisms:		Commented [S137]: #97 AZLGMA
		Fecal coliforms	11	proposes a threshold of 1,000 MPN/g for fecal coliform; does not support a lower threshold of 100
		• Salmonella spp.		Commented [G138]: #98
		• STEC	///	Larney, F.J., Yanke, L.J., Miller, J.J. and McAllister, T.A.
		Acceptance Criteria:	/	(2003), Fate of Coliform Bacteria in Composted Beef Cattle Feedlot Manure. J. Environ. Qual., 32: 1508-
		 Fecal coliforms: < 100 (AZ: 1,000) MPN / gram of total solids (dry weight basis) 		1515. https://doi.org/10.2134/jeg2003.1508 shows that a
		 Salmonella spp.: Negative or < DL (< 1 MPN / 30 grams) 		proper composting process can achieve TC levels below 100 MPN:
		 STEC: Negative or < DL (< 1 MPN / 30 grams) 		Brinton WF Jr, Storms P, Blewett TC. Occurrence and levels
		Recommended Test Methods:		of fecal indicators and pathogenic bacteria in market-
		 Fecal coliforms: U.S. EPA Method 1680; multiple tube MPN 		ready recycled organic matter composts. J Food Prot. 2009 Feb;72(2):332-9. Doi: 10.4315/0362-028x-72.2.332. PMID:
		 Salmonella spp.: U.S. EPA Method 1682 		19350977 shows when composting is conducted properly FC
		 STEC: Any laboratory validated method for compost sampling. 		levels should be less than 100 MPN. This article bridges Dr. D
		 Other U.S. EPA, FDA, AOAC, TMECC or validated/accredited methods may be 		Ingrams perspective that proper compost process controls must be in place and Dr. T Suslow's recommendation to
		<u>used as appropriate.</u>		reduce FC acceptance criteria from 1000 to 100 MPN
		Sampling Plan:		Arslan Topal, E.I., Ünlü, A. & Topal, M. Effect of aeration
		 A composite sample shall be representative and random and obtained as 		rate on elimination of coliforms during composting of vegetable-fruit wastes. Int J Recycl Org Waste
		described in the California state regulations. ³ (See Appendix E)		Agricult 5, 243-249 (2016). https://doi.org/10.1007/s40093-
		 Verification and COA testing should have statistically relevant sample units 		016-0134-6 This research shows that ASP can achieve 99.9-100% reduction
		(minimum n=60) to provide high probability of detection.		in FC counts when the process is controlled properly.

Commented [S139]: #100 AZLGMA proposes addition of this phrase.

Commented [S140]: #101 AZLGMA CALGMA proposed bullet AZLGMA proposes deleting this bullet point.

Amendment	Metric/Rationale	
	 Sample may be taken by a trained representative. 	
	Testing Frequency:	
	 Each lot before application to production fields. A sampling lot is defined as a 	
	unit of production equal to or less than 5,000 cubic yards.	
	 A unit of production is meant to be physically unique. Some characteristics 	
	could include the same ingredients, same time of production, same	
	production conditions, same equipment, etc. i.e. for each production lot, take	
	one sample per each 5,000 cu yards.	
	 Reconditioned/re-processed product suspected of being contaminated. 	
	 Bulk finished product, not enclosed or packaged, must be re-tested at 	
	minimum annually if it is stored for greater than one calendar year and none	
	of the product has been distributed.	Commented [G141]: #102
	Application Interval:	Additional language for consideration: "If some part has been distributed the remaining product
	 Must be applied > 45 days before harvest. 	should be reconditioned minimally annually and re-tested."
	Note: See best practices regarding what to consider when applying materials	
	that may contact the edible portion of the crop.	Commented [G142]: #99 This language is similar to 7a.
	Documentation:	
	All products must have documentation that demonstrates they are free of	
	pathogens of <mark>concern</mark> .	Commented [GK143]: #103
	 Any biological soil amendment or crop input that DOES NOT contain products 	Added language based on group discussions. Pathogen free materials are a requirement throughout Issue 7
	of animal origin must have documentation that shows the material is free of	
	products of animal origin.	Commented [GK144]: #104
	 All test results, Certificates of Analysis, and documentation shall be current, 	This is similar to original language regarding soil amendments and crop treatments not of animal origin.
	reviewed before use, and available for verification from the grower (the	
	responsible party) for a period of two years. Policies, procedures, letters of	
	guarantee, and similar types of documents, must be updated annually.	
	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.	Commented [G145]: #105 This is similar to 7a language.
	Rationale:	This is similar to 7a language.
	 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.	
	All products must be used in accordance with all local, state, and federal	
	regulations.	Commented [G146]: #106
		This is similar to 7a language.

<u>70 - Non – Composted,</u>	Proc
Solid and Liquid, Soil	Proc
Amendments and Crop	bio-
Inputs Not Containing	othe
products of Animal	
origin (fungal/bacterial	Targ

extracts, green/plant waste, plant extracts, vegetative material. algae, veast extract. pre/post-consumer waste not containing products of animal origin, etc) *These products have

not gone through a validated treatment process to reduce microorganisms of concern.

ducts ducts included in this section could include: Biofertilizers, biologicals, biorationals, stimulants, biopesticides, agricultural and compost teas not of animal origin, and er products not derived from ingredients of animal origin.

et Organisms:

- Fecal coliforms:
- Salmonella spp.
- STEC ٠
- Listeria monocytogenes

Acceptance Criteria:

- Fecal coliforms: < 100 (AZ: 1,000) MPN / gram of total solids (dry weight basis)
- Salmonella spp.: Negative or < DL (< 1 MPN / 30 grams)
- STEC: Negative or < DL (< 1 MPN / 30 grams)
- Listeria monocytogenes: Negative
- **Recommended Test Methods:**
 - Other U.S. EPA, FDA, AOAC, TMECC or validated/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.⁴ (See Appendix E).
- Sample may be taken by a trained sampler and/or verified automated process For solids a minimum of n=60 samples or equivalent based on the manufacturer's production process. For Liquids sample size needs to be per production process lot sizes.

Testing Frequency:

• Each lot before application to production fields.

- Lot means a specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
- Reconditioned/re-processed product suspected of being contaminated

Application Interval

• If a COA is available demonstrating that the input meets the microbial acceptance criteria outlined above, then no time interval is needed between application and harvest.

Note: See best practices regarding what to consider when applying materials that may contact the edible portion of the crop.

Commented [SS147]: POLL QUESTION (after comment

• Do proposed metrics for composted solid/liquid, soil amendment and crop inputs not containing products of animal origin enhance food safety and are feasible to implement?

•If any, do you have a top concern? And Why? CHAT

Commented [G148]: #107 New proposed language to better define the materials that are part of this section.

Commented [SS149]: POLL QUESTION (after comment

• Does the addition of STEC enhance food safety and is feasible?

What is your top concern with proposed revisions to the target organisms and acceptance criteria? And why? CHAT

Commented [SS150]: POLL QUESTION

•Is the modification of the acceptance criteria from 1,000 to 100 MPN/gr enhance food safety and is feasible?

What is your top concern with proposed revisions to the target organisms and acceptance criteria? And why? CHAT

Commented [S151]: #109 AZLGMA

proposes a threshold of 1,000 MPN/g for fecal coliform; does not support a lower threshold of 100

Commented [G152]: #108 Similar language as above

Commented [S153]: #110 AZLGMA proposes addition of "composite" & the phrase "and obtained as described...". (Highlighted in yellow)

Commented [G154]: #111 New proposed language includes automated sampling.

Commented [G155]: #112 New proposed language to align with the sampling

requirements in the compost sections but also considers that the products may be solids and liquids that are different than compost and made from unique production processes.

Commented [G156]: #113 Lot language based on the Lot glossary term for products other than compost.

Commented [G157]: #114 Same as language proposed above.

Commented [G158]: #115 This is similar to original language for products that are considered low risk.

•	All products must have documentation that demonstrates they are free of
	pathogens of concern.
•	_All test results, and/or Certificates of Analysis, and /or Certicates of Process
	Validation documentation shall be current, reviewed before use, and available
	for verification from the grower (the responsible party) for a period of two
	years. Policies, procedures, letters of guarantee, and similar types of
	documents, must be updated annually. 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.
•	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.
٠	Lot information (volume, weight, size, etc) shall be described on the COA.
•	Lot information shall be described on the COA or lot information must
	accompany the COA if the information cannot be described on the COA. Lot
	information is required to be able to conduct traceability for the material
	applied to the growing location and to link the product to a test result.
	Information that could be used to confirm the lot description could be lot
	identification # associated with a treatment step, shift, time parameters,
	sanitation breaks, volume, weight, size but other parameters could also be
	used based on a specific production process.
•	Any biological soil amendment or crop input that DOES NOT contain products
	of animal origin must have documentation that shows the material is free of
	products of animal origin.
Ration	ale:
•	Verification and COA testing should have statistically relevant sample units to
	provide high probability of detection. For solids a minimum of n=60 samples.
	For Liquids sample size needs to be per production process lot sizes.
•	All products must be used in accordance with all local, state, and federal
	regulations.

Commented [G159]: #116 This is similar language as proposed above.

Commented [G160]: #117 New proposed language to assure the product being received is the actual product that was tested.

Commented [S161]: #118 AZ LGMA

AZ offers alternative language regarding lot information declared on COA's. As voted on within the CA LGMA, lot sizes that were sampled were to be listed on COA's. It has come to our attention, that this practice may divulge proprietary business information. Suggested language was shared with AZ LGMA and CA LGMA. In the event that CA was not able to obtain approval, we offer the suggested language approved at the most recent AZ LGMA Technical Subcommittee meeting.

Commented [S162]: #119 Greg – New bullet added by CALGMA

Commented [G163]: #120 New proposed language to assure sample sizes are sufficient for the materials being tested. Also, new proposed language to assure all products are used in accordance to all applicable laws and regulations.

<u>7c– Biological</u> soil	Please see Figure 7B: Decision Tree for Use of Heat-Treated Soil Amendments.	
amendments and/or	Heat Process Validation	Commented [S165]: LGSC would like to see a prohibition
crop inputs that have	 The heat treatment processes applied to the soil amendment-containing 	on direct contact with crops for any soil amendments containing animal manure, even after processing
gone through a	animal manure shall be done via a process validated to assure the process is	containing animal manure, even after processing
validated treatment	capable of reducing pathogens of human health significance to acceptable	
process (not including	levels.	
<u>composting)</u>	Target Organism:	Commented [SS166]: POLL QUESTION (after comment #
(Chicken pellets, blood	Fecal coliforms	82)
meal, bone meal,	Salmonella spp.	 Does the addition of STEC enhance food safety and is feasible?
feather meal, soybean	• E . coli 0157:H7 STEC	
meal, kelp meal, alfalfa	Listeria monocytogenes	What is your top concern with proposed revisions to the target organisms and acceptance criteria? And why? CHAT
meal, cotton seed meal,	Acceptance Criteria:	
mustard meal, rice bran,		
treated fish emulsion, treated agricultural teas,	 Fecal coliforms Negative or <dl gram<="" li="" per=""> Salmonella: Negative or <dl (<1="" 30="" grams)<="" li=""> </dl></dl>	Commented [SS167]: POLL QUESTION
etc.)containing animal	 Summerica: Negative of <dl (<1="" 30="" grams)<="" li=""> E. coli O157:H7STEC Negative orf <dl (<1="" 30="" grams)<="" li=""> </dl></dl>	•Is the modification of the acceptance criteria from 1,000 to 100 MPN/gr enhance food safety and is feasible?
manure that has been		
heat-treated or		What is your top concern with proposed revisions to the target organisms and acceptance criteria? And why? CHAT
processed by other	Recommended Test Methods:	Commented [S168]: LGSC would like to see established
equivalent methods.	Fecal coliforms: U.S. EPA Method 1680; multiple tube MPN	protocol for what to do if unacceptable results are returned
	Salmonella spp.: U.S. EPA Method 1682	and the inputs need to be further processed
	• E. coli O157:H7 and Listeria monocytogenes: Any laboratory validated method	Commented [DS169]: Content, should have a detection
	for testing soil amendments.	limit. Still <1000 per gram same as compost? Or is it <dl (<1="" gram)?<="" td=""></dl>
	 U.S. EPA, FDA, AOAC_or other <u>validated /</u> accredited methods may be used as appropriate 	Commented [S170]: Original language is <dl (<1="" gram)<="" td=""></dl>
	appropriate.	Commented [G164]: #121
	Sampling Plan:	New proposed language to assure there is clarity regarding
	A sample shall be representative and random.	the types of products that fall under category 7c and that any treatment that is validated will be accepted. i.e. heat,
	Sample may be taken by a trained sampler and/or verified automated process.	chemical, other
	For solids a minimum of n=60 samples or equivalent based on the	Commented [G171]: #122
	manufacturer's production process. For Liquids sample size needs to be per	Proposed language is similar to 7b.
	production process lot sizes.	
	 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.	Commented [S172]: LGSC would like to revisit this
	Testing Frequency:	sampling plan to determine efficacy. N=60 is the standard we want to work towards with a defined sample lot size and detail
	 Each lot before application to production fields. 	around sampling locations.
	 Lot means a specific quantity of a finished product or other material that is 	
	intended to have uniform character and quality, within specified limits, and is	
	produced according to a single manufacturing order during the same cycle of	
	manufacture.	
	 Reconditioned/re-processed product suspected of being contaminated. 	Commented [G173]: #123
	 In lieu of the above analysis requirement, a Certificate of Process Validity 	Proposed language is similar to 7b
	issued by a recognized process authority can be substituted. This cortificate 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:		Commented [S174]: #124
If the heat treatment process used to inactivate human pathogens of significant		Greg: Proposed changes are for simplification but similar to
public health concern that may be found in animal manure containing soil		original language.
amendments, is validated and meets the microbial acceptance criteria outlined		
above, then no time interval is needed between application and harvest.		Commented [S175]: LGSC would like to explore further the
 If the heat treatment process used to inactivate human pathogens of significant 	\leq	level of data required to be considered a validated process.
public health concern that may be found in animal manure containing soil		Commented [S176]: LGSC: Even with a documented
amendments is not validated but will likely significantly reduce microbial		process, we support a buffer of at least 7 days prior to harvest (no later than the earliest possible pre-harvest risk
populations of human pathogens and product COAs meets microbial		assessment). This is given a sampling program and process
acceptance criteria outlined above, then a 45-day interval between application	\backslash	validation plan that we have confidence in.
and harvest is required.		Commented [DS177]: Clarification, this seems like a
•		potential loophole or area of future debate unless this standard specifies bounds on the terms "likely to reduce" and
Note: See best practices regarding what to consider when applying materials that may contact the edible potion of the crop.		"significantly reduce"?
		Sonia: Review language to clarify
Documentation:		
 All test results, and/or Certificates of Analysis and documentation shall be 		
current, reviewed before use, /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. Policies, procedures, letters of		
guarantee, and similar types of documents, must be updated annually. 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.		
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.		
 Lot information (volume, weight, size, etc.) shall be described on the COA. 		Commented [G178]: #125
 Lot information shall be described on the COA or lot information must 		This is new language for consideration regarding lot info on COAs
accompany the COA if the information cannot be described on the COA. Lot		
information is required to be able to conduct traceability for the material		Commented [S179]: #126 AZLGMA
applied to the growing location and to link the product to a test result.		AZLGMA proposes this language as an alternative
Information that could be used to confirm the lot description could be lot		
identification # associated with a treatment step, shift, time parameters,		
sanitation breaks, volume, weight, size but other parameters could also be		
used based on a specific production process.		
All products must be used in accordance with all local, state, and federal		
regulations.		Commented [G180]: #127
Rationale:		Proposed language is similar to 7b.
The microbial metrics are based on allowable levels from California state		
regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7) with the		

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	 addition of testing for <i>E. coli</i> 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. 		
7 <mark>d – synthetic and/or inorganic Soil Amendments or Crop inputs Soil Amendments Not Containing Animal Manure</mark>	 Any soil amendment or crop input that is synthetic or inorganic must have documentation that it is free of non-synthetic products and not containing ingredients of animal origin or manure. All products shall be produced, transported, stored, and applied to prevent contamination of lettuce and leafy greens crops and production areas. All products must be used in accordance with all local, state, and federal regulations. Any soil amendment that DOES NOT contain animal manure must have documentation that it is free. The documentation must be available for verification before <u>use-harvest begins</u>. 		Commented [SS181]: POLL QUESTION (after comment # 128/comment) • Do proposed metrics for synthetic and/or inorganic soil amendments or crop inputs enhance food safety and are feasible to implement? • If any, do you have a top concern? And Why?
	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. Note: See best practices regarding what to consider when applying materials that may contact the edible potion of the crop. 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.		Commented [G182]: #128 Synthetic products are considered a low food safety risk. Proposed language reflects the requirement to have assurances that the products are synthetic and that they are being managed to prevent contamination and used according to all laws and regulations. Commented [S183]: LGSC: Even with a documented
7 <u>e – Combined</u>	 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. Any soil amendment or crop input that is combined must follow the criteria for the 	-	process, LGSC supports a buffer of at least 7 days prior to harvest (no later than the earliest possible pre-harvest risk assessment). This is given a sampling program and process validation plan that we have confidence in.
<u>Components</u>	 highest risk ingredient. (See 7a, 7b, 7c, and 7d above) The documentation must be available for verification before use. 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. 		 Commented [SS184]: POLL QUESTION (after comment # 129) Do proposed metrics for synthetic and/or inorganic soil amendments or crop inputs enhance food safety and are feasible to implement? If any, do you have a top concern? And Why?
	NOTE: MIXTURES OF SOIL AMENDMENT MATERIALS		Commented [G185]: #129 New proposed language is for simplification purposes but similar to the original language used for mixed products.

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).

223	4 BOCH WOW STATISTIC CROP TREAMMENTS	/	This
224 225 226 227 228 229	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.		
230	The Best Practices Are:		
231 232	 Do not use crop treatments that contain raw manure or other untreated animal products or by products for lettuce or leafy green produce. 		
233 234	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.		
235 236 237	 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. 		
238 239 240	 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. 		
241 242 243	 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. 		
244 245	 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. 		
246 247	 Segregate equipment used for crop treatment applications or use effective means of equipment sanitation before subsequent use. 		
248 249 250	 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 <i>Technical Basis Document</i> (Appendix B) describes the process used to develop these metrics. 		

251 • Retain documentation of all test results available for inspection for a period of at least two years.

Commented [G186]: #130 This language was combined with Issue 7.

252 TABLE 4. 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.

Examples include but are not limited to:

- Agricultural / Compost teas,
- Fish emulsions
- Fish meal
- Blood meal
- <u>"Bio-fertilizers" commonly used</u> 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 0157: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

Treatment	Metric/Rationale
	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 crop 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 crop 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 <i>E. coli</i> 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.

254	NOTE: MIXTURES OF SOIL AMENDMENT MATERIALS
255	For soil amendments that contain mixtures of materials, each component must meet the requirements of its
256	respective class of materials. The usages allowed will conform to that of the most stringent class of materials
257	utilized in the mixture.
258	For example, soil amendments containing animal manure that has been heat treated or processed by other
259	equivalent methods that are mixed with soil amendments not containing animal manure would require a process
260	certification for the heat treated (or processed by other equivalent methods) materials and the components from
261	non-animal manure would require documentation attesting to its manure-free status. The resulting mixture could
262	then be applied in accordance with the guidelines associated with the heated treated class of materials (most
263	stringent limits).

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