

330 CMR 34.00: PRODUCE SAFETY AND MARKET ACCESS REGULATIONS

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34.01: Purpose

The purpose of 330 CMR 34.00 is to establish statewide science-based minimum standards relating to the sanitary and safe growing, harvesting, labeling, packing, and holding of fresh fruits and vegetables grown for human consumption in the Commonwealth of Massachusetts consistent with those established by the FDA under 21 C.F.R. § 112 et seq.

34.02: Definitions

For the purpose of 330 CMR 34.00, the following definitions shall apply:

Adjusted For Inflation. Equal to an amount calculated by the Department using 2011 as the baseline year and adjusting the baseline amount in view of inflation; provided, however, that the Department will provide public notice, including on its website, of any such calculations.

Adulterated Produce. Shall have the same meaning as adulterated Food in M.G.L. c. 94, § 186.

Agricultural Water. Water used in Covered Activities on Covered Produce where water is intended to, or is likely to, contact Covered Produce or Food Contact Surfaces, including water used in growing activities (including irrigation water using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested Produce and water used for preventing dehydration of Covered Produce).

C.F.R. The Code of Federal Regulations.

Commissioner. The Commissioner of the Massachusetts Department of Agricultural Resources.

Commonwealth. The Commonwealth of Massachusetts.

Covered Activity. Growing, harvesting, packing, or holding Covered Produce on a Farm, including manufacturing, processing of Covered Produce on a Farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of Farm.

Covered Farm. A Farm engaged in growing, harvesting, packing, or holding Covered Produce on a Farm with an average annual monetary value of Produce sold during the previous three (3) year period of more than \$25,000 (on a rolling basis), Adjusted For Inflation.

Covered Produce. Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw, and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfafa and mung bean), strawberries, summer squash (such as patty pan, yellow, and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and mixes of intact fruits and vegetables (such as fruit baskets). The term “Covered Produce” refers to the harvested or harvestable part of the crop.

CQP. The Commonwealth Quality Program.

Department. The Massachusetts Department of Agricultural Resources.

Destruction. Deliberate destruction of Produce to render it useless for processing or consumption.

Destruction Order. An official Department action under M.G.L. c. 128, § 124 requiring Destruction.

DPH. The Massachusetts Department of Public Health.

Egregious Condition. A practice, condition, or situation on a Farm that, if corrective action is not immediately taken, is reasonably likely to result in adverse health impacts, up to and including illness, death, or any other imminent public health hazard.

Embargo or Embargoed. The mandatory holding or detention of Produce.

Embargo Order. An official Department action under M.G.L. c. 128, § 124 requiring Embargo.

EPA. The United States Environmental Protection Agency.

Farm. Shall have the same meaning as provided in 21 C.F.R. § 112.3.

FDA. The United States Food and Drug Administration.

Federal Food, Drug and Cosmetic Act. 21 U.S.C. § 301 et seq.

Follow-up Inspection. A subsequent inspection to an Initial Inspection, which occurs to review an issue or concern identified and documented during such Initial Inspection.

Food. Articles used for food or drink for humans or other animals, chewing gum, and articles used for components of any such article.

Food Contact Surface(s). 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 Surface(s)” includes Food Contact Surfaces of equipment and tools used during harvest, packing, and holding.

For-Cause Inspection. An inspection that occurs in response to a specific issue or Produce safety concern, including, without limitation, an outbreak, a complaint, or a recall.

Initial Inspection. The first regulatory inspection conducted at a Covered Farm.

Inspection Certificate. A document demonstrating compliance with 330 CMR 34.00 et seq.

Inspector. An inspector from the Department’s Produce Safety, Market Access, and Certification Division.

Misbranded Produce. Shall have the same meaning as misbranded Food in M.G.L. c. 94, § 187, as it pertains to Produce.

Non-Covered Produce. Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts. Produce that is produced by an individual for personal consumption or produced for consumption on the Farm or another Farm under the same management. Produce that is not a Raw Agricultural Commodity.

Order. An official Department action under M.G.L. c. 128, § 124.

Person(s). Any individual, partnership, association, firm, company, corporation, department, agency, group, public body (including a city, town, district, county, authority, state, federal, or other governmental unit), trust, or any other entity responsible in any way for any activity, facility, or operation subject to 330 CMR 34.00.

Produce. Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as Food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include Food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of Food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Produce Inspection Observation Form. A report issued by the Department, which notes conditions observed during an inspection or audit.

Produce Safety Rule. 21 C.F.R. § 112 et seq.

Qualified End User(s). The consumer of the Food (where the term consumer does not include a business), a restaurant, or a retail Food establishment that is located in the Commonwealth or not more than 275 miles from where the Produce is grown.

Qualified Exempt or Qualified Exemption. Meeting the eligibility requirements under 34.10(1).

Qualified Exempt Farm. A Farm meeting the eligibility requirements under 34.10(1).

Quarantine or Quarantined. The isolation and confinement of Produce as a result of an Egregious Condition.

Quarantine Order. An official Department action under M.G.L. c. 128, § 124 requiring Quarantine.

RAC or Raw Agricultural Commodity. Any Food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled, natural form prior to marketing.

Recall. An action taken by a Farm to remove Produce from the market. A recall may be conducted on a Farm's own initiative, by Department request, or by a Recall Order issued by the Department.

Recall Order. A Quarantine Order or Embargo Order that includes within its scope Produce that was once located at a Farm but is no longer present at the time the Quarantine Order or Embargo Order is issued.

Registry. List of Covered Farms and those Farms that have opted in pursuant to 330 CMR 34.03(2)(a), and information and records collected by the Department pursuant to the Federal Act, the Produce Safety Rule, and M.G.L. c. 128, § 124.

Routine Inspection. A regularly-scheduled inspection carried out by the Department.

USDA. The United States Department of Agriculture.

34.03: Registry

- (1) The Department shall maintain a Registry. Any Covered Farm shall annually, but no later than December 31, provide the Department with records sufficient to show the following information or, in the alternative, provide the Department with the following information in a form issued by the Department:
 - (a) Name and address of the Covered Farm;
 - (b) Person(s) owning or operating the Covered Farm;
 - (c) Address of Person(s) owning or operating the Covered Farm;
 - (d) Description of Produce grown at the Covered Farm;
 - (e) Address of actual location where Produce will be grown and acreage of Farm;
 - (f) Address of actual location where Produce will be grown and type of indoor growing facilities, if any (e.g., greenhouse, hoop house, or residence);
 - (g) Information indicating whether the Farm is a Covered Farm or Qualified Exempt Farm under 330 CMR 34.10(1); and
 - (h) Such other information as the Department may reasonably require promoting and protecting public health and safety.
- (2) Non-Covered Farms and Non-Covered Produce.
 - (a) Any Farm, whether a Covered Farm or Non-Covered Farm, may provide information under 330 CMR 34.03(1) to the Department and request an inspection of such Produce, including Non-Covered Produce, for compliance with the Produce Safety Rule and 330 CMR 34.00. Upon such request, the Department shall conduct inspections in accordance with 330 CMR 34.05, applying the standards set forth in 330 CMR 34.04. In the Department's discretion, if the inspection does not reveal any public health concerns, then the Department may issue an Inspection Certificate to the Farm.
 - (b) A Farm that opts into the Registry and inspection program under 330 CMR 34.03(2)(a) shall sign a form issued by the Department memorializing its consent to inspections under 330 CMR 34.05 and its agreement to be subject to the authority of the Department under M.G.L. c. 128, § 124.

- (3) A Farm that provides records or information to the Department under 330 CMR 34.03(1) or 330 CMR 34.03(2) shall notify the Department, in writing, of any change to the information listed in 34.03(1) within thirty (30) days after such change.

34.04: Standards for Growing, Harvesting, Packing, and Storing Produce for Human Consumption

(1) General Provisions.

Food covered under 330 CMR 34.04 shall be Covered Produce as defined in 330 CMR 34.02; provided, however, that the Department shall apply the standards set forth in 330 CMR 34.04 when conducting an inspection of Non-Covered Produce at a Farm that has elected to register with the Department pursuant to 330 CMR 34.03(2).

(2) General Requirements.

A Covered Farm shall take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, exposure to, Covered Produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into Covered Produce, and to provide reasonable assurances the Covered Produce is not Adulterated Produce on account of such hazards.

(3) Personnel Qualifications and Training.

- (a) A Covered Farm shall assign or identify personnel to supervise (or otherwise be responsible for) operations to ensure compliance with 330 CMR 34.04.
- (b) All personnel (including temporary, part-time, seasonal, and contracted personnel) who handle Covered Produce or Food Contact Surfaces, or who are engaged in the supervision of such personnel, shall receive adequate training, as appropriate to the person's duties, upon hiring, and periodically after, at least once annually.
- (c) All personnel (including temporary, part-time, seasonal, and contracted personnel) who handle Covered Produce or Food Contact Surfaces, or who are engaged in the supervision of such personnel, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with 330 CMR 34.04.
- (d) Training must be conducted in a manner that is easily understood by personnel being trained.
- (e) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established under 330 CMR 34.04.

- (f) At a minimum, all personnel who handle (contact) Covered Produce during Covered Activities or supervise the conduct of such activities shall receive training that includes all of the following:
 - (i) Principles of Food hygiene and Food safety;
 - (ii) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of Covered Produce or Food Contact Surfaces with microorganisms of public health significance; and
 - (iii) Standards established by the Produce Safety Rule and 330 CMR 34.04 that are applicable to the employee's job responsibilities.
 - (g) Persons who conduct harvest activities for Covered Produce shall also receive training that includes all of the following:
 - (i) Recognizing Covered Produce that shall not be harvested, including Covered Produce that may be contaminated with known or reasonably foreseeable hazards;
 - (ii) Inspecting harvest containers and equipment to ensure they are functioning properly, clean, and maintained so as not to become a source of contamination of Covered Produce with known or reasonably foreseeable hazards; and
 - (iii) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.
 - (h) At least one supervisor or responsible party for the Covered Farm shall have successfully completed Food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA.
 - (i) The Covered Farm shall assign or identify personnel to supervise (or otherwise be responsible for) its operations to ensure compliance with the requirements of 330 CMR 34.04.
- (4) Measures Preventing Ill or Infected Persons from Contaminating Covered Produce.
- (a) Measures shall be taken to prevent contamination of Covered Produce and Food Contact Surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea) including:
 - (i) Excluding any personnel from working in any operations that may result in contamination of Covered Produce or Food Contact Surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgment, or observation) is shown to have, or appears to have, an applicable health condition, until the Person's health condition no longer presents a risk to public health; and
 - (ii) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

- (b) Personnel who work in an operation in which Covered Produce or Food Contact Surfaces are at risk of contamination with known or reasonably foreseeable hazards shall use hygienic practices while on duty to the extent necessary to protect against such contamination, including:
 - (i) Maintaining adequate personal cleanliness to protect against contamination of Covered Produce and Food Contact Surfaces;
 - (ii) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of Covered Produce contamination when in direct contact with working animals;
 - (iii) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of 330 CMR 34.04(5) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices before starting or returning to work, before putting on gloves, after using the toilet, as soon as practicable after touching animals (including livestock and working animals), or any waste of animal origin, and at any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of Covered Produce with known or reasonably foreseeable hazards;
 - (iv) Maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;
 - (v) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which Covered Produce is manipulated by hand; and
 - (vi) Not eating, chewing gum, or using tobacco products in an area used for a Covered Activity (however, drinking beverages is permitted in designated areas).
- (c) The Covered Farm shall make visitors aware of policies and procedures to protect Covered Produce and Food Contact Surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. Toilet and hand-washing facilities shall be accessible to visitors.

(5) Agricultural Water.

- (a) All Agricultural Water shall be safe and of adequate sanitary quality for its intended use.
- (b) At the beginning of the growing season, as appropriate, but at least once annually, a Covered Farm shall inspect all Agricultural Water systems, to the extent they are under the Covered Farm's control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto Covered Produce or Food Contact Surfaces in light of the Covered Farm's Produce, practices, and conditions, including consideration of the following:
 - (i) The nature of each Agricultural Water source (e.g., ground water or surface water);
 - (ii) The extent of the Covered Farm's control over each Agricultural Water source;
 - (iii) The degree of protection of each Agricultural Water source;

- (iv) Use of adjacent and nearby land; and
 - (v) The likelihood of introduction of known or reasonably foreseeable hazards to Agricultural Water by another user of Agricultural Water before the water reaches the Covered Farm.
- (c) The Covered Farm shall adequately maintain all Agricultural Water distribution systems to the extent they are under the Covered Farm's control as necessary and appropriate to prevent the water distribution system from being a source of contamination to Covered Produce, Food Contact Surfaces, areas used for a Covered Activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.
- (d) The Covered farm shall adequately maintain all Agricultural Water sources to the extent they are under the Covered Farm's control (e.g., wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto Covered Produce or Food Contact Surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of Covered Produce to the extent practicable and appropriate under the circumstances.
- (e) As necessary and appropriate, the Covered Farm shall implement measures necessary to reduce the potential for contamination of Covered Produce with known or reasonably foreseeable hazards as a result of contact of Covered Produce with pooled water (e.g., using protective barriers or staking to keep Covered Produce from touching the ground or using an alternative irrigation method).
- (f) Treating Agricultural Water
- (i) Any method used to treat Agricultural Water (e.g., physical treatment, including using a pesticide device as defined by the EPA; EPA-registered antimicrobial pesticide product; or other suitable method) shall be deemed effective to make the water safe and of adequate sanitary quality for its intended use provided such method ensures the Agricultural Water meets the relevant microbial quality criteria in 330 CMR 34.04(5)(g), as applicable.
 - (ii) The Covered Farm shall deliver any treatment of Agricultural Water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and consistently meets the relevant microbial quality criteria in 34.04(5)(g), as applicable.
 - (iii) The Covered Farm shall monitor any treatment of Agricultural Water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and consistently meets the relevant microbial quality criteria in 34.04(5)(g), as applicable.
- (g) Microbial Quality Criteria

- (i) When a Covered Farm uses Agricultural Water for any one or more of the following purposes, the Covered Farm shall ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of Agricultural Water, and the Covered Farm shall not use untreated surface water for any of the following purposes:
 - 1. As sprout irrigation water;
 - 2. Applied in any manner that directly contacts Covered Produce during or after harvest activities (e.g., water applied to Covered Produce for washing or cooling activities, and water applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts Covered Produce during or after harvest activities;
 - 3. To contact Food Contact Surfaces, or to make ice that will contact Food Contact Surfaces; and
 - 4. For washing hands during and after harvest activities.
- (ii) When a Covered Farm uses Agricultural Water during growing activities for Covered Produce (other than sprouts) using a direct water application method, the following criteria apply (unless the Covered Farm establishes and uses alternative criteria in accordance with 330 CMR 34.04(5)(m)):
 - 1. A geometric mean (GM) of the Covered Farm's Agricultural Water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of the Covered Farm's water quality distribution); and
 - 2. A statistical threshold value (STV) of the Covered Farm's Agricultural Water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of the Covered Farm's water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).
- (h) If a Covered Farm determines or has reason to believe that Agricultural Water is not safe or of adequate sanitary quality for its intended use as required under 330 CMR 34.04(5)(a) or if the Agricultural Water does not meet the microbial quality criterion for the specified purposes as required under 330 CMR 34.04(5)(g), the Covered Farm shall immediately discontinue that use(s), and before the Covered Farm may use the water source and distribution system again for the intended use(s), the Covered Farm shall either:
 - (i) Re-inspect the entire affected Agricultural Water system to the extent it is under the Covered Farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto Covered Produce or Food Contact Surfaces, make necessary changes, take adequate measures to determine if the changes were effective, and, as applicable, adequately ensure the Agricultural Water meets the microbial quality criterion in 330 CMR 34.04(5)(g);
or
 - (ii) Treat the water in accordance with the requirements of 330 CMR 34.04(5)(f).
- (i) If a Covered Farm has determined its Agricultural Water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required

under 330 CMR 34.03(5)(g), as soon as practicable and no later than the following year, the use shall be discontinued unless the Covered Farm either:

- (i) Applies a time interval(s) (in days) or a (calculated) log reduction, or both, by:
 1. Applying a time interval between last irrigation and harvest using either:
 - A. A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of the geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in 330 CMR 34.04(5)(g) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of four (4) consecutive days; or
 - B. An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with 330 CMR 34.04(5)(m); or
 2. Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, or both, to meet the microbial quality criteria in 330 CMR 34.04(5)(g) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided there is adequate supporting scientific data and information;
 - (ii) Re-inspects the entire affected Agricultural Water system to the extent it is under the Covered Farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto Covered Produce or Food Contact Surfaces, make necessary changes, take adequate measures to determine if the changes were effective, and adequately ensure the Agricultural Water meets the microbial quality criteria in 330 CMR 34.04(5)(g) (or any alternative microbial criteria, if applicable); or
 - (iii) Treats the water in accordance with the requirements of 330 CMR 34.04(5)(f).
- (j) Agricultural Water Testing Frequency
- (i) There is no requirement to test any Agricultural Water that is subject to the requirements of 330 CMR 34.04(5)(g) when:
 1. The Covered Farm receives water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 C.F.R. part 141, that furnishes water meeting the microbial requirements under those regulations or under 310 CMR 22.00, and there are Public Water System results or certificates of compliance demonstrating the water meets that requirement;
 2. The Covered Farm receives water from a public water supply furnishing water that meets the microbial quality requirement in 330 CMR 34.04(5)(g), and the Covered Farm has public water system results or certificates of compliance demonstrating the water meets that requirement; or
 3. The Covered Farm treats water in accordance with 330 CMR 34.04(5)(f).
 - (ii) Except as provided in paragraph (i) of this section, the Covered Farm shall take the following steps for each source of water used for purposes that are subject to the requirements of 330 CMR 34.04(5)(g)(ii):

1. Conduct an initial survey to develop a microbial water quality profile of the Agricultural Water source, which shall be conducted:
 - A. For an untreated surface water source, by taking a minimum total of twenty (20) samples of Agricultural Water (or an alternative testing frequency the Covered Farm establishes and uses, in accordance with 330 CMR 34.04(5)(m)) over a minimum period of two (2) years, but not greater than four (4) years.
 - B. For an untreated ground water source, by taking a minimum total of four (4) samples of Agricultural Water during the growing season or over a period of one (1) year.
2. The samples of Agricultural Water shall be representative of the Covered Farm's use of the water and shall be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic Escherichia coli (E. coli) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. The Covered Farm shall determine the appropriate way(s) in which the water may be used based on the Covered Farm's microbial water quality profile in accordance with 330 CMR 34.04(5)(i).
3. Update the microbial water quality profile annually as required under this section, and otherwise required under paragraph (ii)(4) of this section.
4. Conduct an annual survey to update the microbial water quality profile of the Covered Farm's Agricultural Water.
 - A. After the initial survey described in paragraph (ii)(1) of this section, the Covered Farm shall test the water annually to update its existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. The Covered Farm shall analyze:
 - a. For an untreated surface water source, a minimum number of five (5) samples per year (or an alternative testing frequency that the Covered Farm establishes and uses, in accordance with 330 CMR 34.04(5)(m)).
 - b. For an untreated ground water source, a minimum of one (1) sample per year.
 - B. The samples of Agricultural Water shall be representative of the Covered Farm's use of the water and shall be collected as close in time as practicable to, but prior to, harvest.
 - C. To update the microbial water quality profile, the Covered Farm shall calculate revised GM and STV values using current annual survey data, combined with the most recent initial or annual survey data from within the previous four (4) years, to make up a rolling data set of:
 - a. At least twenty (20) samples for untreated surface water sources; and
 - b. At least four (4) samples for untreated ground water sources.
 - D. The Covered Farm shall modify water use, as appropriate, based on the revised GM and STV values in its updated microbial water quality profile in accordance with 330 CMR 34.04(5)(i).
5. If the Covered Farm determines or has reason to believe the microbial water quality profile no longer represents the quality of the water (e.g., if there are

significant changes in adjacent land use that are reasonably likely to adversely affect the quality of the Covered Farm's water source), it shall develop a new microbial water quality profile reflective of the time period at which the Covered Farm believes the water quality profile changed.

A. To develop a new microbial water quality profile, the Covered Farm shall calculate new GM and STV values using its current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:

- a. At least twenty (20) samples for untreated surface water sources; and
- b. At least four (4) samples for untreated ground water sources.

B. The Covered Farm shall modify its water use based on the new GM and STV values in its new microbial water quality profile in accordance with 34.04(5)(i).

(iii) If the Covered Farm uses untreated ground water for the purposes that are subject to the requirements of 330 CMR 34.04(5)(g)(i), it shall initially test the microbial quality of each source of the untreated ground water at least four (4) times during the growing season or over a period of one (1) year, using a minimum total of four (4) samples collected to be representative of the intended use(s). Based on these results, the Covered Farm shall determine whether the water can be used for that purpose, in accordance with 330 CMR 34.04(5)(i). If the four (4) initial sample results meet the microbial quality criteria of 330 CMR 34.04(5)(g), the Covered Farm may test once annually thereafter, using a minimum of one (1) sample collected to be representative of the intended use(s). The Covered Farm shall resume testing at least four (4) times per growing season or year if any annual test fails to meet the microbial quality criteria in 330 CMR 34.04(5)(g).

(k) Testing Personnel

(i) A Covered Farm may meet the requirements related to Agricultural Water testing required under 330 CMR 34.04(5)(j) using:

1. Test results from the Covered Farm's Agricultural Water source(s) performed by the Covered Farm or a Person or entity acting on the Covered Farm's behalf; or
2. Data collected by a third-party or parties, provided the water source(s) sampled by the third-party or parties adequately represents the Covered Farm's Agricultural Water source(s) sampled by the third-party or parties and all other applicable requirements of this section are met.

(ii) Agricultural Water samples shall be aseptically collected and tested using a method as set forth in 330 CMR 34.04(11)(a).

(l) Water Used During Harvest, Packing, and Holding Activities for Covered Produce

(i) The Covered Farm shall manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of Covered Produce and Food Contact Surfaces with known or reasonably foreseeable hazards (e.g., hazards that may be introduced into the water from soil adhering to the Covered Produce).

- (ii) The Covered Farm shall visually monitor the quality of water used during harvest, packing, and holding activities for Covered Produce (e.g., water used for washing Covered Produce in dump tanks, flumes, or wash tanks, and water used for cooling Covered Produce in hydrocoolers) for buildup of organic material.
- (iii) The Covered Farm shall maintain and monitor the temperature of water at a temperature appropriate for the commodity and operation (consider both time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into Covered Produce.

(m) Alternative Requirements

- (i) The Covered Farm may establish and use one or more of the following alternatives:
 1. An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in 330 CMR 34.04(5)(g)(ii).
 2. An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in 330 CMR 34.04(5)(i)1.
 3. An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under 330 CMR 34.04(5)(j)(ii)1.A..
 4. An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under 330 CMR 34.04(5)(j)(ii)(4)4.A..

(6) Biological Soil Amendments of Animal Origin and Human Waste.

(a) Requirements

- (i) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of 330 CMR 34.04(6)(d), or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.
- (ii) A biological soil amendment of animal origin is untreated if it:
 1. Has not been processed to completion in accordance with the requirements of 330 CMR 34.04(6)(d), or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea is untreated surface water, or the water used to make the tea has detectable generic *E. coli* in 100 mL of water;
 2. Has become contaminated after treatment;
 3. Has been recombined with an untreated soil amendment of animal origin;
 4. Is or contains a component that is untreated waste that the Covered Farm knows or has reason to believe is contaminated with a hazard or has been associated with Foodborne illness; or

5. Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

(b) Handling, Conveying, and Storing

- (i) The Covered Farm shall handle, convey, and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to Covered Produce, Food Contact Surfaces, areas used for a Covered Activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.
- (ii) The Covered Farm shall handle, convey, and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.
- (iii) The Covered Farm shall handle, convey, and store any biological soil amendment of animal origin it knows or has reason to believe may have become contaminated as if it was untreated.

(c) Prohibitions Regarding Use of Human Waste

- (i) The Covered Farm may not use human waste for growing Covered Produce, except sewage sludge biosolids used in accordance with the requirements of 310 CMR 32.00 and 330 CMR 31.00.

(d) Acceptable Treatment Processes

- (i) Each of the following treatment processes are acceptable for a biological soil amendment of animal origin the Covered Farm applies in the growing of Covered Produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of 330 CMR 34.04(6)(f):
 - 1. A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical, or biological processes that have been validated to satisfy the microbial standard in 330 CMR 34.04(6)(e) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157; or
 - 2. A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, or biological processes that have been validated to satisfy the microbial standard in 330 CMR 34.04(6)(e)(ii) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in 330 CMR 34.04(6)(e)(ii) include:
 - A. Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 degrees F (55 degrees C) for three (3) consecutive days and is followed by adequate curing; and
 - B. Turned composting that maintains aerobic conditions at a minimum of 131 degrees F (55 degrees C) for fifteen (15) days (which do not have to be

consecutive), with a minimum of five (5) turnings, and is followed by adequate curing.

(e) Microbial Standards

The following microbial standards apply to the treatment processes in 34.04(6)(d).

(i) *L. monocytogenes*:

1. Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.

(ii) *Salmonella* species:

1. Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.

(iii) *E. coli* O157:

1. Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

(iv) *Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams (or milliliter, if liquid is being sampled) of total solids; and less than 1,000 MPN fecal coliforms per gram (or milliliter, if liquid is being sampled) of total solids.

(f) Application Requirements and Minimum Intervals

The Covered Farm shall apply the biological soil amendments of animal origin in accordance with the following:

(i) If the biological soil amendment of animal origin is untreated, then it shall be applied in a manner that does not contact Covered Produce during or after application and minimizes the potential for contact with Covered Produce after application.

(ii) If the biological soil amendment of animal origin is treated by a scientifically valid controlled physical, chemical, or biological process, or combination of processes, in accordance with 330 CMR 34.04(6)(d)(i)2. to meet the microbial standard in 330 CMR 34.04(6)(e)(iv), then it shall be applied in a manner that minimizes the potential for contact with Covered Produce during and after application.

(iii) If the biological soil amendment of animal origin is treated by a scientifically valid controlled physical, chemical, or biological process, or combination of processes, in accordance with 330 CMR 34.04(6)(d)(i)1. to meet the microbial standard in 330 CMR 34.04(6)(e)(i)-(iii), then it shall be applied in any manner (i.e., no restrictions)..

(7) Domesticated and Wild Animals.

(a) Requirements Where Covered Activities Occur

(i) The requirements of 330 CMR 34.04(7) apply when a Covered Activity occurs in an outdoor area or a partially-enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate Covered Produce.

(ii) The requirements of 330 CMR 34.04(7) do not apply:

1. When a Covered Activity occurs in a fully-enclosed building; or
 2. To fish used in aquaculture operations.
- (b) Requirements Regarding Grazing Animals, Working Animals, and Animal Intrusion
- (i) If there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate Covered Produce, the Covered Farm shall:
 1. Assess the relevant areas used for a Covered Activity for evidence of potential contamination of Covered Produce as needed during the growing season (based on the Covered Produce; the Covered Farm’s practices and conditions; and observations and experience); and
 2. If significant evidence of potential contamination is found (such as observation of animals, animal excreta, or crop destruction), the Covered Farm shall evaluate whether the Covered Produce can be harvested and take measures reasonably necessary during growing to assist the Covered Farm later during harvest when it shall identify, and not harvest, Covered Produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.
 - (c) Nothing in this regulation authorizes the “taking” of any animals defined as endangered, threatened, or of special concern under M.G.L. c. 131A; 321 CMR 10.00; or listed under the Federal Endangered Species Act (16 U.S.C. § 1531-1544). In reference to animals, “taking” is to harass, harm, pursue, hunt, shoot, hound, kill, trap, capture, collect, process, disrupt the nesting, breeding, feeding, or migratory activity, or attempt to engage in any such conduct, or to assist such conduct. This regulation does not require Covered Farms to take measures to exclude animals from outdoor growing areas, to destroy animal habitat, or otherwise clear farm borders around outdoor growing areas or drainages.
- (8) Growing, Harvesting, Packing, and Holding Activities
- (a) Preventive Measures for Covered and Non-Covered Produce
 - (i) If a Covered Farm grows, harvests, packs, or holds Non-Covered Produce and conducts such activities on Covered Produce, and the excluded Produce is not grown, harvested, packed, or held in accordance with 330 CMR 34.04(8), the Covered Farm shall take measures during such Covered Activities, as applicable, to:
 1. Keep Covered Produce separate from Non-Covered Produce (except when Covered Produce and Non-Covered Produce are placed in the same container for distribution); and
 2. Adequately clean and sanitize, as necessary, any Food Contact Surfaces that contact nNon-Covered Produce before using such Food Contact Surfaces for Covered Activities on Covered Produce.
 - (b) Preventive Measures Immediately Prior to and During Harvest
 - (i) The Covered Farm shall take all measures reasonably necessary to identify, and not harvest, Covered Produce that is reasonably likely to be contaminated with a

known or reasonably foreseeable hazard, including steps to identify and not harvest Covered Produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting Covered Produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all Covered Produce to be harvested, regardless of the harvest method used.

(c) Handling Harvested Covered Produce During Covered Activities

- (i) The Covered Farm shall handle harvested Covered Produce during Covered Activities in a manner that protects against contamination with known or reasonably foreseeable hazards (e.g., by avoiding, to the degree practicable, contact of cut surfaces of harvested Produce with soil).

(d) Dropped Covered Produce Requirements

- (i) The Covered Farm shall not distribute dropped Covered Produce. Dropped Covered Produce is Covered Produce that drops to the ground before harvest. Dropped Covered Produce does not include root crops that grow underground (e.g., carrots), crops that grow on the ground (e.g., cantaloupe), or Produce that is intentionally dropped to the ground as part of harvesting (e.g., almonds).

(e) Preventive Measures During Packing

- (i) The Covered Farm shall package Covered Produce in a manner that prevents the formation of Clostridium botulinum toxin if such toxin is a known or reasonably foreseeable hazard (e.g., mushrooms).

(f) Preventive Measures During Food-Packing

- (i) The Covered Farm shall use Food-packing material that is adequate for its intended use, which includes being:
1. Cleanable or designed for single use; and
 2. Unlikely to support growth or transfer of bacteria.
- (ii) If the Food-packing material is reused, the Covered Farm shall take adequate steps to ensure that Food Contact Surfaces are clean, such as by cleaning Food-packing containers or using a clean liner.

(9) Equipment, Tools, Buildings, and Sanitation

- (a) Equipment and tools subject to 330 CMR 34.04(9) requirements are those that are intended to, or likely to, contact Covered Produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance (e.g., knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested Covered Produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact Covered Produce).

- (b) Buildings subject to the requirements in 330 CMR 34.09 include:
 - (i) Any fully- or partially-enclosed building used for Covered Activities, including minimal structures that have a roof but do not have any walls; and
 - (ii) Storage sheds, buildings, or other structures used to store Food Contact Surfaces (such as harvest containers and Food-packing materials).

- (c) General Requirements for Equipment and Tools
 - (i) The Covered Farm shall use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and
 - (ii) Equipment and tools shall be:
 - 1. Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and
 - 2. Stored and maintained to protect Covered Produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.
 - (iii) Seams on Food Contact Surfaces of equipment and tools used shall be either smoothly bonded or maintained to minimize accumulation of dirt, filth, Food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.
 - (iv) The Covered Farm shall inspect, maintain, and clean and, when necessary and appropriate, sanitize all Food Contact Surfaces of equipment and tools used in Covered Activities as frequently as reasonably necessary to protect against contamination of Covered Produce.
 - (v) The Covered Farm shall maintain and clean all non-Food Contact Surfaces of equipment and tools subject to 330 CMR 34.04(9) used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of Covered Produce.
 - (vi) If equipment such as pallets, forklifts, tractors, and vehicles are used such that they are intended to, or likely to, contact Covered Produce, the equipment shall be used in a manner that minimizes the potential for contamination of Covered Produce or Food Contact Surfaces with known or reasonably foreseeable hazards.

- (d) Requirements for Measuring, Regulating, or Recording Instruments or Controls
 - Instruments or controls used to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent growth of microorganisms of public health significance, shall be:
 - (i) Accurate and precise as necessary and appropriate in keeping with their purpose;
 - (ii) Adequately maintained; and
 - (iii) Adequate in number for their designated uses.

- (e) Requirements for Equipment Used in Covered Produce Transport
 - Equipment subject to 330 CMR 34.04(9) used to transport Covered Produce shall be:
 - (i) Adequately cleaned before use in transporting Covered Produce; and
 - (ii) Adequate for use in transporting Covered Produce.

(f) Requirements for Buildings

(i) All of the following requirements apply regarding buildings:

1. Buildings shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for Covered Activities to reduce the potential for contamination of Covered Produce or Food Contact Surfaces with known or reasonably foreseeable hazards. Buildings shall:
 - A. Provide sufficient space for placement of equipment and storage of materials;
 - B. Permit proper precautions to be taken to reduce the potential for contamination of Covered Produce, Food Contact Surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination shall be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and
2. The Covered Farm shall provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.

(ii) The Covered Farm shall implement measures to prevent contamination of Covered Produce and Food Contact Surfaces in the buildings, as appropriate, considering the potential for such contamination through:

1. Floors, walls, ceilings, fixtures, ducts, or pipes; and
2. Drip or condensate.

(g) Requirements for Domesticated Animals

(i) The Covered Farm shall take reasonable precautions to prevent contamination of Covered Produce, Food Contact Surfaces, and Food packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:

1. Excluding domesticated animals from fully-enclosed buildings where Covered Produce, Food Contact Surfaces, or Food-packing material is exposed; or
2. Separating domesticated animals in a fully-enclosed building from an area where a Covered Activity is conducted on Covered Produce by location, time, or partition.

(ii) Guard or guide dogs may be allowed in some areas of a fully-enclosed building if the presence of the dogs is unlikely to result in contamination of Produce, Food Contact Surfaces, or Food-packing materials.

(h) Requirements for Building Pest Control

(i) The Covered Farm shall take those measures reasonably necessary to protect Covered Produce, Food Contact Surfaces, and Food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.

(ii) For fully-enclosed buildings, the Covered Farm shall take measures to exclude pests from its buildings.

- (iii) For partially-enclosed buildings, the Covered Farm shall take measures to prevent pests from becoming established in its buildings (e.g., by use of screens or by monitoring for the presence of pests and removing them when present).
- (i) Requirements for Toilet Facilities
 - All of the following requirements apply to toilet facilities:
 - (i) The Covered Farm shall provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.
 - (ii) The toilet facilities shall be designed, located, and maintained to:
 - 1. Prevent contamination of Covered Produce, Food Contact Surfaces, areas used for a Covered Activity, water sources, and water distribution systems with human waste;
 - 2. Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper; and
 - 3. Provide for the sanitary disposal of waste and toilet paper.
 - (iii) During growing activities that take place in a fully-enclosed building, and during harvesting, packing, or holding activities, the Covered Farm shall provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.
- (j) Requirements for Hand-Washing Facilities
 - All of the following requirements apply to hand-washing facilities:
 - (i) The Covered Farm shall provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during Covered harvest, packing, or holding activities.
 - (ii) Hand-washing facilities shall be furnished with:
 - 1. Soap (or other effective surfactant);
 - 2. Running water that satisfies the requirements of 330 CMR 34.04(5)(g)(i) for water used to wash hands; and
 - 3. Adequate drying devices (e.g., single service towels, sanitary towel service, or electric hand dryers).
 - (iii) The Covered Farm shall provide for appropriate disposal of waste (e.g., waste water and used single-service paper towels) associated with hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating Covered Produce, Food Contact Surfaces, areas used for a Covered Activity, Agricultural Water sources, and Agricultural Water distribution systems with known or reasonably foreseeable hazards.
 - (iv) The Covered Farm shall not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.
- (k) Requirements for Controlling and Disposing of Sewage
 - All of the following requirements apply for the control and disposal of sewage:
 - (i) The Covered Farm shall dispose of sewage into an adequate sewage or septic system or through other adequate means.

- (ii) The Covered Farm shall maintain sewage and septic systems 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 with known or reasonably foreseeable hazards.
 - (iii) The Covered Farm shall manage and dispose of leakages or spills of human waste in a manner that prevents contamination of Covered Produce, and prevents or minimizes contamination of Food Contact Surfaces, areas used for a Covered Activity, Agricultural Water sources, or Agricultural Water distribution systems.
 - (iv) After a significant event (e.g., flooding or an earthquake) that could negatively impact a sewage or septic system, the Covered Farm shall take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate Covered Produce, Food Contact Surfaces, areas used for a Covered Activity, Agricultural Water sources, or Agricultural Water distribution systems.
- (l) Requirements for Controlling and Disposing of Trash, Litter, and Waste
All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for Covered Activities:
- (i) The Covered Farm shall convey, store, and dispose of trash, litter, and waste to:
 1. Minimize the potential for trash, litter, or waste to attract or harbor pests; and
 2. Protect against contamination of Covered Produce, Food Contact Surfaces, areas used for a Covered Activity, Agricultural Water sources, and Agricultural Water distribution systems with known or reasonably foreseeable hazards
 - (ii) The Covered Farm shall adequately operate systems for waste treatment and disposal so they do not constitute a potential source of contamination in areas used for a Covered Activity.
- (m) Requirements for Plumbing
The plumbing shall be of an adequate size and design, and be adequately installed and maintained to:
- (i) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for Covered Activities, for sanitary operations, or for hand-washing and toilet facilities;
 - (ii) Properly convey sewage and liquid disposal waste;
 - (iii) Avoid being a source of contamination to Covered Produce, Food Contact Surfaces, areas used for a Covered Activity, or Agricultural Water sources; and
 - (iv) Not allow backflow from, or cross connection between, piping systems that discharge wastewater or sewage and piping systems that carry water used for a Covered Activity, for sanitary operations, or for use in hand-washing facilities.
- (n) Requirements for Controlling Animal Excreta and Litter
- (i) If the Covered Farm has domesticated animals, to prevent contamination of Covered Produce, Food Contact Surfaces, areas used for a Covered Activity, Agricultural Water sources, or Agricultural Water distribution systems with animal waste, the Covered Farm shall:
 1. Adequately control their excreta and litter; and

2. Maintain a system for control of animal excreta and litter.

(10) Sprouts.

- (a) The requirements of 330 CMR 34.04(10) apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.
- (b) Requirements for Seeds or Beans Used to Grow Sprouts
In addition to the requirements of 330 CMR 34.04(1)-(9), all of the following requirements apply to seeds or beans used to grow sprouts.
 - (i) The Covered Farm shall take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans used for sprouting.
 - (ii) Except as provided in paragraph (iii) of this section, any Person who knows or has reason to believe that a lot of seeds or beans may be contaminated with a pathogen (either because it has been associated with foodborne illness; or based on microbial test results, including a positive finding of a pathogen in tests required under 330 CMR 34.04(10)(d)), the Covered Farm shall:
 1. Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter commerce; and
 2. Report the information (association with illness or findings from microbial testing, or both) to the seed grower, distributor, supplier, or other entity from whom the Covered Farm received the seeds or beans.
 - (iii) If the Person's reason to believe that a lot of seeds or beans may be contaminated was based only on microbial test results:
 1. The Covered Farm is not required to take the steps set forth in paragraph (ii)1. of this section if it treats the lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans; or
 2. The Covered Farm is not required to take the steps set forth in paragraphs (ii)1. and 2. of this section if it later determines, through appropriate follow-up actions, that the lot of seeds or beans is not the source of contamination (e.g., the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).
 - (iv) The Covered Farm shall visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.
 - (v) The Covered Farm shall either:
 1. Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or
 2. Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when

applying appropriate additional treatment of the seeds or beans at the Covered Farm immediately before sprouting), provided it obtains documentation (e.g., Certificate of Conformance) from the grower, distributor, or supplier that:

- a. The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and
- b. The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

(c) Requirements for Growing, Harvesting, Packing, and Holding Sprouts

The Covered Farm shall take all of the following measures for growing, harvesting, packing, and holding sprouts:

- (i) The Covered Farm shall grow, harvest, pack, and hold sprouts in a fully-enclosed building.
- (ii) Any Food Contact Surfaces used to grow, harvest, pack, or hold sprouts shall be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts.
- (iii) The Covered Farm shall conduct testing during growing, harvesting, packing, and holding sprouts, as specified in 330 CMR 34.04(10)(d).
- (iv) The Covered Farm shall establish and implement a written environmental monitoring plan, as specified in 330 CMR 34.04(10)(e).
- (v) The Covered Farm shall take certain actions if it detects *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment, as specified in 330 CMR 34.04(10)(f).
- (vi) The Covered Farm shall establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens, as specified in 330 CMR 34.04(10)(g).
- (vii) The Covered Farm shall take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen, as specified in 330 CMR 34.04(10)(h).

(d) Requirements for Testing During Growing, Harvesting, Packing, and Holding Sprouts

All of the following testing shall be done during growing, harvesting, packing, and holding sprouts:

- (i) The Covered Farm shall test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of 330 CMR 34.04(10)(f).
- (ii) The Covered Farm shall either:
 1. Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (iii) of this section, in accordance with the requirements of 330 CMR 34.04(10)(g); or
 2. If testing spent sprout irrigation water is not practicable for *E. coli* O157:H7, *Salmonella* species, and any other pathogens meeting the criteria in 330 CMR 34.04(10)(d)(iii), in accordance with the requirements of 330 CMR 34.04(10)(g).

- (iii) In addition to *E. coli* O157:H7 and *Salmonella* species, the Covered Farm shall conduct tests as provided in paragraph (ii) of this section for additional pathogens when the following conditions are met:
 - 1. Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and
 - 2. A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water, or sprouts.

- (e) Requirements for Testing Environment for *Listeria* species or *L. monocytogenes*
All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes*.
 - (i) The Covered Farm shall establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment.
 - (ii) The written environmental monitoring plan shall be directed to sampling and testing for either *Listeria* species or *L. monocytogenes*.
 - (iii) The written environmental monitoring plan shall include a sampling plan that specifies:
 - 1. What the Covered Farm will test collected samples for (i.e., *Listeria* species or *L. monocytogenes*);
 - 2. How often environmental samples will be collected, which shall be no less than monthly, and at what point during production the samples are collected; and
 - 3. Sample collection sites; the number and location of sampling sites shall be sufficient to determine whether measures are effective and shall include appropriate Food Contact Surfaces and non-Food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.
 - (iv) The Covered Farm shall aseptically collect environmental samples and test them for *Listeria* species or *L. monocytogenes* using a method as set forth in 330 CMR 34.04(11)(c).
 - (v) The written environmental monitoring plan shall include a corrective action plan that, at a minimum, requires the Covered Farm to take the actions in 330 CMR 34.04(10)(f), and details when and how those actions will be accomplished, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*.

- (f) Requirements for Positive *Listeria* species or *L. monocytogenes* Test
The Covered Farm shall, at a minimum, take the following actions if it detects *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment:
 - (i) Conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche;

- (ii) Clean and sanitize the affected surfaces and surrounding areas;
 - (iii) Conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated;
 - (iv) Conduct finished product testing when appropriate;
 - (v) Perform any other actions necessary to prevent recurrence of the contamination; and
 - (vi) Take appropriate action to prevent any Adulterated Produce from entering into commerce.
- (g) Requirements for Collecting and Testing Samples of Spent Sprout Irrigation Water or Sprouts
- All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for spent sprout irrigation water or sprouts for pathogens, as required in 330 CMR 34.04(10)(d):
- (i) The Covered Farm shall establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure the collected samples are representative of the production batch when testing for contamination.
 - (ii) In accordance with the written sampling plan under paragraph (i) of this section, the Covered Farm shall aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens. The Covered Farm shall not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in 330 CMR 34.04(10)(d)(iii).
 - (iii) The written sampling plan shall include a corrective action plan that, at a minimum, requires the Covered Farm to take the actions in 330 CMR 34.04(10)(h), and details when and how it will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in 330 CMR 34.04(10)(d)(3).
- (h) Requirements for Spent Sprout Irrigation Water or Sprouts Testing Positive for Pathogen
- The Covered Farm shall, at a minimum, take the following actions if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in 330 CMR 34.04(10)(d)(iii).
- (i) Take appropriate action to prevent any Food that is adulterated under section 402 of the Federal Food, Drug and Cosmetic Act from entering into commerce;
 - (ii) Take the steps required in 330 CMR 34.04(10)(b)(ii) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under 330 CMR 34.04(10)(b)(iii));
 - (iii) Clean and sanitize the affected surfaces and surrounding areas; and
 - (iv) Perform any other actions necessary to prevent recurrence of the contamination.

(11) Analytical Methods.

- (a) The Covered Farm shall use the following methods to test the quality of water to satisfy the requirements of 330 CMR 34.04(5)(j):
 - (i) The method of analysis published by the EPA, “Method 1603: Escherichia Coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA-821-R-09-007,” December, 2009, as cited in 21 C.F.R. § 112.151; or
 - (ii) A scientifically valid method that is at least equivalent to the method of analysis in (i) of this section, in terms of accuracy, precision, and sensitivity; or
 - (iii) For any other indicator of fecal contamination the Covered Farm may test for pursuant to 330 CMR 34.04(5)(m)(i)1., a scientifically valid method.

- (b) The Covered Farm shall use the following methods to test the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes to satisfy the requirements of 330 CMR 34.04(10)(d)(i):
 - (i) The method of analysis described in “Testing Methodology for Listeria species of L. monocytogenes in Environmental Samples,” Version 1, October 2015, FDA, as cited in 21 C.F.R. § 112.152; or
 - (ii) A scientifically valid method that is at least equivalent to the method of analysis in (i) of this section, in terms of accuracy, precision, and sensitivity.

- (c) The Covered Farm shall use the following methods to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of 330 CMR 34.04(10)(d)(ii), (iii):
 - (i) For E. coli O157 Salmonella species:
 1. The method of analysis described in “Testing Methodologies for E. coli O157 and Salmonella species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, October 2015, FDA, as cited in 21 C.F.R. § 112.153; or
 2. A scientifically valid method that is at least equivalent to the method of analysis in (i)1. of this section, in terms of accuracy, precision, and sensitivity; and
 3. For any other pathogen(s) meeting the criteria in 330 CMR 34.04(10)(d)(iii), a scientifically valid method.

(12) Off Farm Standards.

- (a) Inspections for Produce holding, washing, and packing facilities owned fully or in part, or jointly owned, with a majority interest by a primary production Farm, but not located on a primary production Farm or on acreage in close proximity are subject to all pertinent sections in compliance with M.G.L. c. 128, § 124 and 330 CMR 34.00.

(13) CQP.

- (a) Audits conducted under the CQP for Produce may be deemed to be in compliance with M.G.L. c. 128, § 124 and 330 CMR 34.00.

34.05: Inspections.

(1) Right of Entry.

- (a) In the case of a Covered Farm, the Department shall have the right to enter upon and inspect such Covered Farm during reasonable hours to ensure compliance with the Produce Safety Rule and 330 CMR 34.00 et seq.
- (b) In the case of a Farm that has opted into the Registry and inspection program under 330 CMR 34.03(2)(a), the Department may enter upon and inspect such Farm during reasonable hours to ensure compliance with the Produce Safety Rule and 330 CMR 34.00 et seq.
- (c) Inspection areas may include, without limitation, any area or conveyance that is part of or used by the Farm, including the following:
 - (i) fields;
 - (ii) buildings;
 - (iii) vehicles; and
 - (iv) any other location where Produce is grown, harvested, packed, stored, or held.

(2) Initial; Routine Inspection.

- (a) Initial and Routine Inspections shall be coordinated with the Farm and shall take place during the normal business hours of the Farm being inspected, on an annual basis.
- (b) Inspectors shall be given access to all areas of a Covered Farm the ability to review and copy any and all records required to be maintained pursuant to the Produce Safety Rule, M.G.L. c. 128, § 124, and 330 CMR 34.00.

(3) Follow-up Inspections.

- (a) Follow-up Inspections shall:
 - (i) Be conducted to ensure that identified corrective actions, prior non-compliance is corrected and documented;
 - (ii) Take place during normal business hours; and
 - (iii) Will consider the priority of the corrective action.

(4) For-Cause Inspections shall:

- (a) Occur in response to a Produce safety concern; or
- (b) Occur when a complaint, recall, or report of action related to a health risk has occurred or is imminent.

(5) Completion of Inspections:

- (a) Upon completion of an inspection during which the Department does not observe any violations, whether an Initial Inspection, Routine Inspection, Follow-up Inspection, or a For-Cause Inspection, the Department may issue an Inspection Certificate to the Farm.
 - (b) Upon completion of an inspection during which the Department observes violations, whether an Initial Inspection, Routine Inspection, Follow-up Inspection, or a For-Cause Inspection, the Department shall issue a Produce Inspection Observation Form, which shall outline corrective actions to be taken prior to a Follow-up Inspection.
- (6) Covered Farms or Farms that voluntarily request inspection under 34.03(4) shall be subject to unannounced inspections, as determined by the Department to protect public health and safety.
- (7) Inspections initiated from a specific complaint or request need not be limited to that complaint or request. At the time of inspection, the Inspector shall record all observations and violations. Such inspections may include obtaining samples and specimens for laboratory analysis.
- (8) A certificate of analysis from a laboratory of the DPH, the FDA, the USDA, or other accredited laboratory acceptable to the Department shall be considered evidence of the ingredients and contents of any sample or specimen submitted for analysis by the Department.

34.06: Adulterated and Misbranded Produce

- (1) The sale, or offering for sale, of Adulterated Produce or Misbranded Produce in the Commonwealth shall be prohibited.
- (2) The Department may investigate any allegation of adulteration, misbranding, illness, or injury related to or alleged to have been caused by Produce grown and offered for sale in the Commonwealth.

34.07: Compliance and Enforcement

- (1) Violations of 330 CMR 34.03, 34.04, and 34.06 shall be subject to the enforcement provisions in 330 CMR 34.07.
- (2) If an inspection or investigation reveals any violation of 330 CMR 34.00, which does not rise to the level of an Egregious Condition, the Farm shall be notified in writing of such violation(s) and of any corrective actions necessary to cure the violation, in addition to the time period within which corrective actions shall be completed.

- (3) Notices of violation(s) shall be provided in writing and shall include the following information when applicable:
- (a) Statement of violation(s) found;
 - (b) Legal basis for findings;
 - (c) Level of severity;
 - (d) Corrective actions to be implemented; and
 - (e) Time period to correct violations.
- (4) After notification, if the Farm fails to correct a violation within the specified time period, the Department may suspend or revoke an Inspection Certificate issued under 330 CMR 34.03.
- (5) The Department may withdraw a Covered Farm's Qualified Exemption at any time if it identifies through any Inspection, report, documentation, or finding that an Egregious Condition or imminent threat to public health and safety exists or has existed.
- (6) If an inspection or investigation reveals a violation of 330 CMR 34.00, which constitutes an Egregious Condition warranting immediate action, the Department may issue an Order for:
- (a) Recall;
 - (b) Embargo;
 - (c) Quarantine; or
 - (d) Destruction.
- (7) The Department shall provide an Order issued under 330 CMR 34.07(6), to the Farm, or if no one is present, shall conspicuously post the Order on the premises. The Order shall specify the:
- (a) Statement of violation(s) resulting in the Order;
 - (b) Legal basis for findings;
 - (c) Actions to be taken; and
 - (d) Appeal rights and procedures.

- (8) The Department shall affix a tag, label, or otherwise identify any Produce subject to the Recall, Embargo, Quarantine, or Destruction Order. Such identification shall state that the Produce:
- (a) Is believed to be Adulterated Produce, Misbranded Produce, or is or has been associated with an Egregious Condition, or presents an immediate risk to public health;
 - (b) Has been Embargoed, Quarantined, or ordered Destroyed; and
 - (c) Cannot be moved, used, sold, or disposed of without prior Department permission.
- (9) The Department shall permit storage of the Produce under conditions specified in the Quarantine Order, unless storage is not possible without imminent threat to public health, in which case immediate Destruction of the Produce may be ordered. If the Quarantine Order addresses Adulterated Produce or Misbranded Produce, the Department shall take necessary steps for the Destruction, or reconditioning of the Produce.
- (10) The Farm shall be responsible for the storage of Embargoed or Quarantined Produce. If appropriate storage is unavailable, the Farm shall be responsible for any costs incurred to store such Produce. The Farm is responsible for any additional fees associated with the storage of such Produce, including any transportation costs.
- (11) Any Person who is an owner or operator of a Farm that is subject to an Order issued under 330 CMR 34.07 shall be jointly and severally liable for compliance with the Order.
- (12) Nothing in this section shall be construed to limit the Department's authority to issue an Order to respond to a condition that may present a public health hazard, or to issue Orders necessary to effectuate the purposes of the Produce Safety Rule and 330 CMR 34.00. This shall apply whether the Produce is Adulterated Produce through microbial or non-microbial means, or Misbranded Produce.

34.08: Appeals

- (1) Any Person aggrieved by an Order may, within twenty-one (21) days after the Department provides such order under 330 CMR 34.07(7), request a hearing before the Department pursuant to M.G.L. c. 30A. A request for an adjudicatory hearing shall be made in writing to the Department as instructed in the Order.

34.09: Records

- (1) Records required to be maintained shall:

- (a) Include, as applicable:
 - (i) The name and location of the Farm;
 - (ii) Actual values and observations obtained during monitoring;
 - (iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of Covered Produce applicable to the record;
 - (iv) The location of growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record;
 - (v) The date and time of the activity documented;
 - (vi) Any information required under the Federal Act, the Produce Safety Rule, and 330 CMR 34.00 et seq.; and
 - (vii) Any other information the Department shall require.
- (b) Be created at the time an activity is performed or observed;
- (c) Be accurate, legible, and indelible;
- (d) Be signed and dated by the Person who performed the activity documented;
- (e) Be kept for at least two (2) years from the date of creation;
- (f) Be kept as:
 - (i) Original records;
 - (ii) True copies; or
 - (iii) Electronic records.

34.10: Qualified Exemption

- (1) A Covered Farm is eligible for a Qualified Exemption and associated modified requirements in a calendar year if:
 - (a) During the previous three (3) year period preceding the applicable calendar year, the average annual monetary value of the Food the Covered Farm sold directly to Qualified End-Users during such period exceeded the average annual monetary value of the Food the Covered Farm sold to all other buyers during that period; and
 - (b) The average annual monetary value of all Food the Farm sold during the three (3) year period preceding the applicable calendar year was less than five-hundred thousand dollars (\$500,000), Adjusted For Inflation.
- (2) Qualified Exempt Farms are subject to the requirements of:
 - (a) 330 CMR 34.03;
 - (b) 330 CMR 34.06;

(c) 330 CMR 34.07; and

(d) 330 CMR 34.09.

(3) In addition to the portions of this regulation enumerated in (2) above, Qualified Exempt Farms are subject to the following modified requirements:

- (a) When a Food packaging label is required on Food that would otherwise be Covered Produce under the Federal Food, Drug and Cosmetic Act, the Qualified Exempt Farm shall include prominently and conspicuously on the Food packaging label the name and the complete business address of the Farm where the Produce was grown;
- (b) When a Food packaging label is not required on Food that would otherwise be Covered Produce under the Federal Food, Drug and Cosmetic Act, the Qualified Exempt Farm shall prominently and conspicuously display, at the point of purchase, the name and complete business address of the Farm where the Produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the Produce in the normal course of business, or, in the case of Internet sales, in an electronic notice; and
- (c) The complete business address required under (3)(a) and (3)(b) of this section shall include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

REGULATORY AUTHORITY

330 CMR 34.00: M.G.L. c. 128, § 124.