

# Produce Safety Inspection & Compliance Manual (ICM)

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# 1 INTRODUCTION

## 1.1 PURPOSE OF THE MANUAL

This manual provides instructions for the Agency of Agriculture, Food and Markets' (the Agency) regulatory staff regarding produce safety farm inspections and compliance activities. This manual may also be used by stakeholders wanting to learn about the Agency's produce safety inspection and compliance procedures.

Additional information can be found in key documents referenced throughout the manual and included in the [Appendices section](#). This manual represents the Agency's thinking at the time it is written. Additional information may be issued in separate documents or notices, as necessary.

## 1.2 PRODUCE PROGRAM

The Agency's Produce Program assists produce farms of all sizes and stages of development to enhance produce safety. Produce Program regulatory staff conduct routine produce farm inspections to ensure substantial compliance with the Food Safety Modernization Act, Product Safety Rule.

For more information about the Produce Program, visit:

<https://agriculture.vermont.gov/produceprogram>.

## 1.3 FOOD SAFETY MODERNIZATION ACT (FSMA) PRODUCE SAFETY RULE

The *Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, 21 C.F.R. part 112 (the Produce Safety Rule), establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. The Produce Safety Rule is part of the US Food & Drug Administration's (FDA) ongoing efforts to implement the Food Safety Modernization Act (FSMA). The Produce Safety Rule was adopted by Vermont statute in 2015 and went into effect in January 2016. The Agency has the authority to implement the Produce Safety Rule in Vermont under 6 V.S.A. Chapter 66.

For more information about the Produce Safety Rule, visit:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>.

## 1.4 EDUCATIONAL APPROACH

The Agency is committed to an "educate before and while we regulate" approach to implementing the Produce Safety Rule. This approach is embodied in the Produce Program's efforts to provide growers with educational resources and produce safety trainings, and to raise stakeholders' awareness of best practices. The Agency's educational approach is integrated within the inspection and compliance protocols detailed throughout this manual. Inspectors should strive to work collaboratively with

farms to achieve prompt compliance and to direct farms to resources to assist with compliance.

## 1.5 REGULATORY AUTHORITY

The Agency is authorized to enforce the Produce Safety Rule per 6 V.S.A. chapter 66, as well as any rules adopted thereunder. To uphold these requirements, the Agency may conduct inspections and issue orders necessary to effectuate the purposes of this chapter, including, but not limited to, orders to condemn, confiscate, or establish restrictions on the use, sale, or distribution of adulterated raw agricultural commodities. The Agency may issue administrative penalties for violations of the Produce Safety Rule. The Agency is also authorized to take any action under 6 V.S.A. § 21, including the authority to respond to and remediate public health and food safety issues. See [Compliance & Enforcement, section 3](#).

## 1.6 FEDERAL, STATE, AND OTHER PARTNERS

### FDA & NASDA

The Agency works closely with the FDA, including FDA staff within the Produce Safety Network (PSN), Office of Regulatory Affairs (ORA), and Center for Food, Science, and Applied Nutrition (CFSAN). The Agency also works collaboratively with the National Association of State Departments of Agriculture (NASDA).

The Agency's Produce Program is funded by a cooperative agreement with the FDA to implement the Produce Safety Rule. The Agency maintains its own enforcement authority to conduct inspections and enforcement activities under 6 V.S.A. chapter 66.

### Vermont Department of Health (VDH)

The Agency coordinates with the Vermont Department of Health (VDH) on certain food safety issues where joint jurisdiction or a collaborative approach is helpful in achieving public health goals.

### Educational Partners

The Agency coordinates with educational partners to develop and share best practices, deliver educational trainings and On-Farm Readiness Reviews, and coordinate workshops and other events. Key partners include:

- UVM Extension
- The Northeast Center to Advance Food Safety (NECAFS)
- The Produce Safety Alliance (PSA)

## 2 INSPECTIONS

### 2.1 CONDUCTING INSPECTIONS

This section includes instructions for conducting routine inspections. See [Non-Routine Inspections, section 2.1.9](#), for additional instructions for initial, follow-up, for-cause, and unannounced inspections.

#### 2.1.1 Role of Inspectors (Inspections)

As an inspector, you are responsible for scheduling and conducting inspections, and for reporting the outcome of each inspection. Inspections are to be conducted during reasonable hours for the purposes of ensuring compliance with the Produce Safety Rule. You are also responsible for identifying opportunities to educate growers about the Produce Safety Rule, the supporting science, and regulatory process.

The concept of "educate before and while we regulate" is critical to relationship building with farms. Your goal should be to work collaboratively with farms to achieve prompt compliance, and to direct growers to resources to assist with compliance and to promote produce safety best practices.

Remember that the Produce Safety Rule is new, having been issued as a final rule in November 2015 with an effective date of January 2016, and with compliance dates beginning in 2018. Do not assume farms are familiar with the defined terminology and requirements of the Produce Safety Rule. When it is necessary to employ specific terminology, use plain, common language to facilitate understanding of the terminology. For example, if inquiring about the use of "Biological Soil Amendments of Animal Origin" (BSAAOs), use common examples such as composted manure, table waste, or fish emulsion. Avoid using acronyms such as FSMA, PSR, or GAPS. Ask questions to confirm a mutual understanding of an issue before moving to the next discussion topic. Before an inspection you may have opportunities to discuss the Produce Safety Rule and the regulatory process with the farm. Managing a farm's expectations from the outset by explaining what the inspection entails may minimize concerns and provide the farm an opportunity to ask additional clarifying questions.

During an inspection:

- DO establish a two-way dialog with the farm to obtain a comprehensive understanding of the practices and conditions associated with any regulatory concerns.
- DO use critical thinking and a whole-systems approach when evaluating practices and conditions on the farm.
- DO discuss observations of potential regulatory concerns with the farm as they are observed.
- DO follow farm etiquette, biosecurity, and food safety protocols.

- DO NOT recommend specific solutions, products, or services, or otherwise act as a consultant.
- DO NOT make promises or jump to conclusions without considering all relevant facts (e.g., regarding the outcome of the inspection, how long the inspection will take, or whether something is acceptable or not).
- DO NOT accept anything from the farm as a gift (e.g., produce, food, or services). Politely let the farm know that it is against agency policy to accept gifts. You may purchase products from a farm during off-work hours.

## 2.1.2 Step 1: Prepare for Inspection

### 2.1.2.1 *Inspection Team & Equipment*

#### Inspection Team

Determine the composition of the inspection team. Most routine inspections are conducted by a single inspector, however, there may be circumstances where additional team members are helpful to carrying out the inspection. Members of an inspection team should be Agency personal who have received appropriate training, and/or who have experience conducting or supervising food safety inspection and compliance activities. Do not invite non-Agency persons to an inspection.

When the inspection team includes more than one person, coordinate your arrival such that all team members arrive at the same time or carpool together.

Designate a lead inspector. This is generally the most experienced inspector but may also be an inspector with a strong working relationship with the farm or background in a specific commodity or production practice. The lead inspector is responsible for directing the inspection, keeping team members on task, and communicating all discussion topics with the farm's management. The lead inspector should instruct other team members on how best to support the team during the inspection.

Avoid overwhelming or confusing the farm's management by asking questions from multiple team members at the same time. Designate a lead questioner at the outset (typically the lead inspector), or divide up questions among inspectors, e.g., by topics or subparts of the Rule. If the inspection team needs to discuss an issue collectively, pause the inspection and discuss together before proceeding to avoiding crosstalk during the inspection. Only the lead inspector should communicate discussion topics, such as reportable observations, with the farm's management. See [Discussions with Management, section 2.2.4](#).

Each team member's notes and observations are crucial to the overall outcome of the inspection and reporting process. It is important that each team member contributes to the inspection process and knows what is expected from them at the outset. The



inspection team should stay together during the inspection and individual members should not split up or wander away from the team.

### Equipment

Determine what equipment is needed to conduct the inspection. Inspectors are responsible for their own equipment unless otherwise instructed. Examples of equipment include:

- Work vehicle
- Work cell phone with camera
- Tablet computer or paper inspection forms
- Inspection notepad and pen
- Mobile printer and printer paper
- Hardcopies of guidance documents and other educational material
- Agency identification (e.g., a business card or official ID)
- Appropriate clothing
- Boots
- Sunscreen
- Insect repellent
- Water for hydrating
- Hand sanitizer
- Flashlight
- Boot wash/sanitizer
- Boot brush
- Water for washing/sanitizing boots
- Container for washing/sanitizing boots
- Container/bag for disposing of any inspection waste

#### *2.1.2.2 Review Farm Compliance History*

Review the farm's recent compliance history prior to inspection. Become familiar with the farm's covered activities and commodities, as well as the farm's size, location, management structure, growing period, production practices, and other relevant information. Review documents from at least the most recent inspection and become familiar with past issues of non-compliance, discussion items of concern, and the status of any corrective action and preventative measures taken by the farm. Confirm whether the farm is subject to existing enforcement measures, such as conditions established in an Assurance of Discontinuance or a Notice of Violation (see [Enforcement Measures, section 3.1.3](#)). Consult with your supervisor when existing enforcement measure are in place to determine an appropriate inspectional approach.

You may also review the farm's website and social media for additional information. These sources may provide timely information about the farm's operations, for example, seasonal information for farm visitors and PYO, CSA, or farm stand customers.

#### *2.1.2.3 Inspection Etiquette*

Practice the following etiquette when conducting farm inspections:

- Ask if the farm has a visitor policy so you are fully aware of restrictions before arriving.
- Read and adhere to the farm's rules, biosecurity, and food safety protocols unless they conflict with Agency policies or legal requirements.
- Introduce yourself and inspection team members immediately upon arrival. Show identification as appropriate and explain the reason for the inspection.
- Set a positive tone for the inspection. Maintain a friendly, courteous, focused, and respectful demeanor. Remember that you are a guest on their farm, which may also be a home or primary residence.
- Remain flexible in the inspection schedule to allow the farm to address daily variations in their business and personal priorities.
- Confer with the farm's management before talking with farm employees as they work.
- Be reasonable in the scope and flexible in the timing of any inspection-related requests that you may have.
- Wear appropriate attire.
- Park in designated parking areas or as discussed during the pre-inspection call. If it is not clear where the designated parking area is, park in a clean dry area that is not blocking farm roads or field access.
- Drive slowly on farm roads to minimize dust and splash onto crops.
- Do not drive off designated farm roads into growing fields, even if no crop is visible.
- Leave closed gates/doors closed and leave open gates/doors open.
- Minimize entry into rows of crops in fields or in-door growing areas; observe conditions and practices from adjacent paths or sides of growing areas when possible.
- Do not enter a private residence or other buildings that are not part of the inspection.
- Do not pick or consume any produce or other food.
- Leave no trash behind; pack out what you pack in.

#### *2.1.2.4 Biosecurity Protocols*

Biosecurity is a set of preventive measures designed to protect farm crops and livestock from bacterial, fungal, and viral diseases and agricultural pests. Abide by the rules, policies, and procedures of each farm. Prior to entering the growing area, ask if the farm

has implemented biosecurity practices or procedures and adhere to their requirements. At minimum and in the absence of farm-specific requirements, follow these general practices:

- Do not work when ill.
- Maintain vehicles in a sanitary manner, including vacuuming the interior and washing the wheels, wheel wells, and the vehicle undercarriage as appropriate to remove mud and dirt between farm inspections.
- Park vehicles in a designated area or an area without mud, debris, or manure where you will not interfere in farm activities. Obey restricted access signs on the property.
- Arrive at the farm with clean boots and be prepared to reclean and sanitize your boots as needed. Clean and sanitize boots between each farm inspection. You should carry with you clean water, a sanitizing agent, a sanitizing tub, a long-handled brush, and containers for disposing of used cleaning/sanitizing solutions.
- Always wear clean clothing when conducting inspections.
- Avoid contact with growing, harvested, packed, and held produce; composting materials; and with food-contact surfaces.
- Avoid contact with wild or domestic animals, including dogs and cats.
- Do not consume food, tobacco, or gum in growing, packing, harvesting, or holding areas. Consume beverages in designated areas only.
- Do not spit anywhere on the farm.
- If you utilize farm restrooms, dispose of waste in a sanitary manner and use hand washing stations in accordance with the Produce Safety Rule.
- If the farm offers waste receptacles, you may use these receptacles for its intended purpose with prior permission; otherwise, you should take all waste materials with you when you leave the farm. This includes any inspection generated waste such as used boot sanitizer solutions, disposable boot covers, and sampling waste.

#### *2.1.2.5 Safety Precautions*

Farm environments contain unique safety hazards that you should be aware of and take appropriate precautions. Potential safety hazards that may be encountered on the farm include:

##### Lack of Cell Phone Coverage

Be aware that cell phone coverage may be an issue. Always let someone know where you are going, especially if you do not have someone with you.

##### Heat Exposure or Stroke

To avoid heat stroke, consume liquids, limit sun exposure, and consider scheduling on-farm inspection activities in the morning or early evening to avoid peak temperatures.

### Drowning

Stay a safe distance from rivers, streams, and irrigation ponds.

### Confined Space Asphyxiation

Confined spaces can become oxygen depleted and cause asphyxiation. Do not enter common identified confined spaces such as tanks, storage bins, silos, or modified atmosphere storage rooms. Recognize potential unidentified confined spaces such as enclosed or underground well housing or utility access, drainage pipes, and any enclosed building containing stored chemicals or containing any equipment that burns fuel such as propane, natural gas, alcohol, diesel, or gasoline.

### Pesticides

Avoid being present when pesticides are sprayed, including pesticide applications on adjacent properties.

### Farm Equipment and Vehicle Safety

Keep a safe distance from farm equipment to avoid accidents. Maintain situational awareness when walking around moving vehicles. Be aware that equipment lifted off the ground by hydraulics can suddenly drop from a loss of pressure, and that any machinery with an engine running can unexpectedly begin to move itself or anything attached to it. Other hazardous equipment on a farm can include knives, ladders, tools, and heavy machinery.

### Unguarded Railroad Crossings

Look both ways before crossing railroad tracks. Do not walk on railroad tracks or railroad trestles to cross any physical barrier. Do not stop or park your vehicle on railroad tracks.

### Hunting Accidents

To avoid hunting accidents be aware of local hunting seasons, wear easily visible colors, and reschedule the inspection if hunting gunshots are heard in the growing area.

### Plants

Long sleeves can prevent skin exposure to unseen hazardous plants. If you notice that you had accidental skin contact to poison ivy, poison oak, or poison sumac, wash the affected skin with soap and water as soon as possible to remove the plant oils that cause the allergic reaction on your skin.

## Animals

Be wary of domestic or feral dogs that are showing aggressive behavior or are traveling in packs.

Wildlife that may be encountered on farms includes rodents, snakes, raccoons, skunks, rabbits, geese, birds, opossum, pigs, moose, deer, coyotes, bobcats, and bears.

Familiarize yourself with local wildlife species, signs of wildlife activity, and with wildlife encounter safety practices.

Lyme disease is one of the infection threats from ticks. Avoid walking through tall brush or paths frequented by deer, wild pigs, or other common wildlife carriers of ticks. Know the symptoms and check yourself.

West Nile virus and Zika virus may be transmitted through mosquito bites, and vector mosquitoes may be active at all hours of day and night. Protective clothing and DEET mosquito repellent are two ways to minimize mosquito-transmitted diseases.

Hanta virus is transmitted to humans through the inhalation of airborne dust that is contaminated with the urine or feces of certain rodents. Avoid being present when rodent feces contaminated dust may be disturbed such as during the cleaning of rodent droppings from farm buildings.

### 2.1.3 Step 2: Schedule the Inspection

Routine inspections should generally be scheduled (1) during the growing season, (2) when the farm performs covered activities on covered produce (growing, harvesting, packing, and/or holding produce), and (3) at a time when most or all covered activities can be observed. If none of these activities are being conducted, the inspection should be rescheduled. Other factors that may influence when to schedule a routine inspection include:

- Agency directives and work plans, which may include mandatory inspection frequency.
- To observe specific covered activities. For example, an inspection may be scheduled at a specific time and location to observe harvesting activities; on a specific day to observe packing activities; or across multiple days to observe a combination of covered activities (including those that may happen over a 24-to-48 hour period, such as cleaning and sanitizing practices).
- To observe covered activities on priority crops.
- To observed covered activities occurring outside of the farm's primary growing season(s) when those activities would not otherwise normally occur. For example, an inspection may be scheduled at an apple orchard to inspect covered packing and holding activities occurring during winter months when no growing activities occur. Another example is an inspection scheduled during

early spring or late fall to observe growing activities in hoop houses or other activities associated with season extension practices on a diversified vegetable farm.

- In coordination with another state and/or federal agency when a coordinated inspection is required.

Routine inspections are generally pre-announced and scheduled in coordination with the farm to optimize inspection productivity and to support a positive relationship between the inspector and the farm. However, you may initiate an unannounced inspection in certain circumstances, such as during a for-cause investigation or when the farm is unresponsive after multiple documented attempts were made to contact the farm. Always seek prior approval from your supervisor or Agency management before initiating an unannounced inspection. See [Non-Routine Inspections, section 2.1.9](#).

The inspection should be scheduled at a time that works for both the inspector and the farm. Respecting the farm's time is the first step in building a relationship. You should be flexible in scheduling an inspection and open to variability the farm may have in their operation within reason.

If the farm is unreachable by phone, send a letter or email (requesting an email delivery receipt) to schedule the inspection, including a specific date, time, and meeting location as well as your contact information. You should make two documented attempts to reach the farm by phone, email, or mail at least five business days before arriving on the farm unannounced. It is important to document any attempted and actual communication with the farm.

During the pre-inspection call, explain what the farm can expect during the inspection and discuss the logistics of the inspection. Read and follow the guidelines in [Appendix 4, Pre-Inspection Call Job Aid](#).

#### 2.1.4 Step 3: Conduct the Inspection

##### 2.1.4.1 *Initiate the Inspection and Opening Meeting*

The purpose of the opening meeting is to introduce the inspection team to the farm's primary contact(s), formally initiate the inspection, and coordinate the scope of the inspection for the day.

- Be punctual and prepared. Arrive to the agreed meeting location at the scheduled time, in appropriate inspection attire, and with everything that you need to conduct the inspection.
- Ask to speak with the farm's primary contact(s) or other farm personnel as agreed upon during the pre-inspection call.
- Introduce yourself and each inspection team member. Show your Agency identification if requested.

- Confirm the reason for the inspection and describe the scope of the inspection.
- Explain that it is best if someone from the farm is available to answer questions and escort the inspection team for the entire duration of the inspection.
- Work with the farm to coordinate inspection activities for the day. Prioritize opportunities to observe labor-intensive or time-limited farm activities such as harvesting and packing (this should already be a consideration when scheduling the date and time for the inspection).
- Remain open-minded and do not make assumptions regarding the scope of the inspection or inspectional outcome. Remember that you may not know the full scope of the inspection at the outset. It is not uncommon to discover covered activities or practices that were not apparent at the outset of an inspection that require further investigation.
- Ask if the farm has any questions before proceeding.

#### *2.1.4.2 Evaluate Farm Practices & Conditions*

Assess the farm's compliance with the Produce Safety Rule by asking questions, reviewing records, and evaluating covered activities and conditions on the farm.

##### Use Critical Thinking and a Whole-Systems Approach

Apply critical thinking and a whole-systems approach when evaluating farm practices. Critical thinking is "disciplined thinking that is clear, rational, open-minded, and informed by evidence" (Webster's Dictionary). An inspector that uses critical thinking avoids making assumptions and traces issues to their root cause. A whole-systems approach, also referred to as systems thinking, recognizes that there are complex systems, such as environmental, social, and economic, that influence the day-to-day operations on a farm. An inspector that applies a whole-systems approach recognizes how relationships and systems are interconnected and considers all the relevant factors that may affect conditions and practices on a farm.

##### Scope of the Inspection

The Produce Safety Rule is extensive, and it is unlikely that all topics can be covered during every farm inspection. Follow Agency directives and use your best judgement in determining which topics, covered activities, covered crops, or other factors should be prioritized during a given inspection. Prioritize topics that pose the greatest produce safety risk for the farm. For farms that have undergone consecutive routine inspections, you may prioritize certain topics that have not been fully assessed in previous inspections, such as certain growing areas used periodically or covered activities that take place outside of the farm's primary growing seasons.

Plan the inspection such that you can observe the most time-sensitive activities first. Because most farms harvest early in the morning and transition to washing and/or

packing later in the day, it may be necessary to follow this sequence to observe farm activities as they naturally occur. It is always preferable to observe an actual farm activity rather than a verbal description or a staged activity (such as a mock harvest).

When observing covered activities, try and observe the activity for its entire duration, or if this is not possible, at least for the beginning of the activity. For example, when observing a harvest, try to observe farm workers as they prepare for and begin harvesting. Pay attention to whether workers follow hygiene practices (such as hand washing), how they handle harvest tools and equipment, whether they scout for wildlife, their harvest practices, field packing activities, the use of restrooms, breaks, and the condition of vehicles and transportation.

### Establish Facts and Document Evidence

Reportable observations must be supported by facts and evidence. During the inspection it is important that you establish relevant facts and evidence to support your observations. Ask open ended questions; avoid asking leading questions that may encourage the farm to reply with what they think the inspector wants to hear, rather than a more truthful answer. When evaluating farm practices and conditions, make sure you investigate a topic with the level of detail necessary to answer: What, When, Where, Why, How Much, How Often, and So What? (regarding its significance). It is not sufficient to simply report that, for example, a food contact surface was not adequately clean. You must also answer why it matters (e.g., regarding compliance with the Produce Safety Rule). This topic is discussed in further detail in [Reportable Observation, section 2.2.2](#).

The remainder of this section includes recommendations specific to each Subpart of the Rule.

### 21 CFR 112 Subpart A: General Provisions

- Confirm the information provided by the farm during the pre-inspection call and determine if the farm is conducting a covered activity on covered produce.
- Confirm that the farm handles covered produce as listed in 21 CFR 112.2.
- If the farm grows, harvest, packs or holds covered produce that is intended for commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., a kill step), the produce may be eligible for a commercial processing exemption (see 112.2(b)(1)).
  - Determine if the farm distinguishes between produce intended for processing (eligible for exemption) and produce not intended for processing (subject to the Produce Safety Rule).
  - If the farm does not handle the produce for processing according to Produce Safety Rule requirements, discuss the method of disclosing to



consignees that the produce intended for processing is not grown, harvested, or handled to adequately reduce the presence of microorganisms of public health significance.

- The regulation also requires the farm to obtain written assurances from the consignee; however, FDA is currently exercising enforcement discretion for the written assurance requirement. Do not request information about written assurances and do not cite deviations relative to the written assurance requirement (see 21 CFR 112.2(b)). For more information see <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM590661.pdf>.
- If a farm indicates that some of its produce goes to processing, review how the farm is disclosing to its customers that the produce is not processed to adequately reduce the presence of microorganisms of public health significance.
- Determine if the farm uses its own crews or uses a contract crew for certain activities, such as harvesting.

#### 21 CFR 112 Subpart C: Personnel Qualifications and Training

- Responsible Personnel: Identify the person assigned by the farm to be responsible for food safety requirements, specifically those covered by the Produce Safety Rule.
- Confirm that at least one supervisor or responsible party has completed produce safety training equivalent to a standardized curriculum recognized by FDA.
- Training:
  - Observe personnel at work on covered activities, with particular attention to traffic patterns, hand washing, glove use, and basic hygiene. If employees are not performing their jobs consistent with food safety principles, review training records to determine if the employees are adequately trained.
  - Determine if re-training occurs when observations or information indicates that produce safety standards are not being met.
  - Training records must include date of training, topics covered, and persons trained.
  - Identify responsibility for training and monitoring of food safety practices. If the farm uses contract workers for any covered activities, determine who trains the workers.

#### 21 CFR 112 Subpart D: Health and Hygiene

- Determine if the operation has a health and hygiene policy for personnel and visitors, and that all visitors are made aware of this policy (policies and procedures do not have to be written).
- Determine how the farm handles ill workers.
- When possible, observe worker practices in all production areas (field, harvesting, transport, storage, and packing), with special attention to:
  - appropriate handwashing/glove practices
  - consumption of food and/or tobacco in product handling areas
  - jewelry
  - outer garments suitable to protect against contamination
  - contact with animals
  - general hygiene practices
- Ensure that employees working with covered produce and food contact surfaces use appropriate hand-washing techniques and that both employees and visitors have access to toilet and hand-washing facilities.

#### 21 CFR 112 Subpart E: Agricultural Water

- The compliance dates for the Agricultural Water provisions of the Produce Safety Rule have been extended. At this time, farms should not be evaluated against these standards and no citations under 21 CFR 112 Subpart E should be reported.
- Farms should be familiar with their water sources and are still required to provide reasonable assurances (e.g., produce is not adulterated); therefore, during inspections the following should be covered:
  - When possible, observe all water sources and distribution systems (including wells, springs, irrigation canals, municipal connections, holding tanks and ponds, reservoirs, pumps, etc.) for signs of gross contamination.
  - Identify sources of water used by the farm, specifically water used in a way that may come into direct contact with covered produce or food contact surfaces (such as water used during pre-harvest activities, crop sprays, and for post-harvest activities such as washing, cooling, or ice use).
  - Identify any measures the farm uses to treat the water before use.
  - For post-harvest water, determine if the farm takes any measures to minimize contamination of the water or covered produce it contacts.

#### 21 CFR 112 Subpart F: Biological Soil Amendments of Animal Origin and Human Waste

- Determine if the farm uses BSAAO. If not, no further review is needed under this section.

- If the farm uses BSAAO, determine if the BSAAO are treated.
  - If the BSAAO are treated by a third party, review records (such as a Certificate of Conformance) from the third party to show that the BSAAO were treated using a scientifically validated process and that the BSAAO were conveyed and stored to minimize the risk of contamination.
  - If the farm treats its own BSAAO, review documentation that process controls were achieved. Review the storage and handling of the BSAAO used on the farm to determine if appropriate precautions are taken to prevent contamination of a treated BSAAO with an untreated BSAAO.
- If the BSAAO was treated and stored properly, there are no restrictions on use.
- If the BSAAO was not treated or was not handled to prevent recontamination, determine when the BSAAO is applied.

#### 21 CFR 112 Subpart I: Domesticated and Wild Animals

- Determine if the farm conducts covered activities in outdoor areas or a partially enclosed building.
- Determine if the farm's animal monitoring procedures for domestic and wild animals and their identification of trends or high activity areas satisfy the requirements of the Produce Safety Rule.
  - Walk the perimeter of the growing areas and outdoor or partially enclosed operations, noting any evidence of animal intrusion such as animals, animal excreta, bedding areas, animal tracks, and crop destruction.
  - Note whether domesticated animals have unrestricted access to areas where growing, harvesting, packing, and/or holding activities take place, and if there is potential contamination indicated by vulnerability of the crop, conditions and practices.
  - Determine (by observation or interview) how the farm responds to evidence of animal intrusion, how produce is evaluated for potential contamination, and how potentially contaminated produce is handled during harvest.

#### 21 CFR 112 Subpart K: Growing, Harvesting, Packing, and Holding Activities

- Document the growing, harvesting, packing and holding activities the farm performs. Identify if the farm uses contractors for any of these activities.
- Observe, when possible, the farm's growing, harvesting, packing, and holding operations and evaluate whether the farm handles produce in a manner to protect against contamination.
- Determine the steps the farm takes to identify and not harvest covered produce that is likely to be contaminated. For example, does the farm perform a visual

assessment of growing areas prior to and during harvest for evidence of animal excreta?

- Determine if the operation handles both covered and excluded produce. If so, determine if they are handled appropriately to prevent cross-contamination. Consider shared surfaces or equipment, transportation methods, and packing materials.
- Identify packing materials and determine if they are handled/stored properly and are appropriate for use. Consider materials, single use vs. repeated use, liners, storage and packing conditions.

21 CFR 112 Subpart L: Equipment, Tools, Buildings, and Sanitation

- Tools and Equipment: Observe both use and cleaning of tools and equipment, when possible. Tools and equipment should be used and stored appropriately and be maintained in good condition.
  - Cleaning should be conducted with appropriate products and should remove potential sources of contamination, such as soil, grease, and food residues.
  - Examine all equipment and utensils to determine the following: design, materials, workmanship, maintenance, suitability, and ease of cleaning and sanitization.
  - Check the sanitary condition of all machinery. Determine if equipment is cleaned prior to each use (as appropriate) and the method of cleaning.
  - Inspect conveyor belts for build-up of residual materials and pockets of residue in corners and under belts. Look in inspection ports and hard-to-reach places inside, around, underneath, and behind equipment and machinery for evidence of filth, insects, and/or rodent contamination.
  - Determine how brushes, scrapers, brooms, and other items used on product contact surfaces are cleaned and stored appropriately.
  - Observe how cleaning occurs and if there is a possibility of contamination by the cleaning practices used. For example, the use of high-pressure hoses on one system that is idle may contaminate an adjacent system that is operational.
  - If the farm has food contact materials that are not cleanable, determine how the farm ensures the materials are not contaminating the produce. For example, does the farm use liners in its containers?
- Vehicles and Transport Equipment: Observe use when possible and determine if the structural design is appropriate, if the vehicle is adequate for use, clean, well maintained and not contributing to potential contamination of covered produce. Consider equipment such as pallets, forklifts, tractors, trailers, equipment used between growing/harvesting, packing and storage locations, etc.

- **Buildings:** Includes all fully or partially enclosed building (including minimal structures) used for covered activities.
  - Determine if the building is of suitable size, construction and design for covered activities. Buildings, fixtures, and other physical facilities must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent produce from becoming adulterated.
  - Consider storage (appropriate in size for equipment and materials), drainage, plumbing (adequate water pressure, lack of cross-connections and appropriate backflow devices), general construction (walls, floors, fixtures, ducts, and pipes), and pest control. Observe whether the building design/layout minimizes the potential for contamination of covered produce, food contact surfaces, and production areas.
  - Check placement of equipment, storage of materials, lighting, ventilation, and placement of partitions and screening to eliminate product contamination by bacteria, birds, vermin, etc.
  - Observe traffic patterns, build-up of dust and debris, condensation or evidence of dripping, and indications of pest presence (or potential ingress/egress points) in relation to covered produce and activities.
- **Domesticated Animals:** If the farm keeps domesticated animals, determine if they are appropriately excluded or separated from covered produce and activities. Ensure that animal excreta and litter is controlled to prevent contamination of covered produce, food contact surfaces, water sources and areas used for covered activities.
- **Sewage and Sewer Systems:** Determine type of sewer system(s) used by the farm and determine if the system(s) are appropriately maintained and provide effective waste disposal on the premises.
  - Observe for indications of leaks, spills or overflows and determine how the farm would address a spill and how a major event may be addressed.
- **Toilets and Hand-washing Facilities:** Consider the number, location, design and condition of toilet and hand-wash facilities. Observe use by employees. Determine if hand-washing facilities are adequate and supplies available. Determine if waste is properly handled to prevent contamination of water sources, covered produce, food contact surfaces, and production areas.
- **Waste Disposal:** Determine if the farm is appropriately conveying, storing, and disposing of trash and litter. Observe areas around buildings and fields for trash, around hand-wash facilities for overflowing trash cans, and for discarded materials that may act as pest attractant or harborage.
- **Records:** Review records related to the cleaning and sanitizing of equipment used to grow, harvest, pack, and hold covered produce to ensure that they meet the requirements of Subpart O, and specifically include the date and method of cleaning.

## 21 CFR 112 Subpart O: Records

- Evaluate a representative sample of required records for the minimum required information, as addressed in § 112.161.
- Review records to determine if required records were reviewed, signed, and dated within a reasonable time by the supervisor or responsible party.

### *2.1.4.3 Immediate Regulatory Action Needed*

If you encounter conditions or practices that may indicate an immediate public health issue, such as an egregious condition where produce is likely contaminated, pause the inspection and explain the seriousness of the issue with the farm's management. Inform the farm's management that you will contact the Agency to determine the appropriate next steps. Contact your supervisor and wait for further instruction. It is OK to discuss the seriousness of the issue with the farm, however, avoid calling the situation violative or a violation. This is an Agency decision and will be made after considering all relevant facts and evidence. See [Appendix B: Egregious Conditions](#).

### 2.1.5 Step 4: Discuss Regulatory Concerns & Issue Inspection Form

Discussion all reportable observations with the farm's management. See [Preparing & Issuing the Inspection Form, section 2.2](#). Any commitment by the farm to take corrective action and preventive measures should be noted in the inspection form and inspection report as appropriate (see [Annotation, section 2.2.3](#)). Provide a printed copy of the inspection form to the farm's management. Briefly summarize any observations noted on the inspection form as the form is issued and allow time for the farm's management to ask any additional questions. Discuss next steps, including as appropriate, timelines for corrective action and what to expect regarding a follow-up inspection or the farm's next routine inspection.

Conclude the inspection and remember to follow any biosecurity or visitor policies when exiting the premises.

### 2.1.6 Inspection Refusal

A refusal is refusal to permit an inspection or prohibiting you from obtaining information to which the Agency is entitled under the law. Discuss all refusals with the most responsible official present at the farm at the time the refusal was made. In the case of a refusal you must show your inspection was attempted to be conducted in reasonable time, reasonable manner, and reasonable limit to show you exercised prudence to avoid refusal. Inspection refusals may take several forms. All refusals to permit inspection must be reported in the inspection report.

### 2.1.7 Hostile and Uncooperative Interviewees

More often than not inspections are conducted in a reasonable atmosphere. Nonetheless, there may be times you are confronted by unfriendly or hostile persons.

Your activities must always be conducted with tact, honesty, diplomacy, and persuasiveness. Even though you must at times adopt a firm posture, never resort to threats or intimidation. In most cases a calm, patient, understanding and persuasive attitude on your part will overcome the person's reluctance or hostility. Often the mere fact you patiently listen while individuals share their views will make them receptive to your questions.

#### *2.1.7.1 Indicators*

Normally you have no way to predict the nature of the individuals you meet. However, there are often indicators, which can alert you, such as:

1. Inspection reports may show situations where inspectors encountered belligerent or hostile individuals.
2. Discussions and conversations with other state or federal officials may reveal instances where uncooperative individuals and problem situations were encountered.
3. The nature of the assignment, program or information requested may indicate some degree of caution is needed.

If you find yourself in a situation which, in your judgment, indicates violence is imminent, stop the inspection and make an exit as soon as possible. Immediately report to your supervisor.

#### *2.1.7.2 Safety Precautions*

The Agency recognizes there are situations where it is advisable to take precautions for your personal safety. In those situations, consult your supervisor. Some procedures which may be utilized to minimize danger include:

1. Inspections carried out by a team of two or more persons.
2. Request additional information from state agencies who also regulate and inspect the farm in question.
3. In consultation with your supervisor, request assistance from local law enforcement agencies prior to or during investigations.

#### *2.1.7.3 Procedures When Threatened or Assaulted*

In instances when you are assaulted or threatened, you should immediately notify your supervisor. Your supervisor can summon local police. If you are physically attacked, you should get to safety, call your supervisor, report the incident, and seek medical attention if needed.

#### 2.1.8 Protecting Privileged Trade Secrets and other Confidential Information

You should be mindful not to disclose trade secrets or other confidential information obtained during your official duties when communicating with third parties. Do not

volunteer information about other farms or their practices that constitute a trade secret or are otherwise confidential. Be mindful that your casual and seemingly innocuous remarks may reveal information of this nature. Remind farmers that documents provided to and created by the Agency are subject to disclosure under public records laws. If a farm divulges information that may be a trade secret or otherwise confidential, before recording this information, consider whether doing so will ensure or promote compliance with the Produce Safety Rule.

#### 2.1.9 Non-Routine Inspections

You may be assigned to conduct inspections for reasons other than routine inspection purposes.

##### Initial Inspections

An initial inspection is the first inspection conducted on a produce farm for the purposes of assessing compliance with the Produce Safety Rule (see “farm” definition, 21 CFR part 112.3).

Initial inspections should follow standard inspection procedures, except that:

- Only egregious observations should be reported on the inspection form. All other observations should be documented in the Inspection Report, but not included in the Inspection Form. See [Reportable Observations, section 2.2.2](#).

##### Follow-Up Inspections

A follow-up inspection is an inspection conducted to assess issues of noncompliance noted in a previous inspection and to verify corrective action and preventative measures.

Follow-up inspections should follow standard inspection procedures, except that:

- Inspectors may focus the inspection on specific compliance issues, buildings, equipment, processes, commodities, growing areas, or other factors pertinent to the nature of the inspection; and,
- Inspections may be unannounced when, for example, an unannounced inspection may aid in assessing compliance.

##### For-Cause Inspections

A for-cause inspection is an inspection conducted to investigate a specific food safety or compliance issue, such as in response to a consumer complaint, a farm emergency (such as fire or flooding), or as part of a food safety outbreak or compliance investigation.

For-cause inspections should follow standard inspection procedures, except that:



- Inspectors may focus the inspection on specific compliance issues, buildings, equipment, processes, commodities, growing areas, or other factors pertinent to the nature of the inspection;
- Inspections may be unannounced when, for example, an unannounced inspection may aid in assessing compliance and/or when the nature of the investigation requires immediate action; and,
- Sampling or other evidence gathering practices not normally used during routine inspections may be used as appropriate.

### Unannounced Inspections

Discuss with your supervisor before initiating an unannounced inspection.

When an unannounced inspection is deemed necessary in order to assess compliance, you should follow these additional procedures:

- When entering a property unannounced be careful and respectful.
- If a phone number is available, ask to speak with the most responsible person on the farm upon arrival. If a phone number is not available, visually attempt to locate the farm office or ask to meet with the most responsible person available to let them know you are there and the purpose of the inspection. Stay in the immediate area while you wait and do not enter buildings, growing areas or wander about the farm. Remain near your vehicle for safety purposes.
- Introduce yourself and team members as you would during an announced inspection, provide identification as appropriate, and explain the reasons for the unannounced inspection.
- Proceed as normal for an announced inspection.
- Stop the inspection if at any time you feel threatened or unsafe. Leave the farm, document the reason for not conducting the inspection, and contact your supervisor to discuss next steps.

## 2.2 PREPARING & ISSUING THE INSPECTION FORM

The Produce Farm Inspection Form (“inspection form”) is for notifying the farm’s top management in writing of significant objectionable conditions relating to the Produce Safety Rule or other applicable statutes or regulations observed during an inspection. “Significant objectionable conditions” means observations made, when in the inspector's judgment, conditions or practices observed indicate that produce has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

Inspection forms should include the following general characteristics. Specific guidance may supplement these instructions.

1. Observations listed on the inspection form should be significant and correlate to regulated products or practices being inspected.
2. Observations of questionable significance should not be listed but should be discussed with the farm's management so that they understand how uncorrected problems could become a violation (see [Non-Reportable Observations, section 2.2.2.3](#)).
3. Each observation should be:
  - a. Clear and specific,
  - b. Significant,
  - c. Not repetitious,
  - d. Ranked in order of significance.
4. All copies of the inspection form should be legible.
5. If an observation made during a prior inspection has not been corrected or is a recurring observation, it is appropriate to note it on the inspection form.

You should make every reasonable effort to discuss all observations with the management of the farm as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when the inspection form is issued. This discussion should include those observations, which may be written on the inspection form and those that will only be discussed with management during the closeout meeting. The farm's management may use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made during the inspection process. Inspectors are encouraged to verify the farm's completed corrective actions as long as the verification does not unreasonably extend the duration of the inspection.

There may be instances where same day discussion of observations may not be possible due to the volume of documents collected and when document review reveals observations on a different day than the documents were collected or in other circumstances. When these instances occur immediately prior to the conclusion of the inspection, the lack of a daily discussion of observations does not preclude listing significant observations which were not previously discussed on the inspection form.

Record the inspection form and supporting evidence in the WinWam inspection database.

#### 2.2.1 Preparing the Inspection Form

Complete all applicable inspection form headings according to the following instructions.

##### 2.2.1.1 Individual Headings

**Farm name & ID** - Use the WinWam database to look up the farm ID.

Inspection Date - Select the date the form is issued to the farm's management.

Reason - Select the applicable inspection reason (type) from the drop-down list.

Inspector – Select the name of the lead Agency inspector.

Farm Alias – Update the farm alias as needed.

Mailing Address – Update the farm mailing address as needed.

Name and title of the individual to whom report is issued - Enter the first and last name and full title of the person to whom the form is issued.

Commodities - List the common names of commodities observed during the inspection. Include brief descriptors after the commodity name when necessary to distinguish between similar commodities (e.g., lettuce, head, Romaine; lettuce, mesclun mix; Asian greens, pak choi). If the number of commodities exceeds the space provided, list only the most prominent commodities in descending order (from most prominent to least). A full list of covered and non-covered produce should be recorded in the inspection report.

Inspector signature - The lead inspector signs here.

Inspector(s) name(s) & titles – Enter each inspector's name and title.

Sprouts – Indicate if the farm does not grow, harvest, pack, or hold sprouts.

Reportable Observations – Indicate whether there are observations of conditions and/or practices to be reported on this form.

#### 2.2.1.2 Observations

Enter reportable observations according to [Reportable Observations, section 2.2.2](#).

Annotate the form according to [Annotation, section 2.2.3](#), including when no reportable observations are made.

Check all applicable inspection criteria with:

- “Observation” for each reportable observation.
- “Corrective Action Taken” for each observation corrected and verified during the inspection.

Leave blank all other criteria not otherwise noted above.

#### 2.2.2 Reportable Observations

You should cite factual observations of significant deviations from the Produce Safety Rule (21 C.F.R. part 112; 6 V.S.A. § 852), and when applicable, significant deviations from

6 V.S.A. § 21, 18 V.S.A. § 4059, or other acts where the Agency has enforcement authority.

Where applicable, when formulating each observation, answer Who (using titles or initials when necessary), What, When, Where, Why, How Much and How Often? Challenge each observation by asking “So What?” (regarding its significance).

Enter reportable observations succinctly and clearly. Conditions listed should be significant and relate to an observed or potential issue with production areas, buildings, equipment, processes, products, employee practices, or records. “Potential issues” should have a reasonable likelihood of occurring based upon observed conditions or practices. Do not cite deviations from policy or guidance documents on the inspection form. As appropriate, observations should include the relationship of observations to a given population, for example, “Two out of 50 records examined were \*\*\*” or “4 out of 12 containers examined were \*\*\*.” When appropriate, an observation may refer to inadequate situations as long as you provide supporting facts (examples) or explanation as to why the condition, practice, or procedure observed is inadequate.

It is preferred not to identify individuals or farms by name within the inspection form. Where appropriate to support the observation, identify the individual(s) or farm(s) by substituting other nonspecific identifying information. Document your evidence in the inspection report, fully explaining the relationship(s).

#### *2.2.2.1 Adulteration Observations*

Review the Produce Safety Rule (21 C.F.R. part 112; 6 V.S.A. § 852), 6 V.S.A. § 21, and 18 V.S.A. § 4059. Include specific factual observations of:

1. Food that has been produced, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health.
2. Food that consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.
3. Food that bears or contains any poisonous or deleterious substance which may render it injurious to health (see 18 V.S.A. 4059).
4. Food containers composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

#### *2.2.2.2 Other Observations*

Do not include other factual observations of significant deviations from other acts unless specifically directed by the Agency.

### 2.2.2.3 Non-Reportable Observations

Do not report opinions, conclusions, or characterize conditions as "violative." The determination of whether any condition is violative is an Agency decision made after considering all circumstances, facts, and evidence.

Non-reportable observations may include:

1. Observations of deviations from specific laws and/or regulations which in your judgment are of questionable significance and deemed not to merit inclusion on the inspection form, but do warrant discussion with management.
2. Observations which in your judgment deviate from official published guidance, not regulations, but warrant discussion with management.

Non-reportable observations should be discussed with management during the final discussion with management (see [Discussions with Management, section 2.2.4](#)) and documented in the inspection report under the non-reportable observations section.

### 2.2.3 Annotation

Annotate the inspection form during the final discussions with management. The annotations are succinct comments about the status of the observations.

If the farm promises or completes a corrective action to an observation prior to the completion of the inspection, annotate the inspection form with one or more of the following comments, as appropriate:

1. Reported corrected, not verified.
2. Corrected and verified.
3. Promised to correct.
4. Under consideration.

The term "verified" means "to confirm; to establish the truth or accuracy." In this case, you must do the verification. In some situations, you will not be able to verify the corrective action unless there is further Agency review or until there is another inspection of the farm.

The farm's stated objections to any given observation or to the inspection form as a whole should not be annotated. If the farm does not wish to annotate a promised or completed corrective action, then do not annotate. The inspection report should include the farm's objections to the observation and the fact the farm declined to have the observation annotated.

When a farm has promised corrective actions and furnishes a date or timeframe (without a specific date) for completion, then you may add "by xxx date" or "within xxx days or months" in the annotation. Where the inspector and the farm have "agreed to

disagree" about the validity of an observation, you may annotate this observation with "Under consideration" or with no annotation based on the farm's desire.

All corrective actions taken by the farm and verified by the Agency should be discussed in detail in the inspection report.

#### 2.2.4 Discussions with Management

After completion of the inspection, meet with the most responsible person available to discuss the objectionable conditions observed. Objectionable conditions may be identified as reportable (see [Reportable Observations, section 2.2.2](#)) or non-reportable (see [Non-Reportable Observations, section 2.2.2.3](#)). During the discussion, be direct, courteous, and responsive with management.

Explain the significance of each item and relate it to the applicable sections of the laws and regulations administered by the Agency.

If significant deviations are observed during the inspection, you should inform management during the closeout discussion that the conditions observed may, after further review by the Agency, be considered violations of the Produce Safety Rule or other applicable statutes or regulations. Enforcement measures available to the Agency may include mandatory corrective action, monetary penalty, embargo, recall, or a cease and desist order. See [Compliance and Enforcement, section 3](#).

Do not be overbearing or arbitrary in your attitude or actions. Do not argue if the farm's management voices a different view of the observations. Explain, in your judgment, the conditions you observed may be determined by the Agency, after review of all the facts, to be violations. Make clear the prime purpose of the discussion is to call attention to objectionable practices or conditions, which should be corrected.

Determine the farm's management's intentions regarding correcting objectionable conditions, including time frames. They may propose corrections or procedural changes and ask you if this is satisfactory. If this involves areas where your knowledge, skill, and experience are such that you know it will be satisfactory, you can so advise them. Do not assume the role of an authoritative consultant. Do not recommend products or services of particular businesses. Advise the farm's management if the Agency receives an adequate response to the inspection form, or other objectionable conditions, within 15 days of the end date of the inspection, it may impact the Agency's determination of the need for subsequent action.

Document in your inspection report all significant conversations with the farm's management or management representatives. In most instances it is not necessary to quote management's response verbatim. Paraphrasing the replies is sufficient.

However, if the situation is such that quoting the reply or replies is necessary, enclose them in quotation marks.

### 2.2.5 Issuing the Inspection Form

Before leaving the premises at the end of the inspection, present the printed signed inspection form to the most responsible farm representative available. All reasonable measures should be taken to issue the inspection form in an expeditious manner. However, in certain circumstances, it may be necessary to leave the premises and return at a later time to issue and discuss your inspectional observations. In this case, you should advise the farm's management that your inspection has not been completed and you will return to issue the inspection form and discuss inspectional findings.

When it is not possible to issue the inspection form in person, you may issue it by email and/or certified mail only if you have an up-to-date and accurate email and/or mailing address for the recipient, and when the recipient acknowledges receiving the inspection form and date of receipt in writing (e.g., such as with an electronic read receipt or certified mailing receipt).

## 2.3 PREPARING & SUBMITTING THE INSPECTION REPORT

The Produce Farm Inspection Report ("inspection report") is for documenting all reportable observations, discussion items of concern, facts, and evidence in support of the inspectional findings and inspection classification. The inspection report may also be used to document relevant background information about a farm, such as information about the farm size and structure (e.g., acres in production; number of employees; management structure); location of covered activities (e.g., production fields, packing or holding facilities, and irrigation sources); or specific production.

Information should be entered succinctly and clearly. Consult with your supervisor regarding information that should be documented in the report.

Complete all applicable inspection report headings according to the following instructions.

### 2.3.1 Individual Headings

Complete all applicable headings.

### 2.3.2 Reportable Observations

Record each reportable observation under this heading. Record the farm's response to each observation as applicable, including annotations and details of any verified or promised corrective actions and time frames.

### 2.3.3 Discussion Items of Concern

Record all discussion items of concern, including other non-reportable observations, under this heading. Record the farm's response to each discussion item as applicable, including annotations and details of any verified or promised corrective actions and time frames.

2.3.4 Inspection Classification

Inspection classifications are used to classify the outcome of an inspection and recommend whether further action is needed to address issues of non-compliance.

Choose the inspection classification listed below that is most representative of the inspectional findings and supported by observations, facts, and evidence.

2.3.4.1 *No Action Indicated (NAI)*

No objectionable conditions or practices were found during the inspection, or the objectionable conditions found do not justify further action.

2.3.4.2 *Advisory Action Indicated (AAI)*

Significant objectionable conditions were found and documented during the inspection that warrant advisory action. See [Enforcement Measures, section 3.1.3](#).

2.3.4.3 *Official Action Indicated (OAI)*

Significant or egregious objectionable conditions were found and documented during the inspection that warrant official regulatory action. See [Enforcement Measures, section 3.1.3](#).

2.3.4.4 *Comparison of AAFM/FDA Inspection Classifications*

The following table should be used when comparing inspection classifications with the FDA or other state programs.

<b>AAFM</b>	<b>FDA</b>
NAI (No Action Indicated)	NAI (No Action Indicated)
AAI (Advisory Action Indicated)	VAI (Voluntary Action Indicated)
OAI (Official Action Indicated)	OAI (Official Action Indicated)

2.3.5 Endorsement

AAI and OAI inspection classifications must be endorsed. The purpose of endorsement is to provide succinct, factual reasons for why the inspection classification was chosen by the inspection team. The endorsement may include recommendations for compliance actions and/or compliance timelines. The endorsement is not a final determination of compliance. The Agency will make a final determination after reviewing all the facts and evidence.

2.3.6 Submitting the Inspection Report

After all applicable headings are complete, the lead inspector should submit the inspection report and supporting evidence in the WinWam Inspection Database.



### 3 COMPLIANCE & ENFORCEMENT

#### 3.1 POLICY

The purpose of this Policy is to ensure that:

1. An educational approach is taken, with the goals of working collaboratively with farms to achieve prompt compliance and directing farms to resources that can assist them with compliance and the implementation of preventive measures.
2. When enforcement measures and administrative penalties are assessed, they are:
  - a. Appropriate for the gravity of the violation;
  - b. Assessed in a fair and consistent manner; and,
  - c. Sufficient to deter both individual violators and the regulated community as a whole from committing violations.
3. Compliance is expeditiously achieved and maintained to promote food safety and public health.

Under this Policy, the Agency seeks to promote consistency with the FDA and other States at a national level regarding the implementation of the Produce Safety Rule, provide greater predictability for the regulated community and the public, maintain transparency in enforcement, and more effectively promote food safety.

This Policy provides guidance for Agency staff, but does not, nor is it intended to, create a right or benefit, substantive or procedural, enforceable at law or in equity, in any person or company. Although this Policy provides guidance regarding the assessment of proposed penalties and enforcement measures, the Agency retains discretion to assess the full range of penalties authorized by statute or regulation in any particular case.

##### 3.1.1 Statutory Background

The Agency is authorized under Chapter 66 (Produce Inspection) of Title 6 of the Vermont Statutes Annotated to enforce the requirements of the rules adopted under the U.S. Food and Drug Administration Food Safety Modernization Act, *Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, 21 C.F.R. part 112 (i.e. the Produce Safety Rule). 6 V.S.A § 852. The Produce Safety Rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. The Agency also has authority to adopt and enforce rules as needed to implement this chapter. 6 V.S.A. § 852; 6 V.S.A. § 855.

In addition to its Chapter 66 powers the Agency has general authority to respond to and remediate public health hazards and food safety issues per 6 V.S.A. § 21. This includes the authority to condemn, confiscate, or establish restrictions on the use, sale, or distribution of produce that constitutes an “adulterated raw agricultural commodit[y].”

6 V.S.A. § 21(b)(2). “Raw agricultural commodity” is defined as “any food in its raw or natural state, including all fruits or vegetables that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing” and “adulterated.” The word “Adulterated” has the same meaning as in [18 V.S.A. § 4059](#) and includes adulteration as defined in the rules adopted under [18 V.S.A. chapter 82](#).

### 3.1.2 Role of Inspectors (Compliance & Enforcement)

You are authorized to monitor compliance, investigate potential violations, and enforce violations of 6 V.S.A. § 852 or rules adopted under this chapter according to the protocols outlined in this manual or as directed by the Agency. When a statutory or regulatory violation is identified, you may be instructed to pursue one of several enforcement measures (see [Enforcement Measures, section 3.1.3](#)). Enforcement measures must be appropriate to the nature and severity of the violation and the compliance history of the farm (see [Determining Enforcement Measures, section 3.1.4](#) and [Compliance Enforcement Decision Table, section 3.2](#)).

The Agency intends to work with farms and the public to identify opportunities to educate the community about the Produce Safety Rule, the supporting science, and the regulatory process. You should follow an educational approach to regulating and seek to work collaboratively with the produce community to achieve prompt compliance and to direct farms to resources to assist with compliance. You may refer farms to key guidance documents, technical factsheets, or other educational resources, when, based on your knowledge, skill, and experience, believe those resources may assist a farm with addressing a produce safety issue. Do not assume the role of an authoritative consultant, and do not recommend products or services of particular businesses.

### 3.1.3 Enforcement Measures

While voluntary compliance is preferred, the Agency has the authority to take various enforcement measures to address violations and to protect the public health and welfare. See 6 V.S.A. §§ 856-857 and 6 V.S.A. chapter 1.

Enforcement measures include:

#### Written warning

The Agency may issue a written warning that shall be served in person or by certified mail, return receipt requested, when the Agency determines that a person is violating the rules listed in 6 V.S.A. § 852 (the Produce Safety Rule). A warning issued under this section shall include:

- (1) a description of the alleged violation;
- (2) identification of this section;
- (3) identification of the applicable rule violated; and

- (4) the required corrective action that the person shall take to correct the violation.

6 V.S.A. § 856.

Cease and desist order

A cease and desist order may be issued to a person the Agency believes to be in violation of the Produce Safety Rule. 6 V.S.A. § 857.

Verbal order or written administrative order to protect public health

The Agency may issue a verbal order or written administrative order to protect public health, including orders for the stop sale, recall, embargo, destruction, quarantine, and release of produce, when:

- (A) the U.S. Food and Drug Administration requires immediate State action; or
- (B) an alleged violation, activity, or farm practice presents an immediate threat to the public health or welfare.

6 V.S.A. § 857. If a verbal order is issued under this section, the Agency must issue written notice to the farm's management within five days of the issuance of the verbal order. The written notice shall include a statement that the farm's management has 15 days from the date the written notice was received to request a hearing.

Order mandatory corrective actions

The Agency may order mandatory corrective actions. 6 V.S.A. § 857.

Take any action authorized under Title 6 chapter 1

The Agency may take any action authorized under Title 6 chapter 1, including assessing administrative penalties as discussed below and accepting assurances of discontinuance. 6 V.S.A. § 857.

Seek administrative or civil penalties

The Agency may seek administrative or civil penalties in accordance with the requirements of section 15, 16, or 17 of Title 6. 6 V.S.A. § 857. Under Title 6, the Agency may issue administrative penalties, not to exceed \$1,000 for each violation. 6 V.S.A. § 15(a). Each violation of a statute listed in 6 V.S.A. chapter 66, or a rule promulgated thereunder, or each violation listed in an order or assurance of discontinuance, may be a separate and distinct offense, and, in the case of a continuing violation, each day's continuance may be deemed to be a separate and distinct offense, but in no event shall the maximum amount of the administrative penalty assessed exceed \$25,000.00. 6 V.S.A. § 15(c).

### Administrative Hearings

If a person that receives a cease and desist order, a verbal order, an administrative order, or a mandatory corrective action under 6 V.S.A. § 857 does not request a hearing in writing within 15 days of receipt of the order, or within 15 days of written notice for a verbal order, the farm's right to a hearing is waived. Upon receipt of a written request for a hearing, the Agency must promptly set a date and time for a hearing. A request for a hearing on a cease and desist order, verbal order, or administrative order issued under 6 V.S.A. § 857 does not stay the order.

A person aggrieved by a final action or decision of the Agency under 6 V.S.A. § 857 may appeal de novo to the Civil Division of the Superior Court within 30 days of the final decision of the Agency. 6 V.S.A. § 857.

#### 3.1.4 Determining Enforcement Measures

When making a recommendation for an enforcement measure, such as in the endorsement section of an inspection report, consider the severity of the alleged violation(s) and the compliance history of the farm. The severity of a violation is determined based on the likelihood that unsanitary conditions or practices cause contamination or adulteration of produce. Use your judgement based on all the facts and evidence of the case and refer to the requirements and definitions in the Produce Safety Rule, 6 V.S.A. § 21, and/or 18 V.S.A. § 4059 to make this determination. The Compliance and Enforcement Decision Table is designed to assist you in making these determinations (see [section 3.2](#)).

Three general categories of severity include:

Minor: Conditions that are unlikely to cause contamination of produce.

Significant: Conditions that may cause contamination of produce if conditions or practices are not corrected.

Egregious: Produce is contaminated, or conditions will likely cause an imminent public health hazard. See [Appendix B: Egregious Conditions](#).

The severity of inspectional findings should be assessed as a whole and should generally be at least equal to the most severe observation(s) noted on the inspection form unless those findings are corrected and verified during the inspection. There may be circumstances when, for example, multiple minor violations demonstrate a pattern of noncompliance, and thus, the overall severity of inspectional findings may be considered more severe than an individual observation.

A farm's compliance history must also be reviewed to assess whether the farm has been previously warned of a potential violation or made aware of an existing violation. Progressive enforcement measures should be considered if a farm has been repeatedly

notified and evidence has been developed through letters, notifications, meetings, or other means.

### 3.2 COMPLIANCE & ENFORCEMENT DECISION TABLE

The Compliance and Enforcement Decision Table is designed to aid you in determining appropriate enforcement measures and to ensure consistency. The table is to be used in conjunction with the Compliance and Enforcement Policy in this chapter. The Agency retains discretion to assess the full range of penalties authorized by statute or regulation in any particular case.

Compliance & Enforcement Decision Table

Inspection Type	Observation Type	Overall Severity of Reportable Observations <sup>1</sup>	Was the farm previously notified of reportable observations? <sup>2</sup>	Documentation <sup>3</sup>	Inspection Classification <sup>4</sup>
Initial	Non-reportable	N/A	N/A	Inspection Report only.	NAI
	Reportable	Minor	N/A	Inspection Report only.	NAI
		Significant	N/A	Inspection Report only.	NAI
		Significant (elevated compliance warranted)	N/A	Inspection Form and Inspection Report.	AAI
		Egregious	N/A	Inspection Form and Inspection Report.	OAI
Routine, Follow-Up, & For-Cause	Non-Reportable	N/A	N/A	Inspection Report only.	NAI
	Reportable	Minor	No	Inspection Form and Inspection Report.	NAI
			Yes	Inspection Form and Inspection Report.	AAI
		Significant	No	Inspection Form and Inspection Report.	AAI
			Yes	Inspection Form and Inspection Report.	OAI
		Significant (elevated compliance warranted)	N/A	Inspection Form and Inspection Report.	OAI
		Egregious	N/A	Inspection Form and Inspection Report.	OAI

1. See [section 3.1.4](#)
2. Previous notification may include notification of reportable observations in a previous inspection form, advisory letter, official letter, or verbal order.
3. See [sections 2.2.2](#) and [2.3](#)
4. See [section 2.3.4](#)

Compliance & Enforcement Decision Table (cont.)

Inspection Classification	Educational Action	Advisory Action	Official Action	Compliance Timeframe
NAI	Discuss with management. Agree on a time frame for CA/PM. Refer farm to educational resources.	None.	None.	Verify CA/PM during inspection when possible. Assess at next routine inspection.
AAI	Discuss with management. Refer farm to educational resources.	Establish a time frame for CA/PM. Evaluate whether to issue an advisory notice, schedule a F/U inspection, and/or take other advisory action.	None.	Verify CA/PM during inspection when possible. Assess at next routine or F/U inspection.
OAI	Discuss with management. Refer farm to educational resources.	See official action.	Establish a time frame for CA/PM. Evaluate whether to issue an official notice, administrative penalty, schedule a F/U inspection, and/or take other official action necessary to protect public health.	Verify CA/PM during inspection or at F/U inspection.
F/U = Follow-up inspection CA/PM = Corrective action / preventative measures				

### 3.3 PENALTY MATRIX

This penalty matrix is designed to aid in determining administrative penalties based on the nature and severity of the violation(s) and the farm’s compliance history. However, the Agency retains discretion to assess the full range of penalties authorized by statute or regulation in any particular case.

<b>Severity<sub>1</sub></b>	<b>History of Non-Compliance</b>	<b>Recommended Penalty</b>
Minor	None	None
	Repeat or uncorrected violation(s)	Up to \$250 per violation
Significant	None	None
	Repeat or uncorrected violation(s)	Up to \$500 per violation
Egregious	N/A	Up to \$1,000 per violation
1. See <a href="#">section 3.1.4</a>		

See 6 V.S.A. § 15. In determining the amount of the penalty to be assessed, the Agency may also consider one or more of the following:

1. The degree of actual and potential impact on public health, safety, and welfare resulting from the violation.
2. The presence of mitigating or aggravating circumstances.
3. The economic benefit gained by the violation.
4. The deterrent effect of the penalty.
5. The financial condition of the violator.



## 4 CROSS JURISDICTIONAL EVENT RESPONSE AND COORDINATION

### 4.1 EMERGENCY RESPONSE (GENERAL)

The Agency has authority to respond to emergencies on farms in order to remediate public health hazards and has authority to condemn, confiscate, or establish restrictions on the use, sale, or distribution of adulterated raw agricultural commodities. 6 V.S.A. § 21. See [section 3.1.1](#).

Examples of farm emergencies which may require a public health response by the Agency include foodborne illness outbreaks; positive pathogen samples; flooding of cropland; agricultural structure fires; agrichemical spills or contamination events; or acts of intentional adulteration.

### 4.2 JOINT/CROSS JURISDICTIONAL COORDINATION

Event response may often involve cross jurisdictional coordination among state, federal, and local partners.

#### 4.2.1 Partner Agencies and Departments

##### 4.2.1.1 *Vermont Department of Health (VDH)*

VDH has jurisdiction over most food facilities in Vermont, except farms, facilities, and/or food products regulated by the Agency's Produce Program, Maple Program, Dairy Section, or Meat and Poultry Inspection Service. VDH and the Agency may share jurisdiction on certain farms or facilities such as farm-mixed type facilities.

In the event of a produce-related foodborne illness outbreak, VDH and the Agency may coordinate a joint response. For example, VDH may provide epidemiological data analysis, lead initial traceback efforts, and perform investigations of retail food establishments and food facilities. If traceback includes farms, the Agency may lead farm-level traceback and investigations.

##### 4.2.1.2 *Vermont Department of Public Safety – State Emergency Operations Center (SEOC)*

The Vermont SEOC coordinates and manages information flow among state partners (agencies, departments, and local jurisdictions) to ensure statewide coordination during the response and recovery phases of declared emergencies, including emergencies that may impact Vermont produce farms and businesses.

##### 4.2.1.3 *U.S. Food and Drug Administration (FDA)*

The FDA has jurisdiction over most food products involved in interstate commerce under the FD&C Act.

##### 4.2.1.4 *U.S. Centers for Disease Control and Prevention (CDC)*

CDC monitors and coordinates response to multi-state foodborne illness outbreaks and provides guidance to state jurisdictional agencies and departments when necessary.

#### 4.2.1.5 U.S. Department of Agriculture (USDA)

USDA's Food Safety and Inspection Service (FSIS) has jurisdiction over certain food products including meat and poultry, egg products, and catfish.

#### 4.2.2 Cross Jurisdictional Coordination Protocols

When cross jurisdictional coordination is required, follow these protocols:

1. Collect sufficient information from the reporting entity (or from the Agency's own investigative findings) using official forms or reports as applicable (e.g., consumer complaint form; Produce Farm Inspection Form and Produce Farm Inspection Report).
2. Report findings to the FSCP Division Director; await guidance.
3. If a response is warranted, prepare the appropriate regulatory staff, equipment, and/or supplies. See [section 2.1.2.1](#) for a list of inspection-related equipment and supplies.
4. Notify the appropriate partner organizations if/when directed:
  - a. VDH – such as when cross jurisdictional authority is likely, and/or when additional event response capacity or an advisory role is needed.
  - b. FDA – such as when implicated product is involved in interstate commerce and cross jurisdictional authority is likely, and/or when additional event response capacity or an advisory role is needed.
  - c. Others – as needed depending on the circumstances.
5. Initiate event response according to Agency directive(s) and applicable response plans, guidance documents and protocols.

#### 4.2.3 Event Response Contacts

VAAFM – Food Safety and Consumer Protection Division

POC 1: Dr. Kristin Haas, Division Director and State Veterinarian

Address: 116 State St., Montpelier, VT 05620

Phone: (802) 828-2426

Email: [Kristin.haas@vermont.gov](mailto:Kristin.haas@vermont.gov)

POC 2: Dr. Kathy McNamara, Division Deputy Director and Assistant State Veterinarian

Address: 116 State St., Montpelier, VT 05620

Phone: (802) 828-2426

Email: [Katherine.mcnamara@vermont.gov](mailto:Katherine.mcnamara@vermont.gov)

VDH – Food and Lodging Program

POC: Elisabeth Wirsing, Program Chief

Address: 108 Cherry St., PO Box 70, Burlington, VT 05402-0070

Phone: (802) 863-7221

Email: [AHS.VDHFoodandLodging@vermont.gov](mailto:AHS.VDHFoodandLodging@vermont.gov)

FDA

POC 1: Milan McGorty, FDA State Liaison Officer

Email: [Milan.McGorty@fda.hhs.gov](mailto:Milan.McGorty@fda.hhs.gov)

POC 2: Jeannette Fredrick, FDA CAP Project Manager

Email: [jeannette.fredrick@fda.hhs.gov](mailto:jeannette.fredrick@fda.hhs.gov)

Phone: (716) 846-6258

Cell: (240) 704-1341

Vermont Department of Public Safety – State Emergency Operations Center (SEOC)

Address: 45 State Drive, Waterbury, VT 05671-1300

Phone: (802) 244-8721

## 5 APPENDICES

[Appendix A: Pre-Inspection Call Job Aid](#)

[Appendix B: Egregious Conditions](#)

## APPENDIX A: PRE-INSPECTION CALL JOB AID

*This job aid serves as a reference guide when conducting a pre-inspection call.*

Explain to the farm who you are why you are calling. Ask to speak to the farm's primary contact, or other responsible party if the primary contact is not available. Be prepared to provide a brief overview of the Produce Safety Rule and your role as an inspector.

- Reconfirm the farm's coverage and size (based on average annual produce sales). If the farm's coverage and/or size has changed, determine whether an inspection is necessary.
- Reconfirm the farm's primary contact information (first/last name, phone number(s), email, and role).
- Reconfirm the farm's physical and/or mailing address if necessary.

If no inspection is required, thank them for their time and end the call.

When an inspection is required:

Explain that you are calling to schedule an inspection within the next 5 or 10 business days.

- Confirm the farm is in operation and will be conducting covered activities on covered produce during this time.
- Determine which commodities and covered activities can be observed during this time.
- Identify key farm personnel needed during the inspection.
- Determine the inspection date and time.
- Provide a high-level overview of the goals and purpose of the inspection.
- Explain the general flow of the inspection and what the inspection will cover.
- Determine the location where you plan to meet and where you should park.
- Provide the number of team members on the inspection.
- Ask about biosecurity practices on the farm.
- Ask about farm visitor practices such as sign-in requirements.

Optional:

- If the farm has multiple locations/fields, ask whether the farm can provide a list of all addresses or GPS coordinates, or a field map prior to the inspection.

Thank them for their time and end the call.

- Send a follow-up email re-confirming the date and time of the inspection and any other relevant information.

APPENDIX B: EGREGIOUS CONDITIONS

*Working definition agreed upon with NASDA/FDA workgroup*

Definition:

A practice, condition, or situation on a farm or in a packing house that is reasonably likely to lead to:

- Serious adverse health consequences or death from the consumption of or exposure to covered produce;
- An imminent public health hazard is posed if corrective action is not taken immediately (example: edible portions of produce contacting a potential source of contamination).

Covered produce means: produce that is subject to the requirements of 21 CFR Part 112, in accordance with 21 CFR 112.1 (describes covered produce) and 112.2 (describes produce that isn't covered). The term "covered produce" refers to the harvestable or harvested part of the crop (see 21 CFR 112.3).

Application

Conditions as outlined below would trigger a regulatory response, even if observed during a non-regulatory farm visit (e.g. during an On-Farm Readiness Review.) In general, however, if a condition on a farm is corrected and no affected product enters commerce, no regulatory response is required.

Grower's action in response to notification by the regulator of an egregious condition

The grower's action will not change whether or not a condition is considered egregious; however, the grower's action may impact the response of the regulator. This document is not intended to go into depth into enforcement responses. It provides a starting point for other programs, such as inspection approach and the on-farm readiness review.

<b>Grower Action</b>	<b>Regulator Response During a Readiness Review</b>	<b>Regulator Response During an Inspection*</b>	<b>Examples</b>
Grower fails to commit to take effective action	Transition to regulatory inspection (contact regulatory authority)	Immediate action to prevent contaminated product from reaching the marketplace	
Grower takes immediate action to address the problem	No action	Notify via applicable document/form <sup>#</sup>	
Grower has procedures in place to address the	No action	No action; if corrective action will take place in the	Example: evidence of significant animal

issue and applies or will apply the procedures appropriately		future, may want to confirm during reinspection	intrusion, and grower has procedures in place to evaluate before harvest; or grower has blocked off the area and will not harvest it
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\*There may be situations where remediation isn't available for the grower, so regulators may need to be flexible in responding.

# Regulator may consider issuing a regulatory letter

Factors to consider in determining whether a practice, condition, or situation may be an egregious condition

*Note: These factors are not intended to be stand-alone but should be considered together in determining the impact of the findings on the produce.*

The examples listed below are intended to be examples only and should not be considered to be a final determination that the situation is or is not egregious.

Source of contamination

1. Type of contamination  
Examples: biological (microbial, virus, parasite) vs. chemical vs. physical
2. Extent of contamination source: widespread vs. limited or contained (i.e., contamination covers large amount of product vs. contamination limited to a small amount of product)  
Examples:
  - a. contaminated water source used for overhead irrigation vs. grey water on small corner of a field
  - b. rampant animal fecal contamination vs. limited animal intrusion
3. Potential for farm practice, condition or situation to increase contamination risk  
Examples:
  - a. dump tank with dead rats floating
  - b. visibly filthy harvesting bins or trailer beds that cannot be adequately cleaned in direct contact with covered produce
4. One-time event vs on-going practice or condition  
Examples:
  - a. one cow got loose and contaminated one small area of a field vs allowing cattle to roam through the field regularly

- b. birds roosting in a packing house vs. occasional bird flying through a packing house

#### Route of contamination

1. Potential to contact edible portion of the plant  
Examples:
  - a. contaminated water applied to the fruit post-harvest
  - b. crop harvested from the ground as a normal part of harvest (e.g., some nuts) vs. tree fruit harvested from the ground
2. Timing of contamination event in relation to the date of harvest or post-harvest
3. Potential for contamination of produce fields from surrounding areas' land use based on geography of the farm  
Example:  
Septic field uphill from the growing area, with no barriers or mitigation in place
4. Likelihood of spread of contamination  
Example: Harvesting an area of the field with widespread animal feces using automated harvesting equipment and comingling produce harvested.

#### Examples of practices, conditions, or situations that may be egregious conditions

- Farmer applying raw manure in direct contact with edible portion of the plant
- Human or animal waste observed in water used directly on the produce with no treatment of the water
- Significant animal/pest intrusion on farm or in packing house
  - Feral pig intrusion
  - Large flocks of seagulls, geese, and other birds in fields of leafy greens at harvest
- Worker bodily fluids in contact with produce, directly or via equipment such as knives
  - people urinating, defecating, and spitting in produce fields
  - children's diapers in the fields
- Visibly ill workers handling produce
- Human waste systems (e.g., septic systems, portable toilets) not functioning properly.
  - Septic overflow on the farm into an irrigation canal
  - sewage leaking from a porta-potty into a field of leafy greens
- Human and animal incursion in irrigation water
  - Dead body (human or animal) in an irrigation canal
  - Bathing, swimming, and washing clothes in on-farm reservoirs
- Gasoline spill in produce field with impact on product

#### References for Egregious Conditions Appendix

FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables:

<http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlantProducts/UCM169112.pdf>



Dictionary definitions of egregious:

- Merriam-Webster: Egregious: very bad and easily noticed; conspicuously bad
- Dictionary.com: extraordinary in some bad way; glaring; flagrant
- Cambridge: extremely bad in a way that is very noticeable