

WORKER HEALTH, HYGIENE, AND TRAINING TO SATISFY THE REQUIREMENTS OF THE FSMA PRODUCE SAFETY RULE

Worker Health, Hygiene and Training to Satisfy the Requirements of the FSMA Produce Safety
Rule

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Abstract

The Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. Operations covered under the FSMA PSR must meet standards for worker training, health and hygiene. Produce operators (e.g., growers, packers) subject to the PSR will need to comply with the new worker health, hygiene and training requirements. The need for a training curriculum to assist produce operators who are covered under the FSMA PSR is needed for compliance. This training curriculum includes all required standards outlined in subpart D including visual representations of personal health and hygiene; as well as, content to confidently train farm and packinghouse workers. This training curriculum was presented to >20 Virginia Cooperative Extension (VCE) agents and specialists in a train-the trainer model, who also evaluated the curriculum. As a result of the train-the trainer sessions, the curriculum has been refined by incorporation of VCE agent and specialist feedback, and is ready for use by stakeholders and extension educators nationwide. The training is currently available in English and Spanish, and is best taught using technology (e.g., Microsoft PowerPoint), but can be taught without technology (e.g., using printed aids). Overall, this curriculum will assist stakeholders in obtaining FSMA PSR compliance specific to subpart D in approximately <1 h, and can be taught directly by produce operators or through extension educators.

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Introduction

Background and Setting

Food safety is a growing concern for consumers in the United States (US). The US Centers for Disease Control and Prevention estimate 1 in 6 Americans (approximately 48 million people) get sick each year from consuming contaminated food and beverages. These illnesses contribute to a reported 128,000 hospitalizations and 3,000 deaths each year in the US, with an approximate cost of at least \$15.6 billion dollars (Scallan et al., 2011; CDC, 2018). As a result, the Food Safety Modernization Act (FSMA) was signed into law in 2011 to transform the food system to a proactive approach, compared to a reactive approach. FSMA gives authority to the US Food and Drug Administration (FDA) to enforce seven rules, which include Preventive Controls Rules for Human Food, Preventive Controls Rules for Animal Food, Produce Safety Rule, Foreign Supplier Verification Program (FSVP) Rule, Accredited Third-Party Certification, Sanitary Transportation Rule and the Intentional Adulteration Rule.

Of the seven primary FSMA rules, the Produce Safety Rule (PSR), specifically addresses fruits and vegetables. This is important as one study found that 38.1% of all hospitalizations and 22.9% of deaths associated with domestically-acquired foodborne illnesses occurring from 1998 – 2008 were attributed to produce (Painter et al., 2013). In 2015, the final rule was published entitled “*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*” (FDA, 2015). The FSMA PSR establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. This rule applies to most farming operations, who grow, harvest, pack and hold

produce, or perform at least one of these activities. The FSMA PSR describes key requirements for produce operations to meet the standards necessary to satisfy the rule. These requirements include (CFR part 112):

- Worker Health and Hygiene, subpart D
- Agricultural Water, subpart E
- Biological Soil Amendments, subpart F
- Domesticated and Wild Animals, subpart I
- Equipment, Tools and Buildings, subpart L
- Production of sprouts, subpart M

Overall, this rule is the most sweeping reform to the produce industry in almost 80 years, since the US FDA Food, Drug, and Cosmetic Act of 1938 (REF). In many cases, the requirements outlined in the FSMA PSR are being enforced for the first time on produce operations, as produce safety requirements used to be voluntary (e.g., Good Agricultural Practices). Currently, in Virginia, the FSMA PSR is enforced by the Virginia Department of Agriculture and Consumer Services (VDACS) with enforcement for large, small, and very small farms in 2018, 2019, and 2020, respectively.

Statement of the Problem

Produce operations, who are covered by the FSMA PSR, are required to provide worker health and hygiene training to their employees at least once annually. Employers must comprehensively cover all information outlined in the FSMA PSR subpart D as it relates to worker health, hygiene, and training, and the training must also be documented, with records

retained for 2 y. Many produce stakeholders felt this requirement “to train workers annually on FSMA PSR standards” was a significant hurdle, as they were unsure of what needed to be covered, or lacked confidence in the material. I heard this feedback primarily from members of state departments of agriculture and extension educators while at conferences and meetings such as the Southern Regional Integrated Produce Safety meeting. Prior to this project, to our knowledge, a training curriculum did not exist in Virginia, or the US, to achieve this.

Purpose of the research

The purpose of this project was to develop a curriculum that comprehensively met all of the requirements of the FSMA PSR, as it relates to subpart D: worker health, hygiene, and training. The outcome of this project was also to provide produce operators (i.e., farmer, packers) with a curriculum that would increase their workers’ knowledge, and understanding of science-based health and hygiene practices.

Objective of the Research

The objective of this project was to effectively communicate science-based health and hygiene requirements to produce workers to assist in compliance of the FSMA PSR through a training curriculum. The training curriculum was reviewed by VCE extension agents and specialists. This will significantly benefit produce operations who, prior to this study, were required to perform a training, without any assistance.

Definition of Terms

1. *The Food safety Modernization Act (FSMA)* – signed into law in 2011 and seeks to better protect public health by proactively strengthening the food system in the United States through seven primary rules.
2. *The Produce Safety Rule (PSR)* – is one of the seven primary rules in FSMA and was published in November 2015. The PSR establishes science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown for human consumption.
3. *Virginia Cooperative Extension (VCE)* – is a network of educational outreach professionals that provide residents in the Commonwealth of Virginia with resources in the areas of Agriculture and Natural Resources (ANR), Family and Consumer Sciences (FCS), Community Viability, and 4-H Youth Development. Since 1914, and the passage of the Smith-Lever Act, VCE has operated as the primary in-state outreach service, made up of the commonwealth's two land-grant Universities: Virginia Tech and Virginia State University (Virginia Cooperative Extension, 2018)
4. *The Virginia Department of Agriculture and Consumer Services (VDACS)* – Established in 1877, the Virginia Department of Agriculture and Consumer Services (VDACS) promotes the economic growth and development of Virginia agriculture, provides consumer protection and encourages environmental stewardship. It is the government agency in Virginia, responsible for enforcing compliance of the FSMA PSR, under an agreement with the US FDA.

5. *The US Food and Drug Administration (FDA)* – The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation (FDA, 2018).
6. *Covered Farm* – a produce operation that is subject to the FSMA PSR, and must comply with all requirements of the rule.
7. *Food contact surfaces* – includes food contact surfaces of equipment and tools used during harvest, packing and holding under the FSMA PSR (FDA, 2015).
8. *Produce worker* – any employee who handles covered produce and or works with food-contact surfaces (including temporary, part time, seasonal, and contracted employees).

Review of Literature

The purpose of this literature review is to gain an insight into the current understanding and necessity for the curriculum that was developed as a part of this project. As consumption of fresh fruits and vegetable increase, the likelihood of foodborne illnesses related to produce are expected to increase (Carstens et al, 2019). According to US CDC, the number of produce-borne outbreaks increased in the U.S., from 2010 to 2017 (12.7% n= 228), compared to from 2004 to 2010 (9.2% n=163) (CDC, 2017). Additionally, the number of multi-state outbreaks associated with produce commodities increased; as well as, the number of deaths due to these outbreaks (REF). One review (Greig et al., 2007) estimated that 20% of all foodborne bacterial illnesses are due to transmission by food workers. Furthermore, the review also attributed a total of 647 foodborne outbreaks, causing 54,888 illnesses, to food workers. Due to the fact that workers in produce operations are so integral in both the pre- and post-harvest environment, there are

multiple routes of possible produce contamination. Pathogens can be introduced and contaminate produce through a number of different routes. For example, a study (Solomon et al., 2002) observed irrigation water transmitted *Escherichia coli* O157:H7 to crops, such as lettuce. Another route of contamination is biological soil amendments of animal origin that unless treated using a scientifically validated process, such as compost, have been shown to contaminate produce through the spread of enteric pathogens (Doane et al., 2007). A study (Doane et al., 2007) found that *E. coli* O157:H7 was found in 3.6% of beef cattle, 3.4% of dairy cattle, 0.9% of chicken, 7.5% of turkey, and 8.9% of swine samples. Equipment, and tools, such as harvesting knives or buckets, may also become contaminated, and thus may contaminate produce. Therefore, it is vitally important that workers who come in contact with produce, and or equipment/tools be trained in a way that adequately reduces the risk of contamination. Iceberg lettuce heads were cross-contaminated with *E. coli* O157:H7 when on the blade of a field coring device (Taormina et al., 2009). In another study, (McEvoy et al., 2009) a contaminated field coring knife was capable of transferring *E. coli* O157:H7 to lettuce heads.

In addition to potential contamination during pre-harvest and harvest, fresh produce can be contaminated during post-harvest activities, such as during washing and storage. Fresh produce is often washed or flumed, and thus, contact with water may be another route of contamination, as pathogens initially found on one piece of produce could contaminate the rest of the produce as it is being washed. For example, one study (Smolinski et al., 2018) found that both *Salmonella enterica* and *E. coli* O157:H7 cross-contaminated spinach, cilantro, and Romaine lettuce during pilot plant-scale processing including washing/fluming. Processing and cleaning equipment have also been found to contaminate produce. For example, Castillo and

colleagues (2004) observed a 33.3% frequency of *E. coli* from farm environmental samples of a conveyor system at a melon farm in Texas.

Finally, the workers themselves have the potential to contaminate fresh produce at any point during pre-harvest, harvest and post-harvest. Contamination may occur due to poor hygiene, working while sick, and improper or inadequate food safety training. The need for adequate food safety training for workers including handwashing and other practices is essential to the prevention and mitigation of foodborne pathogens (Carstens et al., 2019). In summary, it is clear, based on the literature available, that the implementation of a comprehensive and adequate training curriculum for produce operations/workers is important. Therefore, this project (i.e., development of a worker health, hygiene, and training curriculum), will assist produce operations to mitigate contamination risks during the growing, harvesting, packing and holding of produce.

Theoretical Framework

The theoretical framework that informed this project was the FSMA PSR, and the requirements that it describes for produce operations. The PSR outlines the specific areas of knowledge that produce workers, who are covered by the rule, that must be trained in. In addition, to the PSR, the project was also informed by the PSR guidance document, 'Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption' published by the FDA to provide background and interpretation for the rule (FDA, 2018). This document was used as the foundation for the training curriculum with specific focus on the requirements related to FSMA PSR subpart D. For example, the

guidance document outlines ways to (i) evaluate the required training content, (ii) understand who needs to be trained, (iii) determine the required records for training, (iv) among other guidance. Lastly, the guide for the 'On Farm Readiness Review' (OFRR) program was also used to aid in development of this training curriculum.

Project Overview

Targeted Population and Participating Audience

The target population for the project was VCE agents and specialists, who would be participating in a train-the-trainer, and evaluating (by providing feedback) the program. The participating audience was 20 VCE agents and specialists. Each VCE agent or specialist participated in either an in-person or one of two virtual train-the-trainer sessions. These VCE agents and specialists were recruited through emails and advertisements for the in-person training at the 2020 VCE winter conference.

Methodology

As previously mentioned several resources were reviewed to develop the comprehensive training curriculum, and ensure the training curriculum exhaustively covered every aspect required by the PSR, including the FSMA PSR rule, FSMA PSR guidance document, and OFRR training manual to ensure that the training curriculum exhaustively covered every aspect required by the PSR.

The project had both quantitative and qualitative methods of data collection during the curriculum development stage. For example, participants were asked to answer multiple choice questions, which provided quantitative data; and participants were also asked to provide fill-in-the-blank feedback forms on sections of the curriculum, which provided qualitative data on how the curriculum could be improved. Once the participating audience had completed one of the train-the-trainer sessions, they were asked to complete an anonymous survey (a copy is

included in the appendix). The purpose of the survey was to collect feedback from the participants to improve the training curriculum (i.e., refine), before it would be available to the produce industry. The survey consisted of seven questions, such as *'Would you recommend this curriculum to other VCE agents?'*, *'Would you recommend this curriculum to other state's extension and or departments of agriculture?'* and *'Do you have suggestions on how to improve this curriculum for produce workers?'*. Upon delivery to produce workers, five questions will be asked to reinforce their knowledge. VCE agents and specialists who participated in one of the three train-the-trainer sessions were asked to answer the questions, and evaluate if the questions were too easy, fair, and or too hard for produce workers (the intended audience). The survey data was collected though hard copy (in-person train the trainer); as well as, electronically by Qualtrics (virtual train the trainer). The completed surveys were reviewed, compared, and resulting feedback was used to improve the training curriculum.

Outcomes, Discussion, and Recommendations

Project outcomes

Twenty VCE agents and specialists completed the train-the-trainer session, either in-person or virtually by zoom. All (100%) of these participants completed the evaluation surveys. All of the participants (100%) indicated that the train-the-trainer session better prepared them to train produce workers in the requirements of the FSMA PSR. Of the 12 participants who participated virtually by zoom, 92% (11/12) indicated that the review questions were fair. Additionally, 100% of participants indicated they would recommend the curriculum to VCE extension agents, specialists, or other state's extension and state departments of agriculture. Only 20% of participants (4/20) indicated that they had suggestions on how to improve the training curriculum. Participant suggestions ranged from spelling corrections, use of alternative wording to minimize confusion among workers receiving the training, and to creating an audio recording to be produced for the Spanish version of the curriculum. The training curriculum, and all survey feedback was sent to the VDACS Produce Safety Team to seek input from the PSR enforcement agency in Virginia.

Project Impact and Recommendations

There are a number of anticipated impacts as a result of this project. As the literature has identified, adequate and proper worker training is vital to the proactive mitigation of produce related foodborne illnesses in the US. This project also has resulted in the only curriculum currently available, to our knowledge, that comprehensively addresses all of the requirements

of the FSMA PSR, as it relates to worker health, hygiene, and training (subpart D). Firstly, this project impacts the extension education field, specifically the extension system as it provides a curriculum to agents across the county to train produce workers in their localities. Secondly, this project will benefit produce operations as it provides crucial assistance to address a knowledge gap. Without this project, managers of produce operations would be required to create their own training materials, or at best piece together existing materials, while hoping they are sufficient to fully satisfy the specific FSMA PSR requirements. Finally, this project will have the anticipated long-term impact of reducing the number of produce related foodborne illnesses, and outbreaks.

As a result of this project, it is recommended that this curriculum be presented annually, by trained extension agents, to satisfy FSMA PSR requirements, and aid in regulatory compliance. In additionally, it is recommended this curriculum become available to states outside of Virginia, and disseminated to rural areas who may not have extension services. While, the scope of this project was limited to Virginia (e.g., train the trainers, survey feedback); in the future, this project will be expanded to other state's extension programs and departments of agriculture (for implementation, and use).

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Appendices

Appendix A – Post training survey

Produce Safety Rule Worker Training Curriculum Evaluation

Thank you for participating in my online train-the-trainer session for the Produce Safety Rule Worker Training Curriculum.

Please assist me in improving this curriculum by completing this survey. You will first be asked to complete the review questions.

As a reminder; the produce workers who participate in this training will receive these questions in print form not via Qualtrics. This is simply to obtain your feedback.

Which of the following rules of the Food Safety Modernization Act does this training address?

- Preventative Controls for Human Food (1)
- Sanitary Transport of Food and Animals (2)
- Produce Safety Rule (3)
- International Adulteration of Food (4)

What should you do if you are sick?

- Continue working because you might feel better later (1)
- Don't tell anyone (2)
- Try your best not to vomit on the produce (3)
- Tell your supervisor (4)

You should eat/drink/smoke or use tobacco products in which of the following places:

- While harvesting produce in the field (1)
- While packing produce (2)
- In your designated break area (3)
- While washing produce (4)

Which of these statements about toilet facilities is **NOT** true?

- Toilet facilities should be cleaned to ensure they are suitable to use (1)
- Toilet facilities should be supplied with toilet paper (2)
- Toilet facilities should be accessible to you (3)
- Toilet facilities do not need a handwashing station near them (4)

Which of the following is the correct order to clean and sanitize food contact surfaces?

- 1-Apply a sanitizer and allow to air dry, 2-scrub surface with appropriate detergent, 3-remove dirt from surface with clean water/tools and 4-rinse surface with clean water (1)
- 1-Rinse surface with clean water, 2-apply a sanitizer and allow to air dry, 3-scrub surface with appropriate detergent and 4-remove dirt from surface with clean water/tools (2)
- 1-Remove dirt from surface with clean water/tools, 2-scrub surface with appropriate detergent, 3-rinse surface with clean water and 4-apply a sanitizer and allow to air dry (3)
- 1-Scrub surface with appropriate detergent, 2-remove dirt from surface with clean water/tools, 3-rinse surface with clean water and 4-apply a sanitizer and allow to air dry (4)

Do you think the review questions are:

- Fair (1)
- Too Easy (2)
- Too Hard (3)
- Other/comments (4) _____

Did this train-the-trainer session better prepare you to train produce workers in the requirements of the Produce Safety Rule?

- Yes (1)
- No (2)

Do you intend to use this curriculum to train produce workers?

Yes (1)

No (2)

Would you recommend this curriculum to other VCE agents?

Yes (1)

No (2)

Would you recommend this curriculum to VCE specialists?

Yes (1)

No (2)

Would you recommend this curriculum to other state's extension or departments of agriculture?

Yes (1)

No (2)

Do you have suggestions on how to improve this curriculum for produce workers?

Yes (1) _____

No (2)



Produce Safety Rule Worker Training

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The Food Safety Modernization Act (FSMA)

Food Safety Modernization Act (FSMA) overview

- Most sweeping reform of our food safety laws in more than 70 years
- Signed into law in 2011
- Proactive vs reactive approach
- Aim is to prevent food from becoming contaminated



Seven New Food Safety Regulations

- **Produce Safety Rule**
- Preventive Controls for Human Food Rule
- Foreign Supplier Verification Rule
- Preventive Controls for Animal Food Rule
- Third Party Accreditation
- Sanitary Transport of Food and Animal Food
- International Adulteration of Food



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The Produce Safety Rule (PSR)

- Science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms
- Final rule was published in November 2015
- Requires that workers be trained in food safety principles.
- Upon hire and at least once annually



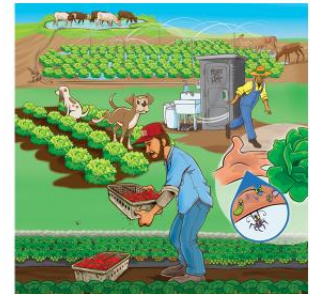
Why food safety matters to you as a worker on this farm

- Workers can contribute to contamination of fresh fruits and vegetables
- Workers can also have the largest contribution to preventing this
- There are simple tasks that can help prevent contamination
- Seek to identify risks and know how to reduce their impact them
- You know this farm better than anyone



How can produce become contaminated?

- All farm activities have the potential to introduce contaminants to fresh produce
- As a result we are here to receive proper training about how to reduce those risks during your daily tasks on the farm.



Worker health

Worker health – Know the symptoms

- Do not work when you are sick!
- Including work with any surface that could contact food
- Open wounds, vomiting, diarrhea
- Is someone at home sick with a contagious disease?
- What if a coworker is sick?



Worker health

Worker health – Report it

- Tell your supervisor
- Open wounds, vomiting, diarrhea
- You can only return to work when your condition no longer poses a contamination risk



Worker hygiene

Proper attire for the work area

The PSR requires that you maintain a certain level of personal cleanliness to protect against the likelihood of contaminating fresh produce and food contact surfaces

Best practices to achieve this include:

- Wearing clean clothes and personal protective equipment
- Removing or covering hand jewelry that can't be cleaned
- Ensuring your gloves (if you use gloves) are in a sanitary condition when they are being used. Change them frequently or clean as needed.
- Washing hands correctly when appropriate



Worker hygiene

Break Areas

- You should only eat, chew gum, smoke or use chewing tobacco products in your designated break area. This will reduce that chance of contaminating produce.
- Drinking beverages is permitted in designated areas.



Worker hygiene

Avoid contact with animals

- When working with fresh produce, avoid contact with animals such as livestock, poultry etc.
- Take steps to reduce the chance of contaminating produce when in direct contact with working animals. An example of this is handwashing.



Worker hygiene - Handwashing

Handwashing is very important in reducing the risk of contaminating produce.

- Toilet breaks
- When you first get to work or start work on a new task with fresh produce
- Food/smoking breaks
- If you use gloves you should wash your hands before you put them on
- If you come into contact with animals (working animals or any other animals) or their waste
- Taking out trash
- Whenever your hands might have become dirty



Worker hygiene - Handwashing

1. Wet your hands with clean water
2. Apply soap
3. Scrub your hands and forearms for at least **20 seconds**. Pay attention to cleaning between your fingers and around your nails
4. Rinse your hands
5. Dry your hands with single use paper towel
6. Throw paper towel in trash

If you choose to use a hand sanitizer; it can only be used in addition to handwashing and can **NEVER** take the place of handwashing

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Worker health & hygiene – Toilet facilities

Place used toilet paper in the toilet – not in trash/floor
Do not wear apron into toilet

Facilities should:

- Be accessible to you
- Be cleaned to ensure they are suitable to use
- Kept supplied with toilet paper
- Be in sufficiently close proximity to a handwashing station so that it is practical to wash your hands.



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Domesticated & Wild Animals

- Keep domesticated animals out of produce fields.
- Assess the relevant areas of your fields for evidence of contamination due to working animals or wildlife.
- Evidence includes animal waste, crop destruction or animal observation
- If produce is contaminated with feces, do not harvest.



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Soil amendment use

- Soil amendments may pose a risk if used incorrectly.
- Biological soil amendments of animal origin (BSAAO)
- Treated – processed to adequately reduce microorganisms
- Untreated – raw manure
- Untreated pose significant microbial risks due to pathogens in feces



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Soil amendment use

So how must you use untreated/raw manure?

- In a manner that does not become a potential source of contamination for covered produce, food contact surfaces, water sources etc.

How must you apply untreated/ raw manure?

1. Applied in a manner that does not contact covered produce **during application** and minimizes the potential for contact with covered produce **after application**
OR
2. Applied in a manner that does not contact covered produce **during or after application**



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Soil amendment handling

Equipment and tools (pitch forks, shovels, etc.) used for handling soil amendments must be used in a manner that minimizes the potential for contamination.

Best practices to achieve this include:

- Designate specific equipment to minimize cross-contamination (tools/clothing)
- Direct traffic (foot/vehicles) around BSAAO storage/application areas
- Do not store BSAAO uphill from produce - runoff
- Minimize animal access
- Cover piles
- Separate treated and untreated BSAAO
- Always wash hands after handling



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Postharvest Handling & Sanitation

Dropped Produce

- Never harvest produce that has been dropped on the ground.
- Damage caused by being dropped on the ground could introduce or cause an increase of pathogens
- Does not include:
 - Root crops (carrots)
 - Crops that grow on the ground (cantaloupe)
 - Intentionally dropped as part of harvest (almonds)

Trash

- Remove trash frequently to avoid contamination and attracting pests



Postharvest Handling & Sanitation

Harvest containers and equipment

- Need to be inspected to ensure they are functioning properly, cleaned and maintained to ensure they don't become a source of contamination.

What to do if containers are not acceptable for use:

- Report such problems to a supervisor
- Cleaning and if necessary sanitizing

This same principle is required for all food contact surfaces including equipment and tools.



Postharvest Handling & Sanitation

Commonly known steps to clean and sanitize your equipment

1. **Remove** dirt/soil/food material/debris from food contact surface with tools/clean water
2. **Scrub** the surface with appropriate detergent/cleaning agent
3. **Rinse** the surface with clean water to remove debris and detergent
4. **Apply** a sanitizer approved for use on food contact surfaces and allow to air dry.



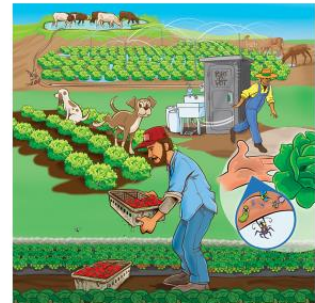
You should always follow the label on cleaning and sanitizing chemicals for your safety, so that you don't waste money and because it is the law.

Summary

There are a number of ways that produce can become contaminated.

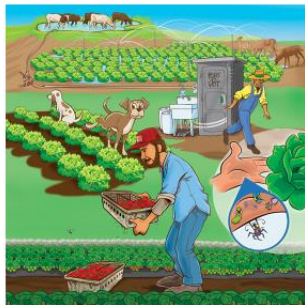
Your daily actions can affect the safety of the produce you grow, harvest, pack and hold in a positive manner.

Your participation in today's training is vitally important



Acknowledgements

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Thank you

What questions do you have?

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