

Produce Safety Rule

PRE-INSPECTION CHECKLIST

DIRECTIONS

This checklist is broken down by the subparts of the Produce Safety Rule.

The language in the standards box at the beginning of each subpart is similar to the rule language. The Food and Drug Administration (FDA) created a draft guidance document to give detailed examples of how to meet each standard. Because of the length of the guidance document, we have included the specific chapters and pages of the draft guidance that are most relevant to each standard.

The FDA draft guidance can be found online at the following address: www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-standards-growing-harvesting-packing-and-holding-produce-human-consumption

We suggest marking the “Check Yes” box for the standards your farm is meeting and noting which areas may need attention prior to an inspection.

SUBPART C: PERSONNEL QUALIFICATIONS AND TRAINING

Chapter 2, Pages 26 – 38 of FDA Draft Guidance

Check Yes	Standards	FDA Draft Guidance
	Is there a designated supervisor for all covered activities?	Part 8, page 38
	Are all personnel (Full time, part time, seasonal, contracted, and temporary), who contact covered produce and food contact surfaces trained in food safety upon hiring relevant to their duties?	Part 3, page 29
	Are personnel who conduct harvest activities trained to recognize covered produce that must not be harvested, know how to inspect harvesting containers and equipment? Are they instructed in what to do if they are contaminated/broken?	Part 6, pages 35- 37
	Is training conducted in a manner that is easily understood by personnel being trained?	Part 4, pages 30 -31
	Is training repeated at least annually, or as necessary?	Part 3, page 29
	Has a supervisor or responsible person attended the Produce Safety Rule Grower training or equivalent?	Part 7, page37
	Does training cover <ul style="list-style-type: none"> • Principles of hygiene and food safety • The importance of health and personal hygiene for all personnel and visitors and recognizing symptoms? 	Part 5, pages 31-35
	Is there an assigned or identified person to ensure compliance with the requirements of personnel qualifications and training?	Part 8, page 38
	Do employee training records include the following required items: names of trained personal, date of training, and topics covered?	Part 9, page 38
	If you have unpaid workers or volunteers assisting with covered activities, do you keep training records for them?	Part 9, page 38

SUBPART D: HEALTH AND HYGIENE

Chapter 3, Pages 39-56 of FDA Draft Guidance

Check Yes	Standards	FDA Draft Guidance
	Are measures taken to exclude any person from working in any operation that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person is shown to have, or appears to have, an applicable health condition?	Part 1, pages 39-41 & Part 1d, pages 43-44
	Are personnel instructed to report illness/injury to supervisor?	Part 1b, pages 41-42
	Are personnel required to maintain adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces?	Part 2, pages 45 -46 & Part 2c, pages 47-48
	Are personnel instructed to avoid contact with animals (or take appropriate steps when in contact with working animals) before working with covered produce or food contact surfaces to minimize contamination of covered produce?	Part 2c, pages 48-49
	Does hand washing training cover how, why and when to wash your hands (i.e. at any time that hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce)?	Part 2c, pages 50-52
	If gloves are used, are they maintained and changed when necessary?	Part 2c, pages 52-53
	Are workers trained to remove or cover hand jewelry, if it cannot be adequately cleaned and sanitized before contacting covered produce?	Part 2c, pages 53-54
	Are eating, chewing gum, and using tobacco products prohibited in areas used for covered activities? Are beverages permitted only in designated areas?	Part 2c, page 54
	<p>Are visitors:</p> <ul style="list-style-type: none"> • Aware of farm practices and rules? • Able to access toilet and hand-washing facilities? 	Part 3, pages 54-57

SUBPART E: AGRICULTURAL WATER

Not enforced until 2022

Check Yes	Standards	FDA Draft Guidance
	Per the FDA, implementation of the standards in subpart E will not start until 2022. The requirements of this subpart will not be a part of any inspections until then. This checklist will be updated with the appropriate standards and guidance at that time.	

SUBPART F: BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE

Chapter 4, Pages 57-73 of FDA Draft Guidance

Check Yes	Standards	FDA Draft Guidance
	Are Biological Soil Amendments of Animal Origin (BSAAOs) or an agricultural tea being used on covered crops?	Part 1, page 58-60
	Are the BSAAOs treated or untreated?	Part 2, pages 61-62
	Are BSAAOS being stored in an area where they will not be a source of contamination on covered crops?	Part 5, page 71
	Are untreated BSAAOs being applied in a manner that will not contact covered produce during or after application?	part 4, pages 66-69
	Are BSAAOs treated to the standard in 112.54b (Scientifically valid controlled process that satisfies the microbial standard for Salmonella species and fecal coliforms) being applied in a manner that minimizes potential for contacting covered produce?	Part 4, pages 69-70
	If there is reason to believe that the treated BSAAOs have been contaminated, are they being handled as if untreated?	Part 5, page 71
	Are farm personnel ensuring that human waste is not being used for growing covered produce, other than sewage sludge biosolids and applicable requirements?	Chapter 4 Introduction, page 57
	Is a scientifically valid treatment process being used for BSAAOs being applied on covered crops?	Part 3, pages 63-65
	Are written records kept documenting applicable process controls for treatment of BSAAOs produced on the farm (e.g. time, temperature, turnings)?	Part 6, pages 72-73 & Chapter 8 Subpart O, pages 131-138
	Do any BSAAOs received from a third party come with documentation that the process used to treat the BSAAO was scientifically valid and carried out with appropriate process monitoring; and that the amendment has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process amendment?	Part 6, pages 72-73

SUBPART I: DOMESTICATED AND WILD ANIMALS

Chapter 5, pages 74-81

Note: These requirements are for outside or partially enclosed growing areas, where there is a reasonable probability that animals will contaminate covered produce. This section **does NOT apply** to activities taking place in a fully enclosed building, or to fish in aquaculture operations.

Check Yes	Standards	FDA Draft Guidance
	Are relevant areas on the farm being assessed as needed for evidence of potential contamination from domestic or wild animals during the growing season?	Part 2, page 79
	If significant evidence of potential contamination from animals is found pre-harvest, are measures taken to ensure covered contaminated produce is not harvested?	Part 3, pages 79-81

SUBPART K: GROWING, HARVESTING, PACKING AND HOLDING ACTIVITIES

Chapter 6, Pages 82-92

Check Yes	Standards	FDA Draft Guidance
	Are measures being taken to separate covered produce from excluded produce, unless they are both being treated as covered?	Part 1, pages 82-84
	Are measures being taken to identify and not harvest contaminated produce?	Part 2, pages 85-86
	If excluded produce is being handled not in accordance with the PSR, are there measures in place to clean and sanitize between covered and excluded crops?	Part 1, pages 82-84
	Are there measures to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard?	Part 2, pages 85-86
	Is harvested covered produce being handled in a manner to protect against contamination from known or reasonably foreseeable hazards?	Part 3, pages 86-87
	<p>Are there measures taken to ensure that dropped covered produce is not being harvested or distributed?</p> <ul style="list-style-type: none"> • Dropped covered produce definition: produce that drops to the ground before harvest. This does not include root crops that grow underground (ex: carrots), crops that grow on the ground (ex: cantaloupe) or produce that is intentionally dropped to the ground as part of harvest (ex: ground cherries) 	Part 4, pages 87-88
	Is produce being packaged in a manner that prevents the formation of Clostridium botulinum toxin in crops that have a known or reasonably foreseeable risk of forming it (ex: mushrooms)?	Part 5, pages 88-89
	Are food packaging materials cleanable or designed for single use, and unlikely to support growth or transfer of bacteria?	Part 6, pages 90-92
	If food packaging material is reused, are adequate steps being taken to ensure that food contact surfaces are clean (ex: using a clean liner, or cleaning the container)?	Part 6, pages 89-92

SUBPART L: GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES

Chapter 7, Pages 93-130

Note: Buildings covered under this part are fully or partially enclosed, being used for covered activities, or for storing materials or equipment used for covered activities.

Check Yes	Standards	FDA Draft Guidance
	Are materials of adequate design, construction and workmanship to enable them to be adequately cleaned and properly maintained?	Part 1, pages 94-95
	Are tools and equipment being stored and maintained as to not be a source of contamination?	Part 1, pages 96-97
	Are tools and equipment installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces?	Part 1, page 95
	Are seams on food contact surfaces smoothly bonded and easy to clean to prevent harborage or growth of microorganisms?	Part 1, pages 95-96
	Are food contact surfaces of equipment and tools being inspected, maintained, cleaned, and when appropriate sanitized, as frequently as reasonably necessary, to protect against contamination of covered produce?	Part 1, pages 97-103
	Are non-food-contact surfaces of equipment and tools used during harvesting, packing and holding cleaned and maintained as frequently as reasonably necessary to protect against contamination of covered produce?	Part 1, page 103
	Are pallets, forklifts, tractors and vehicles properly maintained to minimize contamination of covered produce or food contact surfaces?	Part 1, page 110
	Are instruments or controls (that are used to measure, regulate, or record) accurate, precise, adequately maintained, and adequate in number?	Part 1, pages 110-113
	Are vehicles used to transport covered produce, adequately cleaned before use, and adequate for the intended use?	Part 1, page 110
	Are buildings of suitable size, construction and design to help reduce the potential for contamination of covered produce or food contact surfaces, including sufficient space for placement of equipment and storage of materials?	Part 2, pages 113-115
	Is there adequate drainage where water or other liquid is being discharged onto the ground or floor?	Part 2, page 116
	Are there measures to prevent contamination of covered produce and food contact surfaces in buildings from the floors, walls, ceilings, fixtures, ducts, and pipes?	Part 2, pages 115-116
	Are there measures to prevent drip or condensate from being a source of contamination of covered produce or food contact surfaces?	Part 2, page 116
	Are all domesticated animals excluded or separated from fully enclosed buildings where covered produce, food contact surfaces, or food packing material is exposed or where a covered activity is conducted?	Part 2, pages 118-119
	Is routine monitoring conducted for pests as necessary and appropriate in buildings to protect covered produce, food contact surfaces and food-packing materials from contamination?	Part 2, pages 117-118
	Are measures taken to exclude pests from fully-enclosed buildings?	Part 2, pages 117-118

Subpart L: Growing, Harvesting, Packing, and Holding Activities (Continued)

Check Yes	Standards	FDA Draft Guidance
	Are measures taken to prevent pests from becoming established in partially-enclosed buildings?	Part 2, pages 118-119
	If domestic animals are present on the farm, is there a way to adequately control the excreta and litter from contaminating covered produce, food contact surfaces, areas used for covered activities, and ag water sources and their delivery systems?	Part 2, page 120
	Are toilet facilities readily accessible to all workers and visitors of the farm?	Part 3, pages 120-121
	Are toilet facilities designed, located, and maintained to prevent contamination of covered produce, food contact surfaces, water distribution systems and sources?	Part 3, page 121
	Are toilet facilities accessible for servicing and serviced at a frequency that ensures suitability of use?	Part 3, pages 121-122
	During growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities, is there a hand washing facility in sufficiently close proximity to the toilet facility that is furnished with soap, running water with no detectable E. coli, hand drying device (single use paper towels, sanitary towel surface, or electric hand dryers), and a place for appropriate disposal of any waste (e.g., waste water and used towels)?	Part 3, pages 122-125
	If antiseptic hand rubs or other surfactants are being used on the farm, are personnel ensuring that they are used in addition to soap and water, and not as a substitute for hand washing?	Part 3, page 123
	Is sewage being disposed of through adequate means in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources and agricultural water distribution systems?	Part 3, pages 125-126
	Are any leaks or spills of human waste managed to prevent contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for covered activities, ag water sources or ag water distribution systems?	Part 3, pages 126-127
	If there is flooding, or any other significant event that could have an impact on the sewage system, are appropriate measures taken to avoid contamination of covered produce, food contact surfaces, areas used for covered activities, ag water sources or ag water distribution systems?	Part 3, page 127
	Are trash, litter and waste being stored, conveyed, and disposed of to minimize the potential to attract and harbor pests or be a source of contamination of covered activities, ag water sources, ag water distribution systems or covered crops?	Part 3, pages 127-129
	<p>Is the plumbing of adequate design and size to:</p> <ul style="list-style-type: none"> • Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities? • Properly convey sewage and liquid disposable waste? • Avoid being a source of contamination to covered produce, food contact surfaces, and areas used for covered activities, and ag water sources? • Not allow backflow from cross connections between piping or hoses that discharges waste or sewage and water for covered activities? 	Part 3, pages 129-130

SUBPART O: RECORDS

Chapter 8, Pages 131-138

Check Yes	Standards	FDA Draft Guidance
	Do written records include: <ul style="list-style-type: none"> • farm name and location • actual values and observations obtained during monitoring • an adequate description of covered produce applicable to the record • the location of a growing area applicable to the record • the date and time of the activity documented? 	Part 1, pages 131-134
	Are records: <ul style="list-style-type: none"> • created at the time an activity is performed, • accurate, legible, and indelible, • dated and signed or initialed by the person who performed the activity documented? 	Part 1, page 132-134
	Are required records reviewed, dated, and signed within a reasonable time after the records are made by a responsible party?	Part 1, page 135
	Are records kept and reviewed as required for the following sections: <ul style="list-style-type: none"> • Training (112.30b) Chapter 2, page 38 • BSAAOs produced and treated on your farm (112.60b2)? Chapter 4, Part 6, pages 72-73 	The guidance on these records is maintained in their individual subparts. See the chapter & pages in the standards box for specific locations
	Are the following additional records kept when applicable to document practices on your farm? <ul style="list-style-type: none"> • Documentation from a third-party supplier that BSAAOs were treated using a scientifically valid process and handled in a manner to prevent cross contamination from untreated or in process BSAAOs. Chapter 4, Part 6, pages 72-73 • Documentation of the date and method of cleaning and sanitizing equipment used in covered harvesting, packing, or holding activities. Chapter 7, Part 4, page 130 	The guidance on these records is maintained in their individual subparts. See the chapter & pages in the standards box for specific locations
	Can records be retrieved and provided onsite within 24 hours of request for official review?	Part 2, page 136
	Are records kept for at least 2 years past the date the record was created?	Part 4, page 137
	Are records kept as originals, true copies (photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions) or electronic records?	Part 5, pages 137-138

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

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