Produce Safety
ALLIANCE

FSMA Produce Safety Rule Regulatory Reference Table

Disclaimer

This educational tool was designed to provide produce growers and packers with an easy-to-use reference table that outlines the Food Safety Modernization Act (FSMA) Produce Safety Rule provisions. The regulatory requirements are summarized by subpart within this document, but this document does not represent the regulation in full. Using this tool does not guarantee compliance with the regulation but is meant to help navigate the regulation to quickly identify requirements. The complete *Title 21 of the Code of Federal Regulations, Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (a.k.a., the Produce Safety Rule)* can be found at the FDA's website at: **http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf**. The codified section is included in the FSMA section of this manual.

Tool Design and Use

The first table shown in this tool, the **Summary Table**, provides a broad overview of what is included in each of the regulation's subparts, including their titles and section numbers.

After the Summary Table is a collection of **Subpart Tables** where subparts in the FSMA Produce Safety Rule are outlined with a general description of what they cover. While much of the language in these tables is verbatim from the FSMA Produce Safety Rule, there are instances where some sentences have been shortened for ease of use.

There are four primary columns in each **Subpart Table**.

- The first column denotes the subpart section in which the provision is located.
- The second column identifies the subpart number.
- The third column summarizes the language of the FSMA Produce Safety Rule provision.
- The last column denotes the PSA module where the information can be found. Subparts M, P, Q, and R do not contain references to the PSA modules. These subparts focus on regulatory areas beyond the scope of this curriculum. Subpart O also does not contain references to curriculum modules since this information (Records) applies to all curriculum modules.

Summary Table

Subpart	Numbers	Section Description
A – General Provisions	112.1-112.7	Produce covered and not covered by regulation, definitions, who is subject to requirements, eligibility for qualified exemptions, modified requirements for exemptions, records kept for exemptions
B – General Requirements	112.11-112.12	General requirements, alternatives to requirements
C – Personnel Qualifications and Training	112.21-112.30	Training requirements for those who handle produce or food contact surfaces, supervisor requirements, training record requirements
D – Health and Hygiene	112.31-112.33	Measures to prevent contamination from ill or injured workers, hygienic practices, prevention of contamination from visitors
E – Agricultural Water	112.41-112.50	General water quality requirements, and criteria for certain intended uses, water source and water distribution system inspection, testing frequency, sampling and analysis requirements, corrective actions including treatment of agricultural water, measures to take during harvest, packing, and holding activities, permissible alternatives, recordkeeping requirements
F – Biological Soil Amendments of Animal Origin and Human Waste	112.51-112.60	Determining the status of a biological soil amendment of animal origin, handling, conveying, and storage of soil amendments, prohibitions for use of human waste, acceptable treatment processes, microbial standards, application requirements and intervals, recordkeeping requirements
G – Reserved		
H – Reserved		
I – Domesticated and Wild Animals	112.81-112.84	Requirements for working and domesticated animals, animal grazing in fields, threatened or endangered species protection, management of animal intrusion events
J – Reserved		
K – Growing, Harvesting, Packing, and Holding Activities	112.111-112.116	Measures to take if growing both covered and excluded produce, handling harvested produce, exclusion of dropped produce for fresh market, packaging activities and packing material requirements

L – Equipment, Tools, Buildings, and Sanitation	112.121-112.140	Requirements for maintenance of equipment, tools, and buildings, requirements for calibration of instruments (e.g. thermometers), transportation of covered produce, pest control, toilet and handwashing facilities, sewage disposal, litter management, plumbing, domesticated animal excreta and litter
M – Sprouts	112.141-112.150	Requirements for growing, harvesting, and handling sprouts, testing requirements, management of sprout irrigation water, records required
N – Analytical Methods	112.151-112.153	Acceptable analytical methods for testing agricultural water quality for produce other than sprouts, for the sprout growing, harvesting, packing, and holding environments, and spent sprout irrigation water
O – Records	112.161-112.167	Record keeping requirements, storage, duration, accessibility, acceptable formats, disclosure of records outside FDA
P – Variances	112.171-112-182	Who may request variances, state, tribe and foreign country requests, data and information to submit, processing, approval, denial, modification, revocation of variance requests
Q – Compliance and Enforcement	112.192-112.193	Criteria and definitions as applicable to FD&C Act, failure to comply, coordination or education and enforcement
R – Withdrawal of Qualified Exemptions	112.201-112.213	FDA procedures and reasons for withdrawal of qualified exemptions, procedure for submitting appeals, requirements for requesting an informal hearing, timeframe for appeals, circumstances to reinstate a qualified exemption

Subpart A – General Provisions

	Number	Requirement Description	Module #
A	112.1(a)	Outline of foods covered by the regulation, which in general covers produce (raw agricultural commodities) unless excluded by 112.2	1
A	112.1(b)	Covered produce includes the following: 1) 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 uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guava, 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, pineapple, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, sourop, spinach, sprouts (such as alfalfa 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 2) Mixes of intact fruits and vegetables (such as fruit baskets)	1
A	112.2(a)	Produce that is not covered by this part: 1) 'Rarely consumed raw' produce: 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. 2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and 3) Produce that is not a raw agricultural commodity	1

A	112.2(b)	Produce is eligible for exemption under these conditions (except as noted in 112.2(b)(1), (2), and (3)): 1) The produce receives commercial processing (including refining and distilling) that adequately reduces the presence of microorganisms of public health significance (e.g., processing of tomato paste or shelf stable tomatoes, processing produce into products such as sugar, oil, spirits, wines, and beer) 2) You must disclose in documents accompanying the produce, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance"; and 3) You must either: i) Annually obtain written assurance, subject to the requirements of 112.2(b)(6), from the customer that performs the commercial processing described in 112.2(b)(1) that the customer has established and is following procedures that adequately reduce the presence of microorganisms of public health significance; or ii) Annually obtain written assurance, subject to the requirements of 112.2(b)(6), from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in 112.2(b)(1) and that the customer: A) Will disclose in documents accompanying the food that the food is "not processed to adequately reduce the presence of microorganisms of public health significance"; and B) Will only sell to another entity that agrees, in writing, it will either: 1) Follow procedures that adequately reduce the presence of microorganisms of public health significance; or 2) Obtain similar written assurance from its customer that the produce will receive commercial processing described in 112.2(b)(1) and that there will be disclosure in documents accompanying the food, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance"; and 4) You must establish and maintain documentation of your compliance with requirements in 112.2(b)(2) and (3) in accordance with the requirements of subpart O (Records), including: i) Documents containing disclosures required under 112.2(b)(2); and ii) Annual written assurances obtained from customers required under 112.2(b)(3); and 5) The requirements of subpart A (General Provisions) and subpart Q (Compliance and Enforcement) apply to such produce; and 6) An entity provides a written assurance under 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance	1
A	112.3(a)	Definitions and interpretations of terms in section 201 of the FD&C Act (21 U.S.C. 321) apply to terms used in subpart A	

A	112.3(b)	Definitions of very small and small businesses: 1) Very small business – if subject to subpart A and on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $250,000 2) Small business – if subject to this subpart A and on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $500,000, and your farm is not a very small business as described above	1
A	112.3(c)	Definitions which apply to the FSMA Produce Safety Rule – see curriculum glossary or 112.3(c) for full list of FSMA Produce Safety Rule definitions	Glossary
A	112.4(a-b)	Outlines who is subject to the regulation – a) A "covered farm" is any farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of more than $25,000 (on a rolling basis), use 2011 as the baseline year for calculating the adjustment for inflation b) A farm is not a covered farm if it satisfies the requirements in 112.5 and has not had exemptions withdrawn according to subpart R (Withdrawal of Qualified Exemptions)	1
A	112.5(a)	Qualified exemptions and modified requirements in a calendar year: 1) During the previous 3-year period, the average annual monetary value of **food** sold directly to qualified end users exceeded the average annual monetary value of food the farm sold to all other buyers (See definitions in 112.3(c)) **AND** 2) The average monetary value of all food the farm sold in the 3-year period was less than $500,000, adjusted for inflation	1
A	112.5(b)	To determine whether the average monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, use 2011 as the baseline year for calculating the adjustment for inflation	1
A	112.6(a)	If your farm is eligible for a qualified exemption according to 112.5, you are subject to: 1) This subpart A (General Provisions); 2) Subpart O (Records); 3) Subpart Q (Compliance and Enforcement); and 4) Subpart R (Withdrawal of Qualified Exemptions)	1

A	112.6(b)	In addition to 112.6(a), you are subject to the following modified requirements: 1) When a food packaging label **is** required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown 2) When a food packaging label **is not** required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must 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 3) The complete business address must include the street address or PO box, city, state, and zip code for domestic farms, and a comparable full address for foreign farms	1, *7*
A	112.*7*(a-b)	If your farm is eligible for a qualified exemption in 112.5: a) You must establish and keep records, according to subpart O (Records), except for in 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Receipts must be dated as required in 112.161(a)(4) b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies criteria for a qualified exemption in 112.5, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for exemption	1

Subpart B – General Requirements

	Number	Requirement Description	Module #
B	112.11	You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or 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 that the produce is not adulterated under section 402 of the FD&C Act	1
B	112.12(a)	You may establish alternatives to certain specific requirements of subpart E (Agricultural Water), as specified in 112.49, provided you satisfy the requirements of 112.12(b) and (c)	5
B	112.12(b)	You may establish alternatives to the requirements in 112.12(a) provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection and not increase the likelihood that your covered produce would be adulterated under section 402 of the FD&C Act	5
B	112.12(c)	Scientific data and information used to support an alternative may come from available scientific literature, developed by you, or available from a third party. You must maintain documentation in accordance with subpart O (Records). You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.	5

Subpart C – Standards Directed to Personnel Qualifications and Training

	Number	Requirement Description	Module #
C	112.21(a)	All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are supervisors of said personnel, must receive adequate training per person's duties, upon hiring and periodically thereafter, at least once annually	2
C	112.21(b)	All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are supervisors of said personnel, must have a combination of education, training, and experience necessary to perform the person's duties	2
C	112.21(c)	Training must be conducted in a manner that is easily understood by personnel being trained.	2
C	112.21(d)	Training must be repeated, as necessary and appropriate in light of observations or information indicating personnel are not meeting standards in subparts C – O	2

C	112.22(a)	Minimum training requirements for personnel who handle covered produce during covered activities or supervise the conduct of such activities must include: 1) The principles of food safety and hygiene 2) The importance of health and personal hygiene for visitors and all personnel, 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 3) The standards in subparts C through O that apply to the employee's job responsibilities	2, 6
C	112.22(b)	Persons who conduct harvest activities must be trained on the following: 1) Recognizing when covered produce must not be harvested because of contamination risks 2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean and maintained so as not to become a source of contamination 3) Correcting and reporting any problems with harvest containers or equipment	2, 4, 6
C	112.22(c)	At least one supervisor from your farm must complete food safety training at least equivalent to the standardized curriculum recognized as adequate by the FDA	2, 7
C	112.23	You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance	2, 7
C	112.30(a)	You must keep records under this Subpart C (Personnel Qualifications and Training) in accordance with requirements in Subpart O (Records)	2
C	112.30(b)	You must keep records of training that document required training of personnel including: date of training, topics covered, person(s) trained	2, 4, 7

Subpart D – Standards Directed to Health and Hygiene

	Number	Requirement Description	Module #
D	112.31(a)	Measures must be taken to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea)	2, 6
D	112.31(b)	The following measures must be taken to satisfy 112.31(a): 1) Exclude any person from working in any operations that may result in contamination of covered produce or food contact surfaces if they are shown to have or appear to have an applicable health condition 2) Instruct personnel to notify supervisors if they are ill or have an applicable health condition	2
D	112.32(a)	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 must use hygienic practices while on duty to the extent necessary to protect against such contamination	2, 6
D	112.32(b)	The following hygienic practices must be used to satisfy 112.32(a): 1) Maintain personal cleanliness to protect against contamination of covered produce and food contact surfaces 2) Avoid contact with animals other than working animals, and take action to minimize likelihood of contamination of covered produce 3) Wash hands thoroughly using soap (or other effective surfactant) and water (must satisfy requirements in 112.44(a)), dry hands thoroughly using single-service towels, sanitary towel service, electric hand dryers or other hand drying devices: i) Before starting work ii) Before putting on gloves iii) After using the toilet iv) Upon return to the work station after breaks v) As soon as practical after touching animals or animal waste vi) At any other time workers hands may become contaminated 4) If using gloves, maintain in an intact and sanitary manner and replace when necessary 5) Remove or cover hand jewelry that cannot be cleaned and sanitized when covered produce is manipulated by hand; and 6) Do not eat, chew gum, or use tobacco products in the area used for a covered activity (drinking beverages are permitted)	2, 4, 6
D	112.33(a)	Visitors must be made aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and steps must be taken to ensure visitors comply with such policies and procedures	2
D	112.33(b)	Toilet and handwashing facilities must be accessible to visitors	2

Subpart E – Standards Directed to Agricultural Water

	Number	Requirement Description	Module #
E	112.41	All agricultural water must be safe and of adequate sanitary quality for its intended use	*5*
E	112.42(a)	At the beginning of the growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent that they under your control, to identify food safety hazards including consideration of the following: 1) The nature of each agricultural water source (e.g., ground water or surface water) 2) The extent of your control over each agricultural water source 3) The degree of protection of each agricultural water source 4) Use of adjacent and nearby land; and 5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm	*5*
E	112.42(b)	All agricultural water distribution systems must be maintained, to the extent that they are under your control, as necessary to prevent the system from being a source of contamination, including regularly inspecting and adequately storing all equipment used in the system	*5*
E	112.42(c)	All agricultural water sources, to the extent that they are under your control, must be maintained by regularly inspecting each source, correcting any deficiencies, and keeping the source free of debris, trash, domesticated animals, and other sources of contamination to the extent practicable and appropriate	*5*
E	112.42(d)	As necessary and appropriate, measures must be implemented to reduce the potential for contamination of covered produce as a result of contact with pooled water (such as, using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method)	*5*
E	112.43(a)	When agricultural water is treated according to 112.45: 1) Any method used to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in 112.44, as applicable 2) Treatment of agricultural water must be delivered in a manner that ensures the treated water is consistently safe and of sanitary quality for its intended use and/or meets microbial quality criteria in 112.44, as applicable	*5*

E	112.43(b)	Any treatment of agricultural water must be monitored at a frequency adequate to ensure the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets microbial quality criteria in 112.44, as applicable	*5*
E	112.44(a)	You must ensure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes: 1) Used as sprout irrigation water 2) Applied in any manner that directly contacts covered produce during or after harvest activities, including when used to make ice that contacts covered produce 3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces, and 4) Used for washing hands during and after harvest activities	2, 5, 6
E	112.44(b)	When agricultural water is used during growing activities for covered produce using direct water application method, the criteria in 112.44(b)(1) and (2) apply unless you use alternative criteria in accordance with 112.49 1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water; and 2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water	*5*
E	112.45(a)	If you have determined or have reason to believe that your agricultural water does not meet the requirements of 112.41 or 112.44(a) you must immediately discontinue that use(s), and before you resume use of the water source and/or distribution system, you must either: 1) Re-inspect the entire affected agricultural water system, to the extent that it is under your control, identify conditions that introduce foreseeable hazards to covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine effectiveness to ensure the criterion in 112.44(a) are met, as applicable; or 2) Treat the water in accordance with 112.43	*5*

E	112.45(b)	If it is determined that your agricultural water does not meet the microbial quality criteria required under 112.44(b) (or any alternative criteria, if applicable), you must discontinue use as soon as practicable and no later than the following year unless: 1) A time interval (in days) and/or a calculated log reduction is applied by: i) 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 GM and STV to meet the microbial quality criteria in 112.44(b), for no more than 4 consecutive days; or B) An alternative microbial die-off rate and any accompanying maximum time interval according to 112.49; and/or ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data 2) Re-inspect the entire affected agricultural water system under your control, identify conditions that introduce known or reasonably foreseeable hazards, make necessary changes, and take adequate measures to determine effectiveness to ensure criteria in 112.44(b) (or any alternative microbial criteria, if applicable) are met; or 3) Treat the water in accordance with 112.43	*5*
E	112.46(a)	There is no requirement to test any agricultural water that is subject to the requirements of 112.44 when: 1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA), that meets the microbial requirements under those regulations or those of a State approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement; 2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in 112.44(a), and you have public water system results or certificates of compliance; or 3) You treat water in accordance with the requirements of 112.43	*5, 6*
E	112.46(b)	Except for agricultural water as provided in 112.46(a), you must take the following steps for each source of water that is subject to the requirements of 112.44(b) (those that relate to application during growing activities):	*5, 6*

E	112.46(b)(1)	Conduct an initial survey to develop a microbial water quality profile of the agricultural water source i) The initial survey must be conducted: A) For an untreated surface water source, by taking a minimum of 20 samples over a minimum period of 2 years, but not greater than 4 years B) For an untreated ground water source, by taking a minimum of 4 samples during the growing season or over a period of 1 year ii) The samples must be representative of your use and must be collected as close in time as practical to, but prior to, harvest. The microbial water quality profile (consisting of a GM and an STV) of generic *E. coli* per 100 mL is calculated using this data set. You must determine the appropriate way the water may be used based on your microbial water quality profile in accordance with 112.45(b) iii) You must update the microbial water quality profile annually as required by 112.46(b)(2) and (3)	*5*
E	112.46(b)(2)	Conduct an annual survey to update the microbial water quality profile of your agricultural water i) After the initial survey (described in 112.46(b)(1)(i), you must test the water annually to update your existing microbial water quality profile to confirm the appropriate use of the water. You must analyze: A) For an untreated surface water source, a minimum of 5 samples per year B) For an untreated ground water source, a minimum of 1 sample per year ii) The samples of agricultural water must be representative of your use and must be collected as close in time as practicable to, but prior to, harvest iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual water survey data from within the previous 4 years, to make up a rolling data set of: A) At least 20 samples for untreated surface water sources; and B) At least 4 samples for untreated ground water sources iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with 112.45(b)	*5*

E	112.46(b)(3)	If you know or have reason to believe your microbial water quality profile no longer represents the quality of your water, you must develop a new microbial water quality profile reflective of the time period at which you believe the water quality profile changed (e.g. significant changes occur to adjacent land use likely to impact the quality of the water source). i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current water survey (if taken after the time of change), combined with new data, to make up a data set of: A) At least 20 samples for untreated surface water sources; and B) At least 4 samples for untreated ground water sources ii) You must modify your water use based on the revised GM and STV values in your updated microbial water quality profile in accordance with 112.45(b)	*5*
E	112.46(c)	If you use untreated ground water for purposes that are subject to the requirements in 112.44(a), you must initially test the microbial quality of each water source at least 4 times per growing season or over a period of one year, collected to be representative of the intended use. Based on these results, you must determine whether the water can be used for that purpose, in accordance with 112.45(a). If the samples tested meet the microbial quality criterion of 112.44(a) (no detectable generic *E.coli* per 100 mL), you may test once annually thereafter, collecting one sample that is representative of your use. You must resume testing at least 4 times per growing season or year if any annual test fails to meet the applicable microbial quality criterion in 112.44(a).	*5*
E	112.47(a)	You may meet the requirements related to agricultural water testing in 112.46 using: 1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or 2) Data collected by a third party or parties, provided the water source(s) sampled adequately represent your agricultural water source(s) and all other applicable requirements of subpart E are met	*5*
E	112.47(b)	Agricultural water samples must be aseptically collected and tested using a method as set forth in 112.151	*5*
E	112.48(a)	You must manage water used for harvesting, packing, and holding activities as necessary, including by establishing and following water-change schedules for re-circulated water to maintain safety and adequate sanitary quality (for example, from hazards that may be introduced into the water from soil adhering to the covered produce)	*5*, 6
E	112.48(b)	You must visually monitor the quality of water that you use during harvesting, packing, and holding activities (e.g. water used for washing or hydrocooling covered produce) for build-up of organic material (such as soil or plant debris)	*5*, 6

E	112.48(c)	You must monitor the temperature of water and maintain at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) to minimize the potential for contamination through infiltration of microorganisms into the produce	*5*, 6
E	112.49(a-d)	You may establish and use one or more of the following alternatives, provided you satisfy the requirements in 112.12: a) An alternative microbial quality criterion using an appropriate indicator of fecal contamination instead of the microbial quality criteria in 112.44(b) b) An alternative microbial die-off rate and an accompanying maximum time interval instead of those in 112.45(b)(1)(i) c) An alternative minimum number of samples used in the initial survey for an untreated surface water source instead of the minimum required in 112.46(b)(1)(i)(A) d) An alternative minimum number of samples used in the annual survey for an untreated surface water source instead of the minimum required in 112.46(b)(2)(i)(A)	*5*
E	112.50(a)	You must establish and keep records required under subpart E (Agricultural Water) in accordance with the requirements of subpart O (Records)	*5*
E	112.50(b)	You must establish and keep the following records: 1) The findings of your agricultural water system inspection as required by 112.42(a) 2) Documentation of the results of all analytical tests conducted on agricultural water for compliance with Subpart E (Agricultural Water) 3) Scientific data or information you rely on to support the adequacy of the methods used to satisfy 112.43(a)(1) and (2) 4) Documentation of the results of water treatment monitoring as required by 112.43(b) *5*) Scientific data or information you rely on to support microbial die-off or removal rates that are used to determine the time interval (in days) between harvest and end of storage, including other activities, such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *E.coli* in order to satisfy 112.45(b)(1)(ii) 6) Documentation of actions you take in accordance with 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with 112.45(b)(1)(i) and/or (ii), documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities (such as, dates of last irrigation and harvest, the dates of harvest and end of storage, and/or dates of activities such as commercial washing) *7*) Annual documentation of the results or certificates of compliance from a public water system as outlined in 112.46(a)(1) or (a)(2), if applicable 8) Scientific data or information you rely on to support any alternative that you establish and use according to 112.49 9) Any analytical methods you use instead of the method that is referenced in 112.151(a)	*5*, 6, *7*

Subpart F – Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

	Number	Requirement Description	Module #
F	112.51(a)	A biological soil amendment of animal origin is **treated** if it has been processed to completion to reduce microorganisms of public health significance in accordance with 112.54, or in the case of agricultural tea, the biological materials of animal origin have been 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 *E.coli* in 100 mL of water	3
F	112.51(b)	A biological soil amendment of animal origin is **untreated** if it: 1) Has not been processed to completion in accordance with 112.54, or in the case of agricultural tea, the biological materials of animal origin have not been processed, or the water 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 biological soil amendment of animal origin 4) Is or contains a component of untreated waste that you have reason to believe is contaminated or has been associated with foodborne illness 5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive	3
F	112.52(a)	You must handle, convey, and store any biological soil amendment of animal origin in a manner and location so that it does not become a potential source of contamination to covered produce, food contact surfaces, areas where produce packing or handling occur, water sources, water distribution systems, and other soil amendments	3, 4
F	112.52(b)	You must 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	3, 4
F	112.52(c)	You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated	3
F	112.53	You may not use human waste for growing covered produce, except sewage sludge biosolids in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements	3
F	112.54	112.54(a)-(b) provide treatment processes acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce	3

F	112.54(a)	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, and/or biological processes that has been validated to satisfy the microbial standard in 112.55(a) for *Listeria monocytogenes*, *Salmonella* species, and *E. coli* O157:H7; or	3
F	112.54(b)	A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in 112.55(b) for *Salmonella* and fecal coliforms. Scientifically valid controlled biological processes (e.g. composting) include: 1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55 °C) for 3 consecutive days and is followed by adequate curing; and 2) Turned composting that maintains aerobic conditions at a minimum of 131°F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing	3
F	112.55(a)	The following microbial standards apply to the treatment processes in 112.54. For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7, the relevant microbial standards are: 1) *L. monocytogenes*: Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or mL) analytical portion 2) *Salmonella* species: Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or mL) of total solids (dry weight basis) 3) *E. coli* O157:H7: Not detected using a method that can detect 0.3 MPN per 1 gram (or mL) analytical portion; or	3
F	112.55(b)	*Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis)	3

F	112.56(a-b)	a) Requirements and minimum application intervals of biological soil amendments of animal origin that must be met: 1) i) Untreated, applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application: [application interval is Reserved] ii) Untreated, applied in a manner that does not contact covered produce during or after application: 0 day application interval 2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of 112.54(b) to meet the microbial standard in 112.55(b), applied in any manner that minimizes the potential for contact with covered produce during and after application: 0 day application interval 3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of 112.54(a) to meet the microbial standard in 112.55(a), applied any manner (no restrictions): 0 day application interval b) [Reserved]	3
F	112.60(a)	You must establish and keep records required under subpart F (Biological Soil Amendments and Human Waste) in accordance with the requirements of subpart O (Records)	3
F	112.60(b)	For any biological soil amendment of animal origin you use, you must establish and keep records for: 1) A treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that: i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and 2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature and turnings) were achieved	3, 7

Subpart I – Standards Directed to Domesticated and Wild Animals

	Number	Requirement Description	Module #
I	112.81(a)	The requirements of subpart I (Domesticated and Wild Animals) apply when covered activities take place in an outdoor area or a partially-enclosed building and when there is a reasonable probability that animals will contaminate covered produce	4
I	112.81(b)	The requirements of subpart I do not apply: 1) When a covered activity takes place in a fully-enclosed building; or 2) To fish used in aquaculture operations	4
I	112.83(a)	You must take steps listed in 112.83(b) if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce	4
I	112.83(b)	You must: 1) Assess relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and 2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta, or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of 112.112 and take reasonable measures during growing to assist you during harvest when you must identify, and not harvest, covered produce that is likely to be contaminated with a known or reasonably foreseeable hazard	4
I	112.84	This regulation **does not** authorize the "taking" of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation **does not** require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages	4

Subpart K – Standards Directed to Growing, Harvesting, Packing, and Holding Activities

	Number	Requirement Description	Module #
K	112.111(a-b)	If you grow, harvest, pack or hold produce that is not covered in subpart K (i.e., excluded produce in accordance with 112.2) and also conduct activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with subpart K, you must take measures during these covered activities to: a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce	6
K	112.112	You must 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	2, 4, 6
K	112.113	You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards (e.g., by avoiding contact of cut surfaces of harvested produce with soil)	2, 6
K	112.114	You must not distribute covered produce that drops to the ground before or during harvest (dropped covered produce). Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds)	2, 6
K	112.115	You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms)	6
K	112.116(a-b)	a) You must 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 b) If you reuse food-packing material, you must take steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or by using a clean liner	6

Subpart L – Standards Directed to Equipment, Tools, Buildings, and Sanitation

	Number	Requirement Description	Module #
L	112.121	Equipment and tools that are subject to the requirements of Subpart L (Equipment, Tools, Buildings and Sanitation) are those that are intended to, or likely to, contact covered produce and any instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance	6
L	112.122(a-b)	Buildings subject to the requirements of subpart L include: a) Fully and partially enclosed buildings used for covered activities, including those that have a roof but no walls b) Storage sheds, buildings, and other structures used to store food contact surfaces (such as harvest containers and food-packing materials)	6
L	112.123(a)	You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and	6
L	112.123(b)	Tools and equipment must be: 1) Installed and maintained to facilitate cleaning of 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	3, 6
L	112.123(c)	Seams on food contact surfaces of equipment and tools must be smoothly bonded or maintained to minimize the accumulation of dirt, filth, food particles, and organic material, therefore minimizing the opportunity for the harboring or growth of microorganisms	6
L	112.123(d)	1) You must inspect, maintain, clean, and sanitize when necessary and appropriate, all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce 2) You must maintain and clean all non-food contact surfaces of equipment and tools used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce	3, 6
L	112.123(e)	Pallets, forklifts, tractors, and other vehicles that are intended to or likely to contact covered produce must be used in a manner that minimizes the potential for contamination of covered produce or food contact surfaces	3, 6
L	112.124(a-c)	Instruments used to measure, regulate, or record temperatures, pH, sanitizer efficacy, or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be: a) Accurate and precise; b) Adequately maintained; and c) Adequate in number for their designated uses	6

L	112.125(a-b)	Equipment used to transport covered produce must: a) Be adequately cleaned prior to transporting covered produce b) Adequate for use in transporting covered produce	6
L	112.126(a)	All of the following requirements apply regarding buildings: 1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination. Buildings must: i) Provide sufficient space for equipment and storage of materials ii) Permit proper precautions to be taken to reduce the potential for contamination through separation of operations by location, time, partition, enclosed systems, or other effective means; and 2) You must 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	6
L	112.126(b)	You must implement measures to prevent contamination of covered produce and food contact surfaces in your buildings from: 1) Floors, walls, ceilings, fixtures, ducts, or pipes; and 2) Drip or condensate	6
L	112.127(a)	Reasonable precautions must be taken to prevent contamination by: 1) Excluding domesticated animals from fully-enclosed buildings where covered produce is stored, food contact surfaces or food-packing materials are exposed; or 2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted by location, time or partition	4, 6
L	112.127(b)	Guard or guide dogs may be allowed in some areas of fully enclosed buildings as long as they are not likely to contaminate produce, food contact surfaces, or food-packing materials	4
L	112.128(a-c)	Requirements regarding pest control in buildings: a) Measures must be taken as 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 b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established (such as by use of screens) or by monitoring for the presence of pests and removing them when present	4, 6
L	112.129(a)	Adequate, readily accessible toilet facilities, must be provided to personnel, including toilet facilities readily accessible to growing areas during harvesting activities	2

L	112.129(b)	Toilet facilities must 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 distributions systems with human waste 2) Be directly accessible for servicing and be cleaned and stocked on a sufficient schedule to ensure suitability of use 3) Provide for the sanitary disposal of waste and toilet paper	2, 6
L	112.129(c)	During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a handwashing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands	2
L	112.130(a)	Handwashing facilities must be provided to personnel during growing activities that take place in a full-enclosed building and during covered harvest, packing, or holding activities	2
L	112.130(b)	Handwashing facilities must have: 1) Soap or other effective surfactant 2) Running water that satisfies 112.44(a) 3) Drying devices, such as, single use towels, sanitary towel service, or electric hand dryers	2
L	112.130(c)	You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a handwashing facility and take appropriate measures to prevent waste water from a handwashing 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	2
L	112.130(d)	Antiseptic hand rubs may not be used as a replacement for washing hands with soap and water	2
L	112.131(a)	Sewage must be disposed of into an adequate sewage or septic system or through other adequate means	4, 6
L	112.131(b)	You must 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	4, 6
L	112.131(c)	You must 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	2, 4, 6

L	112.131(d)	After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must 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	2, 5
L	112.132(a-b)	Requirements for the control and disposal of trash, litter, and waste: a) You must convey, store, and dispose of trash, liter and waste to: 1) Minimize attracting or harboring pests 2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and water distribution systems b) You must adequately operate systems for waste management and disposal so they are not a potential source of contamination	5, 6
L	112.133(a-d)	Plumbing must be of adequate size and design, and be adequately installed and maintained to: a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or handwashing and toilet facilities b) Properly convey sewage and liquid disposable waste c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources d) Not allow backflow from or cross-connections between piping systems that discharge waste water or carry water for a covered activity, for sanitary operations, or for use in handwashing facilities	5, 6
L	112.134(a-b)	a) Animal excreta and litter from domesticated animals must: 1) Be adequately controlled to prevent contamination 2) Have a system to maintain control of litter and excreta b) [Reserved]	3, 4, 5
L	112.140(a-b)	Records for Subpart L (Equipment, Tools, Buildings, and Sanitation) must: a) Be established and kept in accordance with Subpart O (Records) b) Be established and kept to document the date and method of cleaning and sanitizing equipment subject to subpart L used in: 1) Growing operations for sprouts; and 2) Covered harvesting, packing, or holding activities	2, 6

Subpart M – Standards Directed to Sprouts

	Number	Requirement Description
M	112.141	The requirements of subpart M apply to growing, harvesting, packing, and holding of all sprouts, except soil or substrate-grown sprouts harvested without their roots
M	112.142(a-e)	In addition to requirements in subpart M, all the following requirements apply to seeds or beans used to grow sprouts: a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting. b) If you know or have reason to believe that a lot of seeds or beans may have been contaminated with a pathogen (either because it has been associated with foodborne illness or based on microbial test results, including positive results from tests required in 112.144(b), you must: 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 the market; and 2) Report the information associated with illness and/or findings of microbial testing to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans c) If contamination of seeds or beans is based only on microbial test results: 1) You are not required to discontinue use of all seeds or beans (112.142(b)(1)) if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance; or 2) You are not required to discontinue use of all seeds or beans (112.142(b)(1)) or report the information (112.142(b)(2)) if you later reasonably determine, through followup 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) d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards e) You must 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 seeds or beans, provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that: i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination

M	112.143(a-g)	You must take all of the following measures for growing, harvesting, packing, and holding sprouts: a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building b) Any food contact surfaces you use to grow, harvest, pack, and hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts c) You must test the growing, harvesting, packing, and holding environment as specified in 112.144 d) You must establish and implement a written environmental monitoring plan as specified in 112.145 e) You must take certain actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, and holding environment as specified in 112.146 f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in 112.147 g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in 112.148
M	112.144(a-c)	All of the following testing must be done during growing, harvesting, packing, and holding sprouts: a) You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of 112.145 b) You must 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 112.144(c) in accordance with the requirements of 112.147; or 2) If testing spent sprout irrigation water is not practicable (for example, for soil-grown sprouts or hydroponically grown sprouts), test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for *E. coli* O157:H7, *Salmonella* species and any pathogens meeting the criteria in 112.144(c) in accordance with the requirements of 112.147 c) In addition to *E.coli* O157:H7 and *Salmonella* species, you must conduct tests provided in 112.144(b) 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)

M	112.145(a-e)	All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* a) You must 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 b) Your written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes* c) Your written environmental monitoring plan must include a sampling plan that specifies: 1) What you will test collected samples for (i.e., *Listeria* species or *L. monocytogenes*); 2) How often you will collect environmental samples, which must be no less than monthly and at what point during production you will collect the samples; and 3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment d) You must aseptically collect environmental samples and test them for *Listeria* species or *L. monocytogenes* according to the method in 112.152 e) Your written environmental monitoring plan must include a corrective action plan that at a minimum, requires you to take the actions in 112.146 and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*
M	112.146(a-f)	You must take the following actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment: a) 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; b) Clean and sanitize the affected surfaces and surrounding areas; c) Conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated; d) Conduct finished product testing when appropriate; e) Perform any other actions necessary to prevent reoccurrence of the contamination; and f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into the market

M	112.147(a-c)	All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in 112.144(b): a) You must 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 that the collected samples are representative of the production batch when testing for contamination. b) In accordance with the written sampling plan required in 112.147(a), you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using the method in 112.153. You must not allow the production batch of sprouts to enter into the market 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 112.144(c) c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in 112.148 and details when and how you 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 112.144(c)
M	112.148(a-d)	You must take the following actions if samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species or a pathogen meeting the criteria in 112.144(c): a) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into the market; b) Take steps required in 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under 112.142(c); c) Clean and sanitize the affected surfaces and surrounding areas; and d) Perform any other actions necessary to prevent reoccurrence of the contamination

M	112.150(a-b)	a) You must establish and keep records required under subpart M (Sprouts) in accordance with the requirements of subpart O (Records) b) You must establish and keep the following records: 1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment according to the requirements in 112.142(e); 2) Your written environmental monitoring plan in accordance with the requirements of 112.145; 3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of 112.147(a) and (c); 4) Documentation of the results of all analytical testing conducted for the purposes of compliance with subpart M (Sprouts) 5) Any analytical methods you use instead of the methods that are referenced in 112.152 and 112.153; and 6) Documentation of actions you take in accordance with 112.142(b) and (c), 112.146, and 112.148

Subpart N – Analytical Methods

	Number	Requirement Description	Module #
N	112.151(a-b)	You must test the quality of water using a method of analysis: a) As 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, which is available from U.S. EPA or at http://www.epa.gov/cwa-methods/approved-cwa-microbiological-test-methods; or b) 1) A scientifically valid method that is at least equivalent to the method of analysis in 112.151(a) in accuracy, precision, and sensitivity; or 2) For any other indicator of fecal contamination you may test for pursuant to 112.49(a), a scientifically valid method	5
N	112.152(a-b)	You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* using: a) The method of analysis described in "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples," Version 1, October 2015, U.S. Food and Drug Administration; or b) A scientifically valid method that is at least equivalent to the method of analysis in 112.152(a) in accuracy, precision, and sensitivity	Refer to Sprout Safety Alliance

N	112.153(a-b)	You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using: a) For *E. coli* O157:H7, *Salmonella* species: 1) The method of analysis described in "Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts)," Version 1, October 2015, U.S. Food and Drug Administration; or 2) A scientifically valid method that is at least equivalent to the method of analysis in 112.153(a)(1) in accuracy, precision, and sensitivity; and b) For any other pathogen(s) meeting the criteria in 112.144(c), a scientifically valid method	Refer to Sprout Safety Alliance

Subpart O – Requirements Applying to Records That You Must Establish and Keep

	Number	Requirement Description
O	112.161(a)	1) All records required under subpart O (Records) must include, as applicable: i) Name and location of your 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 a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and v) The date and time of the activity documented; 2) Be created at the time an activity is performed or observed; 3) Be accurate, legible, and indelible; and 4) Be dated, and signed or initialed by the person who performed the activity documented
O	112.161(b)	Records required under 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party
O	112.162(a-b)	Record Storage: a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm
O	112.163(a-b)	a) Existing records kept for compliance with other regulations do not need to be duplicated if they contain all the information required by subpart O b) The information required by subpart O does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by subpart O, may be kept separately or combined with the existing records

O	112.164(a-b)	Record Storage Duration: a) 1) You must keep records required by subpart O for at least 2 years past the date the record was created 2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued
O	112.165(a-c)	You must keep records as: a) Original records; b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or c) Electronic records, in compliance with part 11 of this chapter
O	112.166(a-c)	a) You must have all records required under subpart O (Records) readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request
O	112.167	Records required by subpart O are subject to the disclosure requirements under part 20 of this chapter

Subpart P – Variances

	Number	Requirement Description
P	112.171(a-b)	A State, Federally-recognized tribe (or "tribe"), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of subpart P (Variances), where the State, tribe, or foreign country determines that: a) The variance is necessary in light of local growing conditions; and b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P
P	112.172	To request a variance from one or more requirements of subpart P, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under 10.30 of this chapter
P	112.173(a-c)	In addition to the requirements set forth in 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must: a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P; b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of subpart P to which the variance would apply; c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P
P	112.174	FDA will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request
P	112.175	The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance

P	112.176(a-d)	Process applicable to a petition requesting variance: a) In general, the procedures set forth in 10.30 of this chapter govern FDAs response to a petition requesting a variance b) Under 10.30(h)(3) of this chapter, FDA will publish a notice in the Federal Register, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (e.g., either because their farm is covered by the petition or as a person similarly situated to persons covered by the petition) c) Under 10.30(e)(3) of this chapter, FDA will respond to the petitioner in writing and will also make public a notice on FDA's website announcing their decision to either grant or deny the petition 1) If FDA grants the petition, either in whole or in part, FDA will specify the persons to whom the variance applies and the provision(s) of subpart P to which the variance applies 2) If FDA denies the petition (including partial denials), their written response to the petitioner and their public notice announcing their decision to deny the petition will explain the reason(s) for the denial d) FDA will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied)
P	112.177(a-c)	a) A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with 10.30 of this chapter. These comments must include the information required in 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with 112.172 and 112.173 b) If FDA grants a petition requesting a variance, in whole or in part, FDA may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition c) If FDA specifies that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, FDA will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of their decision in writing and will publish a notice on their website announcing their decision to apply the variance to similarly situated persons in that particular location
P	112.178	FDA may deny a variance request if it does not provide the information required under 112.173 (including the requirements of 10.30 of this chapter), or if FDA determines that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P

P	112.179	A variance approved by FDA becomes effective the date of their written decision on the petition
P	112.180	FDA may modify or revoke a variance if they determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P
P	112.181(a)	a) FDA will provide the following notifications: 1) FDA will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if they determine that a variance granted in response to its petition should be modified or revoked. FDAs direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter 2) FDA will publish a notice of their determination that a variance should be modified or revoked in the Federal Register. This notice will establish a public docket so that interested parties may submit written comments on FDAs determination 3) When applicable, FDA will: i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of their determination that the variance should be modified or revoked; ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and iii) Include in the Federal Register notice, as described in 112.181(a)(2), public notification of their decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located
P	112.181(b)	FDA will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows: 1) FDA will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter i) If FDA grants a hearing, they will provide the State, tribes, or foreign country with an opportunity to make an oral submission. FDA will provide notice on their website of the hearing, including the time, date, and place of the hearing ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about their determination that a particular variance should be modified or revoked, FDA may consolidate such requests (for example, into a single hearing) 2) FDA will consider written submissions submitted to the public docket from interested parties
P	112.181(c)	FDA will provide notice of their final decision as follows: 1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter 2) FDA will publish a notice of their decision in the Federal Register. The effective date of the decision will be the date of publication of the notice

P	112.182(a-c)	Examples of permissible types of variances include: a) Variance from the microbial quality criteria, established in 112.44(b), when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method; b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in 112.45(b)(1)(i); and c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of 112.44(b), established in 112.46(b)

Subpart Q – Compliance and Enforcement

	Number	Requirement Description
Q	112.192(a-b)	a) The failure to comply with the requirements of subpart Q (Compliance and Enforcement), issued under section 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h), is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(vv)) b) The criteria and definitions in subpart Q apply in determining whether a food is: 1) Adulterated within the meaning of: i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or 2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264)
Q	112.193	Under Section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h(b)(2)(A)), FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches

Subpart R – Withdrawal of Qualified Exemption

	Number	Requirement Description
R	112.201(a)	FDA may withdraw your qualified exemption under 112.5: 1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or 2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm
R	112.201(b)	Before FDA issues an order to withdraw your qualified exemption, FDA: 1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction; 2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and 3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption
R	112.202(a-d)	a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with 112.202(a) c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order

R	112.203(a-i)	An order to withdraw a qualified exemption applicable to a farm under 112.5 must include the following information: a) The date of the order; b) The name, address and location of the farm; c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order: 1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or 2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm d) A statement that the farm must either: 1) Comply with subparts B through O of subpart R on the date that is 120 calendar days from the date of receipt of the order; or 2) Appeal the order within 15 calendar days of the receipt of the order in accordance with the requirements of 112.206 e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in 112.213; f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(f)) and of subpart R; g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in 112.208; h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and i) The name and the title of the FDA representative who approved the order
R	112.204(a-b)	The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under 112.5 must either: a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of 112.206

R	112.205(a-b)	a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest. b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order: 1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of subpart R within 120 calendar days of the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and 2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in 112.6 and 112.7
R	112.206(a-b)	a) To appeal an order to withdraw a qualified exemption applicable to a farm under 112.5, the owner, operator, or agent in charge of the farm must: 1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, e-mail address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and 2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies b) In a written appeal of the order withdrawing an exemption provided under 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in 112.207
R	112.207(a-b)	a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm: 1) May request an informal hearing; and 2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with 112.206 within 15 calendar days of the date of receipt of the order b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial

R	112.208(a-b)	If the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request: a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA b) The presiding officer may require that a hearing conducted under subpart R be completed within 1 calendar day, as appropriate
R	112.208(c)	FDA must conduct the hearing in accordance with part 16 of this chapter. **112.208(c)(1-7) are not included on this table for brevity, please see page Please see page 74567 in the codified section*.
R	112.209	The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director
R	112.210(a-b)	a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing: 1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or 2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed
R	112.211(a-d)	An order to withdraw a qualified exemption applicable to a farm under 112.5 is revoked if: a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702

R	112.213(a)	If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption
R	112.213(b)	You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of subpart R as follows: 1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and 2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak
R	112.213(c)	If your qualified exemption was withdrawn under 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under 112.5, and FDA will notify you in writing that your exempt status has been reinstated.
R	112.213(d)	If your qualified exemption was withdrawn under 112.201(a)(1) and (a)(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under 112.5, in accordance with the requirements of 112.213(b)