

COMMODITY-SPECIFIC
FOOD SAFETY GUIDELINES
FOR THE PRODUCTION,
HARVEST, STORAGE, AND
PACKING OF
POTATOES



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PRIMARY SOURCES

These guidelines were created using the following documents as primary sources:

- The Canadian Horticultural Council's (CHC) – *Potato Producer and Packer On-Farm Food Safety Manual*, Version 5.4, January 2011.
- The U.S. Food and Drug Administration's (FDA) guidance for industry – *Guide to Minimize Food Safety Hazards for Fresh Fruits and Vegetables*, October 1998.
- United Fresh Produce Association - *Produce GAPs Harmonized Food Safety Standard, Pre- and Post-Farm Gate*, Version 7/22/2011
- The University of Idaho, College of Agricultural and Life Sciences' – *Managing Foreign Material for Quality Idaho Potatoes*, August 2002.
- The University of Maine's Cooperative Extension Potato Program – *GAP Information*, Version G.3, Parts 1-4, January 2011.
- The U.S. Department of Agriculture's (USDA) *Good Agricultural Practices & Good Handling Practices*, November 9, 2009.
- Oregon State University's *Potato Information Exchange (PIE) Storage and Processing*, April 2010.
- The University of Idaho's *Storage Checklist* by Nora Olsen and Gale Kleinkopf, 2002.
- The National Onion Association's (NOA) *Commodity Specific Food Safety Guidelines for the Dry Bulb Onion Supply Chain*, Version 1.0, December 2010.

PREFACE

In June 2013, the National Potato Council published the first edition of *Commodity Specific Food Safety Guidelines for the Production, Harvest, Storage and Packing of Potatoes*. Publication of the guidelines culminated a three-year process that included a risk assessment conducted to better understand the food safety risks related to potatoes. Completed in September 2011, *A Qualitative Assessment of the Microbial and Chemical Food Safety Risks for Potatoes* identified and evaluated the chemical and microbial hazards relevant to potatoes and their associated health effects. An overall qualitative risk rating of low was derived by combining individual risk ratings for potential adverse health effects resulting from exposure to each microbial or chemical hazard.

The initial draft outlining best practices for growing, harvesting, storing, and packing potatoes was developed by an industry working group during biweekly, web-based meetings held from August 2011 until March 2012. When the initial draft was completed, the document was circulated throughout the industry for further review during the fall of 2012 with feedback provided by industry members in Colorado, Idaho, Oregon and Washington. In December 2012, the working group reconvened to review industry comments and produce a second draft. This draft was sent to academic food safety and potato specialists and an FDA representative for a technical review. Following the technical review, the guidelines were finalized by the industry working group in mid-June 2013.

During the risk assessment and food safety guideline development process, the Food Safety Modernization Act (FSMA) was signed into law by President Obama in January 2011. Two years later, the U.S. Food and Drug Administration (FDA) published their proposed *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Produce Safety Rule) as part of their implementation of FSMA. At the same time, the agency also published *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* (Preventive Controls Rule) to amend current food processing and manufacturing regulation. As part of FDA's risk-based approach to implementing FSMA, fresh produce commodities (e.g., potatoes) that are rarely consumed raw were excluded from the proposed Produce Safety Rule. However, on-farm packing and storage facilities (e.g., grower-shippers) that packed or stored potatoes other than those grown on their own farm were still covered by the Preventive Controls Rule. In September 2014, the FDA published supplements to the proposed Produce Safety and Preventive Controls Rules that amended the definition of farm so that on-farm packing and storage facilities that pack and/or store other growers' potatoes are now covered under the proposed Produce Safety Rule thus exempting on-farm raw fresh potato packing operations from both the proposed Produce Safety and Preventive Controls Rules. As currently proposed, packing and storage facilities that are not physically located on the farm will be covered under the Preventive Controls Rule. Please note, however, that the exemption from these two rules does not eliminate the requirement to make certain that the raw fresh potatoes are not otherwise adulterated under the Federal Food, Drug and Cosmetic Act.¹

In addition to regulatory changes, the buying community (i.e., retail and foodservice) has established food safety specifications for fresh produce commodities that usually involve audit verification. These specifications, which typically address food safety practice for fresh produce

¹ For example, assuring that the potatoes are not held under insanitary conditions, 21 U.S.C. 342 (a) (4).

in general, do not consider commodity-specific risks, and therefore may not reflect appropriate preventive controls for potato-specific food safety hazards.

In preparation for the forthcoming regulatory changes and to promote better understanding of food safety risks within the supply chain, the potato industry has decided to revisit their food safety guidelines and develop additional resources to assist with organizing and documenting their food safety practices.

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ACRONYMS AND ABBREVIATIONS

- CDC: Centers for Disease Control and Prevention
- CFR: Code of Federal Regulations
- COA: Certificate of Analysis
- FDA: Food and Drug Administration
- FFDCA: Federal Food, Drug, and Cosmetic Act
- FSMA: Food Safety Modernization Act
- GAP: Good agricultural practice
- GMP: Good manufacturing practice
- HACCP: Hazard analysis critical control point
- OSHA: Occupational Safety and Health Administration
- RFR: Reportable Food Registry
- SDS: Safety data sheets
- SAs: Soil amendments
- SOPs: Standard operating procedures
- SSOPs: Sanitation standard operating procedures
- USDA: United States Department of Agriculture
- U.S. EPA: United States Environmental Protection Agency
- UV: Ultraviolet

INTRODUCTION

Written food safety guidance for the fresh produce industry was first published by the U.S. Food and Drug Administration (FDA) in partnership with the U.S. Department of Agriculture in 1998. The guidance document entitled, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, provided the fresh produce industry-at-large with good agricultural practices (GAPs) for critical areas where food safety might be compromised during the growing, harvesting, transportation, cooling, packing, and storage of produce commodities. In continued efforts to reduce foodborne illness related to produce consumption, the fresh produce industry has produced numerous commodity-specific food safety guidelines.

In 2011, the potato industry joined these other commodity groups by developing commodity-specific food safety guidelines for potatoes. Prior to developing food safety guidelines, the industry commissioned a risk assessment in order to better understand the food safety risks related to potatoes. An assessment of microbial hazards concluded that the risk of foodborne illness due to the ingestion of human pathogens on potatoes or potato products is low. Although the mere presence of human pathogens in a raw agricultural commodity is, according to the Federal Food, Drug and Cosmetic Act (FFDCA), an adulterated product, presence of a pathogen does not necessarily present a public health risk. The viability of a human pathogen in a consumed product is an important determinant in the risk of foodborne illness. Most human pathogens are readily killed at temperatures typically employed for cooking or baking. Since potatoes are always cooked or baked before being eaten, potatoes are safer than fresh produce items that are consumed raw.

A greater danger of foodborne illness from contaminated potatoes may not be from consuming contaminated potatoes, but from handling contaminated raw fresh potatoes during food preparation and the potential to cross-contaminate other foods. Agricultural practices affect the presence of pathogens on potatoes, and are important in preventing foodborne illness from cross-contamination. Potato growers have, for the most part, adopted GAPs as part of normal operations, and undergo internal and external third-party audits on a regular basis to monitor and verify GAP adherence. Audit results are often shared with customers as verification of a company's commitment to food safety. In addition, even though raw fresh potato packing operations, under current federal regulation, are not considered food manufacturing or processing facilities and therefore not subject to good manufacturing practice (GMP) requirements in the Code of Federal Regulations, Title 21, Part 110, potato packing operations are encouraged to implement pertinent GMPs to prevent conditions that may result in adulterated raw fresh potatoes.

To ensure continued vigilance and improvements in producing a safe nutritious product, the potato industry has taken the initiative to develop these potato-specific food safety best practices to mitigate risks associated with growing, storing, and packing potatoes.

PURPOSE AND SCOPE²

This document is intended to offer food safety guidance for all companies that produce, harvest, store, pack and transport raw fresh potatoes, and does not include guidance for processing, distribution centers, retail, or foodservice (see Figure 1). It is also intended to serve as a basic guideline to harmonize all food safety programs in how they assess and address food safety hazards known to affect the growing, storing and packing of raw fresh potatoes, and may be used in conjunction with other food safety guidelines and standards. Safe production and handling of raw fresh potatoes depend upon numerous factors and the diligent efforts and food safety commitment of many parties. No single resource document can anticipate every food safety issue or provide answers to all food safety questions. The purpose of this document is to provide general guidelines that focus on minimizing food safety hazards by suggesting potential actions to reduce, control, or minimize contamination of raw fresh potatoes in pre-processing and pre-distribution operations; namely the production, harvesting, storage and packing environments. Because of varietal, regional, and operational practice differences, not all of the actions described in this document will be applicable to all raw fresh potato operations. In addition, particular recommendations that address any identified issue are not the only means by which the issue may be addressed.³ It is the responsibility of individuals and companies to determine the appropriate actions for their individual operations and to understand and follow all applicable federal, state, and local regulations.

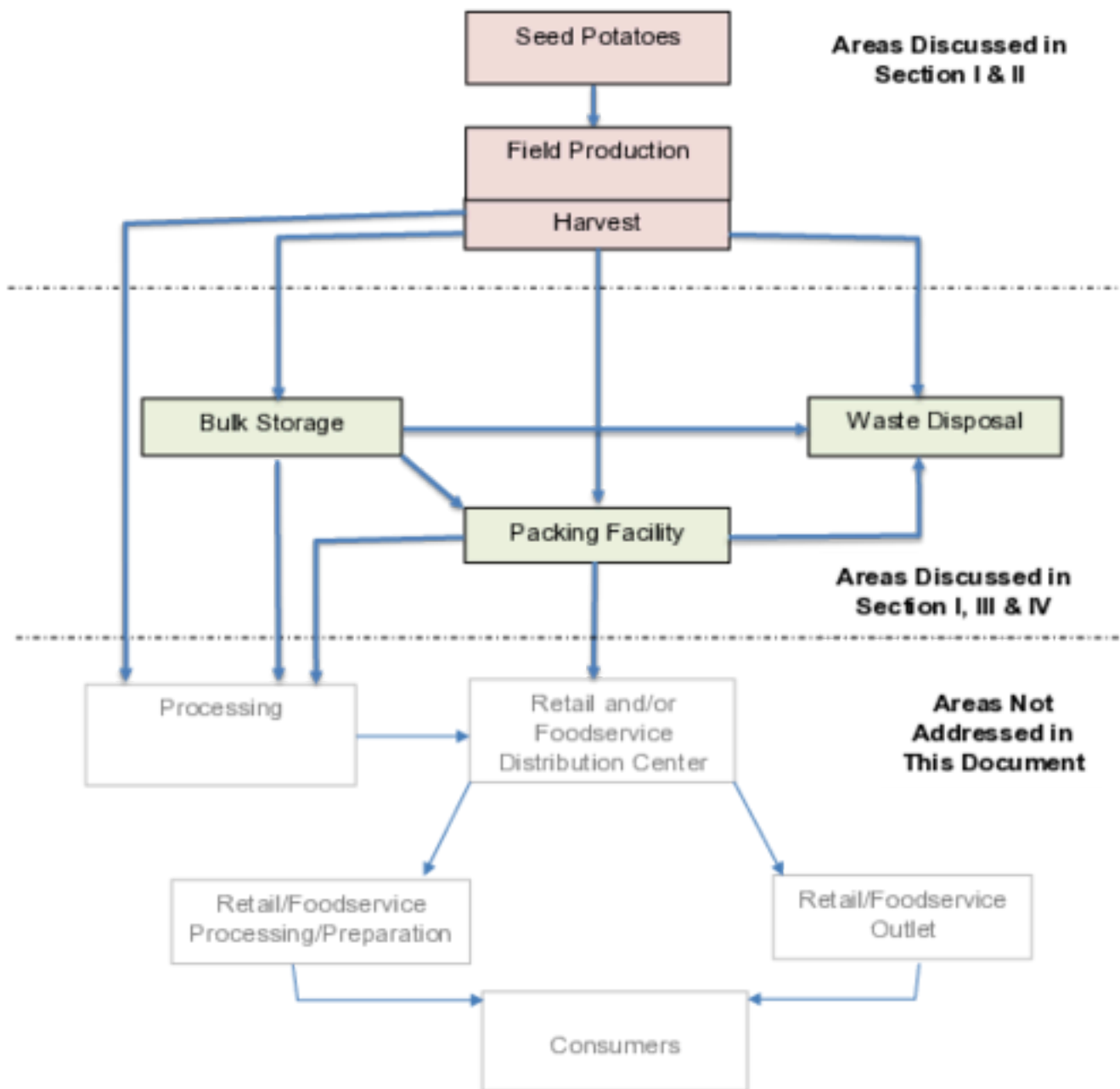
In the sections that follow, a list of best practices was developed to address the potential food safety issue identified. Adoption and customization of these best practices by companies would be an effective tool for developing an operation-specific comprehensive food safety program for the production, harvest, storage and / or packing of raw fresh potatoes (see Figure 1). It includes four sections: I) General Practices, II) Production and Harvest Operations, III) Storage Unit Operations and IV) Packinghouse Unit Operations.

² The National Potato Council (NPC), including its members, the members of the industry working group and the companies and organizations that employ them, in furnishing or distributing these Guidelines, do not make any warranty or representation, either express or implied, with respect to its accuracy, completeness, or utility; nor do they assume any liability of any kind whatsoever resulting from the use of or reliance upon, any information, material, or procedure contained herein, including, but not limited to, any claims for damages, loss or injury, or regarding health, safety, environmental effects, or performance. A company should consult its own technical advisors and counsel for a definitive response to questions applicable to the company's regulatory responsibilities under law.

³ Currently, most on-farm, raw fresh potato production, harvest, storage and packing operations would be exempt from FDA's Produce Safety and Preventive Controls regulations. These regulations when finalized will determine which, if any, requirements are mandatory for a particular raw fresh potato operation. That determination will be specific and individualized to the particular facts and circumstances of the raw fresh potato production and packing operation.

Figure 1. General Supply Chain Flow for Production, Storage, and Packing of Potatoes

(This diagram represents the industry-at-large and may not illustrate operation-specific flow charts.)



SECTION I: GENERAL PRACTICES

INTRODUCTION

These “General Practices” in Section I address food safety best practices that are common across growing, harvesting, storage, and packing operations for raw fresh potatoes. Examples include best practices for worker hygiene, equipment use and sanitation and documentation/recordkeeping. Subsequent sections on production, harvest, storage and packinghouse operations address practices that are specific to each operation.⁴

1.0 GENERAL RECOMMENDATIONS

In addition to the operation specific recommendations discussed in latter sections, there are several general recommendations that are part of an effective food safety program. These recommendations are outlined below.

- Every company should have a written food safety policy signed by senior management that outlines the company’s commitment to food safety and, in general terms, how it is implemented throughout the organization.
- Every company should have a written comprehensive potato food safety plan to address operational risks. The plan should be developed using the best practices contained in this document to address potential physical, chemical, and microbiological hazards and hazard control procedures (preventive controls), including monitoring, verification and recordkeeping. All locations should be covered by the plan.
- Every company should have a written policy that establishes corrective actions when personnel and processes are not in compliance with established food safety policies and to ensure that:
 - Appropriate action is taken to identify and correct a problem that has occurred with preventive control implementation, and, when necessary, to reduce the likelihood that the problem will recur.
 - All affected potatoes are evaluated for adulteration and prevented from entering the supply chain, if you cannot ensure that the potatoes are not adulterated under the FFDCA.
- Every company should have a written procedure outlining the process for handling an unanticipated food safety problem (i.e., a preventive control is found to be ineffective; a corrective action procedure has not been established or was not implemented; the actions taken were not conducted according to the food safety plan; or an inappropriate corrective action was taken).
- Every company should review its potato food safety plan at least annually and make revisions as appropriate:

⁴ This guidance document reflects a mixture of sources, both regulatory and non-regulatory. Also, it assumes that FDA’s revised proposed Produce Safety Rule will be finalized with essentially the same requirements as it was proposed. Consequently, if a potato grower has a specific question regarding whether their operation triggers a regulatory requirement or a specification under their contract with their customer, they should consult the applicable source of the requirement, e.g., FDA’s final Produce Safety Rule or the contract.

- Based on updated or new guidance, regulations, and /or changes to their operations (e.g., new field location or new season).
- After an unanticipated food safety problem.
- When a preventive control is found to be ineffective.
- Every company should have a documented food safety plan self-audit procedure. Self-audits should be conducted at least annually by assigned personnel who are knowledgeable of the food safety plan. The self-audit should be documented.
- Any registered food facility that manufactures, processes, packs, or holds potatoes for consumption in the U.S. is required to report to the Reportable Food Registry (RFR)⁵ when there is a reasonable probability that the use of, or exposure to, an article of food, in this case potatoes, will cause serious adverse health consequences or death to humans or animals. Companies that only have growing operations are exempt from reporting.
- Every company should designate a qualified individual to be responsible for the operation's food safety program, and an alternative qualified individual assigned in the event that the primary designated individual is unavailable.^{1,8} Twenty-four hours a day, seven days a week contact information should be available for these individuals in case of food safety emergencies.
- Every company should develop a written plan of action to be taken in the event that a food safety problem occurs.
- Every company should develop appropriate standard operating procedures (SOPs) and standard sanitation operating procedures (SSOPs) outlining required food safety practices during potato production and handling activities.
- Access to the farm, packinghouse and surrounding areas should be limited to authorized personnel. Each company should have a written visitor's policy.
- Producers and packers should have an up-to-date list of potato suppliers and/or buyers with contact and location information on file.
- Packers should comply with the requirements of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 including those requirements for recordkeeping (traceability), imports, and registration.⁶

Documentation List:

- A written, signed food safety policy
- A written comprehensive potato food safety plan
- A corrective action plan for food safety policy noncompliance

⁵ FDA. 2007. Reportable Food Registry. <http://www.fda.gov/Food/ComplianceEnforcement/CFR/default.htm>

⁶ Establishment and Maintenance of Records—FDA Actions of the Bioterrorism Act of 2002.

<http://www.fda.gov/Food/GuidanceRegulation/Recordkeeping/default.htm>

Food Facility Registration—FDA Actions on Bioterrorism Act of 2002 Legislation.

<http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm>

Prior Notice of Imported Food Shipments—FDA Actions on Bioterrorism Act of 2002 Legislation.

<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm>

- A written procedure for unanticipated food safety problems
- A written food safety plan self-audit SOP
- 24 / 7 contact information for food safety personnel

2.0 WORKER PERSONAL HYGIENE TRAINING AND PRACTICES

Workers and others having access to potato fields and/or storage and facilities can potentially directly or indirectly transfer physical, chemical or microbiological hazards to potatoes. To reduce or control the potential for food safety hazards introduced by workers and others, companies should use appropriate preventive measures outlined in these guidelines and provide training to those who work in or have access to potato fields, storage and/or packing facilities. This section outlines the best practices for worker training, hygiene, physical hazard prevention program, worker health, toilet facilities and hand washing stations.

Worker Training

- Mandatory food safety training for all workers that includes the food safety policy and plan, food safety procedures, and proper sanitation and hygiene practices appropriate to their job responsibilities.
 - Worker training should take place at the time of hire. Follow-up sessions should occur at least annually.
 - Document all training sessions including a general description of the subject matter covered, the trainer name, the date training was conducted and the signature of each worker attending the training indicating that he/she understood the information presented.

Worker Hygiene

- Establish a written program such as a SOP that requires all persons working in direct contact with food, food-contact surfaces, and food-packaging materials to use hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include:
 - Hand washing should occur prior to handling tubers during harvest or in storage, before entering the packing facility and again after eating, using latrines, handling chemicals or garbage, or any other activity that may contaminate hands.ⁱⁱⁱ
 - Workers' clothing should be clean at the start of the day and appropriate for the day's activities.^{iviii}
 - If a company requires or allows employees to wear gloves when handling potatoes or contacting food contact surfaces, they should be changed or cleaned as necessary during the work day and after any event that may cause gloves to become contaminated. A written procedure for glove use should be established and followed.^v
 - Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.^{vi}
 - If a company provides and requires workers to wear protective clothing, a policy regarding use, storage and cleaning of the required clothing should be developed.

- Areas other than where raw fresh potatoes are exposed or where equipment or utensils are washed should be designated where employees can store personal belongings.^{vii}
- Eating and drinking of beverages other than water should be restricted to designated areas outside the immediate production area that are equipped with covered trash receptacles.^{viii}
- Spitting, using tobacco, or chewing gum, seeds or similar products in the field and / or facility should not be permitted.^{ix}
- Urinating and defecating should be restricted to toilet facilities.
- Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including perspiration, hair, cosmetics, chemicals, and medicines applied to the skin.
- Drinking water that meets drinking water standards should be easily accessible to personnel. A receptacle should be available for disposing of cups, water bottles, etc.

Physical hazard prevention program

- Establish a written physical hazard / foreign material prevention policy that addresses the following:
 - Use of acceptable work-related items that are permitted in the field and facilities and instructions for appropriate removal of these items (i.e. immediately after use, prior to harvest).
 - Removal of personal effects that may pose a physical hazard prior to entering the field and / or facility.^x

Worker Health

- Establish a SOP for health practices that addresses the following issues:
 - Persons with diarrhea, fever, vomiting, or other potentially infectious diseases should be restricted from handling potatoes or being in the production areas.^{xi}
 - Persons with open sores, cuts or lesions should be evaluated by a supervisor to determine if a non-permeable covering is adequate to permit work with potatoes.^{xii}
 - A procedure for handling and disposing of product that comes in contact with blood or other bodily fluids. Any food contact surfaces contaminated with blood or other bodily fluids are to be cleaned and sanitized.
 - First aid kits with clean, sanitary, and unexpired supplies should be readily available in the vicinity of field work and facilities.

Toilet facilities and hand washing stations

- Establish a SOP for toilet facilities and hand washing stations to address the following issues:
 - A response plan for major leaks or spills.
 - The condition and placement of facilities.

- Toilet facilities should be in a location that minimizes the impact from potential leaks and / or spills while allowing access for cleaning and service.
- Hand washing stations should always be present with toilets and supplied with potable water. In addition, hand sanitizers or other suitable cleansing agents may be made available for use, but cannot be substituted for washing hands with potable water.
- The number and accessibility of facilities to the work area
 - The toilet facilities and hand washing stations including number and location should be in compliance with applicable local, state, and federal regulations. (See OSHA requirements for agricultural field sanitation⁷ and facility sanitation.)⁸
- Facility supplies
 - Toilet facilities should be stocked with toilet paper – positioned and stored in a sanitary manner.
 - Hand washing stations should have soap or other suitable cleansing agents, single-use towels or air dryers, a covered towel disposal container and a tank that captures used hand wash water.^{xiii}
- Facility maintenance, cleaning, and servicing
 - Establish the frequency and specific protocols of toilet and hand washing station maintenance / sanitation to ensure a clean and sanitary condition.
 - Establish storage and control procedures for portable toilet facility equipment when toilets are not in use.
 - Maintain documentation of maintenance and sanitation schedules and any corrective action for a period of 2 years.
- Facility signage
 - Signage requiring hand washing after use of toilet facilities should be visible and posted in applicable languages and/or pictures.^{xiv}

Documentation List:

- Food safety training documentation
- Hygienic practices SOP
- Physical hazard/foreign material prevention SOP
- Health practices SOP
- SOP for toilet and hand washing facility
- Toilet and hand washing facility maintenance and sanitation schedule

⁷ OSHA. Field Sanitation – 1928.110.

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10959

⁸ OSHA. Sanitation 1910.141

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

3.0 EQUIPMENT USED IN PRODUCTION, HARVESTING, AND STORAGE

This section addresses the proper use, maintenance and cleaning of equipment in the production, harvest, and storage of raw fresh potatoes. Equipment used during these operations should be clean and maintained to prevent contamination of potatoes. The best practices described below outline appropriate equipment handling and cleaning measures to minimize and control the potential introduction of physical, chemical, and microbiological contaminants during production, harvest, and storage activities.

- Companies should have a written policy regarding acceptable use, maintenance, and repair of equipment. The policy should address the following:
 - Prior to use in the fields or storage facility, equipment should be visually inspected and determined to be clean, in good repair and free of foreign materials.
 - Hydraulic hoses, hydraulic motors, and overhead hydraulic fittings should be tight and drip free.
 - Loose or damaged equipment parts should be removed or appropriately repaired.
 - Light bulbs and glass on equipment should be repaired and/or protected in case of breakage.
 - All maintenance should be conducted in a manner that does not pose a risk of contamination
 - If equipment is previously used in a manner that may pose a food safety risk (i.e. to spread raw manure or to apply crop protection chemicals), use effective means to clean and, if necessary, sanitize it before use with or in proximity to potatoes.
- Prepare a written SOP outlining the method and frequency of calibrating monitoring and verification instrumentation.
- Prepare written SOPs for equipment cleaning that address the following:
 - A cleaning schedule to establish and document the frequency of equipment cleaning.
 - Appropriate cleaning procedures of all equipment surfaces that have contact with potatoes.
 - Locating equipment cleaning in an area that minimizes the potential to cross-contaminate potatoes or other equipment.
 - If cleaning agents are used, they should be mixed, handled and used according to the manufacturer's instructions.

Documentation List:

- Equipment use, maintenance and repair policy
- SOP for equipment maintenance, cleaning, and sanitizing

SECTION II: PRODUCTION AND HARVEST UNIT OPERATIONS

INTRODUCTION

This section presents recommended raw fresh potato production practices to minimize microbiological, chemical and physical food safety hazards. Although production practices may vary somewhat among the potato growing regions in the U.S., these best practices address common elements found across U.S. potato production regions including seed potatoes, water and agronomic inputs.

4.0 SEED POTATOES

As starter products, seed potatoes should be handled in a manner so as not to serve as a source of contamination. The best practices for handling seed potatoes are:

- Producers should purchase or select seed potatoes from a certified seed potato producer.
- Producers should comply with label recommendations when applying a seed treatment.
- Seed potatoes should be stored in a manner that minimizes sources of contamination.

5.0 FIELD MANAGEMENT - ENVIRONMENTAL ASSESSMENTS

An environmental assessment of the growing environment is intended to identify any potential risks to potato fields related to topographical and geographical features of the production site and surrounding area, adjacent land uses, historical land use, animal activity or flooding (see [Appendix I. Field Management – Assessment of Environmental Conditions](#)) that might impact product safety. Environmental assessments may be conducted prior to planting, during production, and immediately prior to harvest. It is important to tailor practices and procedures designed to promote food safety to the actual potato production environment. Potatoes are generally grown in rural areas that may have adjacent wetlands, wild lands, and / or parks harboring wildlife. Some wildlife species are known to be potential carriers of various human pathogens (Fenlon 1985; Gorski et al. 2011; Jay et al. 2007; Keene et al. 1997; Williams et al. 2011; Perz et al. 2001). Uncertainties in the literature about which wildlife species might be the most likely to contaminate fields as well as the difficulty in excluding some types of animals from fields (i.e., birds, reptiles) has led to the recommendation that if animal feces are found, measures should be taken to prevent the contamination of potatoes during harvest.

In addition, extensive development in certain farming communities has created urban encroachment and unintentional access for domestic animals, livestock, and human activity that may also pose varying degrees of risk, which should be considered when assessing risks to food safety. Finally, it is possible that some land uses may be of greater concern than others when located near potato production fields. The best practices for environmental assessment are:

- Prior to planting, production site prior use and adjacent agricultural and nonagricultural activities should be assessed for potential microbiological, chemical and physical hazards. In addition before harvest, fields may also be assessed for microbiological and physical hazards that may potentially contaminate potatoes during harvest.
 - Assessment of Adjacent Land Use

- Evaluate all adjacent land and waterways for activities and conditions that present physical, chemical or microbiological hazards that may pose a risk to potato safety. See [Appendix I](#) for guidance in assessing risks related to adjacent land use.
- Be aware of the potential for runoff from adjacent properties that may contain physical, chemical or microbiological hazards.
- Take appropriate measures to mitigate any identified food safety hazard. Such measures may include (but are not limited to) berms, windbreaks, diversion ditches, vegetative filter strips, and buffer zones.
- Implement practices that reduce, control, or minimize the potential for contamination of fields in close proximity to on-farm stacking of manure or manure lagoons.
- Document the location of any adjacent land uses that may present potential risks of physical, chemical or microbiological hazards.
- Assessment of Historical Land Use
 - To the degree practical, determine and document the historical land uses for potato production fields and any potential issues from these uses that might impact food safety.
- Assessment of Animal Activity
 - In assessing the risks associated with animal activity, evaluate all potato fields for animal activity. See [Appendix I](#) for guidance applicable to animal activity.
 - When developing strategies to minimize the risk associated with wild animals that are endemic to a particular production area, producers are advised to check for local, state, and federal laws and regulations that may affect mitigation measures.
 - Evaluate the risk to subsequent potato production on production acreage that has experienced recent post-harvest grazing by domesticated animals that used field culls as a source of animal feed.
- Assessment of Flooding
 - Evaluate the potential for flooding to create conditions that may pose a food safety risk. See [Appendix I](#) for guidance in assessing risks related to flooding.

Documentation List:

- Assessment of adjacent land use
- Assessment of historical land use
- Assessment of animal activity
- Assessment of susceptibility of production land to flood waters

6.0 AGRICULTURAL WATER

Water used for on-farm potato production can be a source or vehicle for microbial or chemical contamination. Therefore, it is critical to conduct a thorough hazard assessment that evaluates sources of water to be used and delivery methods to determine if the quality of the water to be

used for irrigation, crop protection chemical dilution and application, or equipment cleaning on the farm is of sufficient quality for its intended use. The water source may also dictate different risk management measures or strategies. For example, an excellent risk management strategy for water sourced from a well would be to periodically inspect the well-head and conduct microbial water tests. In contrast, microbial testing of a surface water source (e.g., a canal) used for irrigation may not be useful or actionable as the sample is only representative for the moment of sampling (i.e., water in an irrigation canal is flowing and microbial populations fluctuate considerably over time, distance, and environments). Microbial testing of flowing water systems is primarily designed to establish baseline information on the ability of these systems to deliver water of acceptable quality.

As part of a water quality management program, analysis of microbial testing data over time provides valuable information on trends in microbial levels that may be related to environmental conditions or that may indicate the occurrence or existence of a contaminating source or event. When water is sourced from an irrigation canal, it is recommended that risk management strategies focus on keeping the laterals clean to avoid the accumulation of debris and the presence of animals. Water quality management strategies should be in place and should include regular inspections and corrective action protocols. A management program for water quality verification should include documentation of any testing results as well as any preventive or corrective actions taken to minimize or control potential contamination. The best practices for managing agricultural water systems are:

- Agricultural water used in potato production should be sourced from a location and in a manner that is compliant with prevailing regulations relevant for the intended use of the water.
- A water system description should be prepared to facilitate physical water system inspections for the purpose of identifying conditions that may result in the contamination of potatoes. This description may include maps, photographs, drawings, or other means to communicate the location of permanent fixtures such as wells, gates, reservoirs, valves, returns, and other features that make up a complete water distribution system and the flow of the water system (including any water captured for re-use).
- Water source(s) and system(s) at the production site should be assessed for potential physical, chemical, and microbiological hazards that may pose a food safety risk. The water system assessment should be documented and take into consideration historical water source test results and the water application method(s). The water system should be reassessed seasonally as well as when changes are made to the system or when a situation occurs that could potentially contaminate the system.
- A water management plan should be established and documented that includes preventive controls, monitoring and verification procedures, and corrective actions implemented to address hazards identified in the water system assessment. This plan should be reviewed following any changes made to the initial assessment and adjusted accordingly.
- There should be a written procedure for water testing that may include such information as sampling frequency, who is taking the samples, where the samples are taken, the sample volume, how the sample is collected, type of testing conducted and, if applicable, acceptance criteria. The frequency of testing and points where the samples are taken should be determined based on the water system assessment. If all agricultural water is sourced from a

municipal source or an irrigation district/canal company, the municipal/district/company tests can be used.

- Agricultural water systems should not be cross-connected with human or animal waste systems. Water systems intended to convey untreated human or animal waste should be separated from conveyances utilized to deliver agricultural water.
- Documentation should be retained for all water test results and / or certificates of analysis available for inspection for a period of at least 2 years.

Documentation List:

- Water system description
- Water system assessment
- Water management plan
- Water testing procedure
- All test results for the last 2 years

7.0 AGRICULTURAL CHEMICALS AND SOIL AMENDMENTS

This section includes three different categories of agricultural chemicals and soil amendments (SAs):

- Commercial fertilizers and non-animal-based soil amendments
- Animal-based soil amendments - manure, compost/compost tea and other products containing animal by-products
- Crop protection chemicals

Commercial Fertilizers and Non-Animal-Based Soil Amendments

Commercial fertilizers and non-animal-based soil amendments are commonly incorporated prior to planting into agricultural soils used for potato production to add organic and inorganic nutrients to the soil as well as to reduce soil compaction. These agricultural inputs can potentially contaminate potatoes if the incorrect types are spread. The best practices to minimize contamination risk are:

- Commercial fertilizers and non-animal-based soil amendments should meet applicable federal, state and local regulations.
- If a license for application is required, verify that the company applying the material has the appropriate license.
- Commercial fertilizers and non-animal-based soil amendments should be applied and stored according to manufacturer's instructions and prevailing regulation.
- Company or contracted personnel that apply commercial fertilizers and non-animal-based soil amendments should be trained in its proper use.
- Application techniques employed should control, reduce, or minimize potential surface water contamination.

- Commercial fertilizers and non-animal-based soil amendments should be stored in a manner that does not pose a risk of contamination.

Animal-Based Soil Amendments - Manure, Compost/Compost Tea and Other Products Containing Animal By-products

Animal manure represents a significant source of potential contamination. Manure is known to carry pathogenic bacteria (e.g., *E. coli* O157:H7, *Salmonella*). Potatoes may become contaminated with microbiological, chemical or physical contaminants if manure and compost and compost teas are not properly handled, applied or stored. Pathogenic organisms can be eliminated through proper composting of manure (e.g., time, temperature) so that it is not a source of contamination to potatoes. It is important when purchasing manure to know the manure type (e.g., cow, sheep, chicken). Presently there is little scientific information on pathogen survival when other by-products are applied in the field (e.g., seafood waste, vegetable culls).

Human pathogens may persist in animal manures for weeks or even months (Fukushima et al. 1999; Kudva et al. 1998). Proper composting of animal manures via thermal treatment will minimize the risk of potential human pathogen survival. However, the persistence of many human pathogens in agricultural soils depends on many factors (e.g., soil type, soil moisture, relative humidity, UV index, cultivation practices, stress-adaption, etc.) and the effects of these factors is still under extensive investigation (Jiang et al. 2003; Islam et al. 2004a; Islam et al. 2004b; Singh et al. 2010).

Some studies of human pathogens conducted in cultivated-field vegetable production models point towards a rapid initial die-off from high pathogen populations but often maintain a characteristic and prolonged low level pathogen survival (Hutchison et al. 2004; Islam et al. 2004a; Islam et al. 2005; Ingham et al. 2004; Nicholson et al. 2004). Human pathogens do not persist for long periods of time in high UV index and low relative humidity conditions, but may persist for longer periods of time within aged manure or inadequately composted SAs (U.S. EPA 2003). Therefore, establishing suitably conservative pre-plant intervals appropriate for potato production is an effective step towards minimizing risk (Islam et al. 2004b; Suslow et al. 2003). The best practices for using animal-based soil amendments are:

- Producers should not apply biosolids (a.k.a. sewage sludge) to any production site intended for potato production even in rotational years.
- If composted animal-based soil amendments are used, records of composition, dates of treatment, methods utilized and application dates should be documented.
 - Evidence of processing adequate to eliminate pathogens of human concern, such as a letter of guarantee, a certificate of analysis (COA) or any test results or verification data (e.g., time and temperature) demonstrating compliance with process or microbial standards, should be documented.
 - Composted animal-based soil amendments should be produced, stored and applied in accordance with applicable federal and state regulatory requirements.
 - Composted animal-based soil amendments should be properly stored and protected to minimize recontamination.

- If raw or incompletely treated manure is used on potato fields, document the manure composition, and time and method of application.
 - Raw or incompletely treated manure should not be applied <120 days before harvest.
- Manure, compost/compost tea and other animal-based SAs should be stored separately from each other, potatoes, market-ready packaging materials, fuels, oils, chemicals, cleaning agents, and water sources.
- SA application techniques employed should control, reduce, or minimize potential contamination of surface water.
- Equipment used for manure and compost applications should be designated for that particular use or cleaned before being used for other purposes.

Crop Protection Chemicals

The inappropriate use, handling and storage of crop protection chemicals may result in a chemical hazard. The use and application of crop protection chemicals must adhere to all federal, state and local regulations. The best practices for using crop protection chemicals should include, but is not limited to:

- Use crop protection chemicals that are registered with the U.S. EPA for use on potatoes and comply with all state or local regulations.
- Application should be performed by trained, licensed or certified pesticide personnel as required by regulation.
- Use and store crop protection chemicals according to the directions on the label, and U.S. EPA, state, and local regulations.
- Store in a covered, clean, and dry area in a clearly identified and controlled-access or locked location that is dedicated only to crop protection chemicals.
- Store in a manner that maintains the integrity of the containers and prevents leakage (e.g., closed bag, in a container, with a lid).
- Labels/identification should be intact and legible. Information on the label should include the name of the product, active ingredient(s), concentration, CAS#, manufacturer's name and address. The manufacturer's contact information and the instructions for use do not need to be on the label, but should be readily available.
- Develop procedures that protect against product and growing area contamination that include:
 - The disposal of waste crop protection chemicals and empty containers.
 - Cleaning of application equipment.
 - Handling spills or leaks.
- Retain documentation of all crop protection chemicals used for a period of at least 2 years or according to federal, state, and local regulation.
- Keep safety data sheets (SDS) for all regulated chemicals easily accessible.

Documentation List:

- Copies of product labels
- Product spec sheets
- Composted SA process verification paperwork (e.g., COA, test results, etc.)
- Ag chemical and SA application dates
- Copy of required applicator's license
- SOP for cleaning of application equipment

8.0 HARVEST PRACTICES – ENVIRONMENTAL ASSESSMENTS

Because conditions in the field and surrounding area may change from the time of planting to harvest, it is important to assess fields prior to harvest for risk factors that may potentially result in potato contamination. For example, potatoes harvested before a pre-harvest interval has elapsed may be a source of chemical contamination. To minimize the risk of contamination, check that the appropriate intervals have elapsed and assess the production site as part of pre-harvest procedures before harvesting activities begin.

Pre-Harvest Assessment:

A pre-harvest environmental assessment is an evaluation of conditions that may potentially result in physical, chemical, or microbiological contamination of potatoes during harvesting activities. The assessment should demonstrate that the operation is in compliance with the company's food safety plan and provide information on corrective actions in any areas of noncompliance before harvest. The best practices are:

- Establish a pre-harvest environmental assessment procedure that describes how and when the assessment is to be performed, and includes an evaluation of conditions that may potentially result in physical, chemical or microbiological contamination of potatoes during harvest.
- Conduct the assessment prior to harvesting, and focus on any changes that may have occurred in the field and to the surrounding areas since the pre-planting assessment.
- Ensure that the required pre-harvest interval has elapsed between the application of agricultural chemicals and harvest.

Harvest Assessment:

During harvest, personnel should monitor the production field for potential environmental hazards that could result in physical, chemical, or microbiological product contamination. Any condition that is non-compliant with the company's food safety plan should be addressed to minimize the potential risk to the harvested potatoes. The best practices are:

- Personnel in the field during harvest should monitor for physical, chemical, and microbiological hazards.
- Establish a SOP addressing product contamination events and corrective measures.
- If an outside harvesting company is used, provide proper hygienic practices training or verify the outside company's hygienic practices training for its harvest workers.

- Include the name and contact information of the harvesting company and operator on the assessment record.

Documentation List:

- SOP for pre-harvest and harvest environmental assessments
- SOP for corrective action when potatoes are potentially contaminated
- Outside harvesting company information

9.0 FLOODING

Flood waters may contain hazardous chemicals, microorganisms of significant public health concern and/or other contaminants (Casteel et al. 2006; Wachtel et al. 2002a; 2002b). For purposes of this document, flooding is defined as the flowing or overflowing of a field with water outside of a grower's control.^{9,10} The FFDCFA states that if the edible portion of a crop is exposed to flood waters, it is considered adulterated and cannot be used for human consumption.¹¹ The FDA has stated that the FFDCFA applies to all food crops including underground crops which have been in soil covered by flood water.¹⁰ It is important to note that pooled water such as that resulting from rainfall is *not* considered flooding and unlikely to contain human pathogens of significant public health concern and / or other contaminants, which may cause adulteration of potatoes.⁹ The best practices related to flooding are:

- Segregate flood-affected potatoes from potatoes not affected by flood water. Potatoes harvested from a flooded field should be disposed of in a manner that ensures they are kept separate from potatoes or other crops that have not been flood damaged.
- Prevent cross-contamination:
 - Farm equipment should not be used in a non-flooded field after use in a field that was flooded unless the equipment was first cleaned.
 - Do not drive equipment through flooded areas that may contain contaminants such as human pathogens of significant public health concern. Observe an adequate buffer between flooded field areas and non-flooded areas where potatoes will be harvested for human consumption.
- Check well(s) water– If a well head was covered by flood water, well water quality should be tested before use due to the potential for contamination.
- If a field floods before planting begins, the soil should be allowed to dry sufficiently and reworked (aerating, tilling, disking, etc.) before planting to help reduce the survivability of pathogenic microorganisms.
- After a flooding event occurs and before planting in a flood-affected field, conduct an environmental assessment of that field as described in Section 5.0 Field Management.

⁹ FDA. 2009. Draft guidance for industry: Guide to minimize microbial food safety hazards of leafy greens. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlant/Products/ucm174200.htm>

¹⁰ FDA. 2011. Guidance for Industry: Evaluating the safety of flood-affected food crops for human consumption. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/EmergencyResponse/ucm287808.htm>

¹¹ FFDCFA. The Federal Food, Drug, and Cosmetic Act, section 402(a)(4) (21 U.S.C. 342(a)(4))

10.0 TRANSPORTATION OF POTATOES

Following harvest, potatoes are transported to the storage or packing facility. Transportation conditions should be managed to minimize the risk of contamination. Food contact surfaces in transportation vehicles that are not properly maintained are potential sources of potato contamination.

- Develop a SOP that describes the best practices to ensure transport vehicles are not a contamination source. These best practices include, but are not limited to:
 - Visually inspect the transportation vehicle to ensure it is clean, functional, and free of objectionable odors, leaks, and any foreign materials.
 - If trailers are used for hauling items other than potatoes, establish procedures to ensure that transport trailers will not potentially contaminate potatoes.
 - During loading, steps should be taken to minimize potential physical damage to potatoes.
 - Bulk field trailers should be protected during transport.

Documentation List:

- Transport trailer inspection log
- Transportation SOP

11.0 DOCUMENTATION AND RECORDKEEPING¹²

As a food safety practice, it is essential that companies involved in potato production document and retain operating and best practice compliance records along with documents that link harvested product to the field. Although currently farms (as defined in the regulation) are excluded from the recordkeeping requirements in existing FDA regulations such as Title 21 of the Code of Federal Regulations (CFR) - part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” farms should maintain records that identify the production site location of harvested potatoes.¹³

Operational Records

Record maintenance and retention is essential for evaluating actual potato farming practices operations. Records are more reliable than memory and can help identify inconsistencies in operating procedures and practices where corrective actions or employee training may be needed. Furthermore, in the event of a foodborne illness outbreak traced to a particular farm, adequate documentation and records could help identify or rule out the cause of the outbreak and / or contributing factors. The best practices for maintaining operational records are:

- Develop and maintain written food safety programs and SOPs for practices related to potato production that are a part of the company’s overall food safety plan.

¹² The basis for this section is the best practices outlined by the FDA in their draft commodity specific guidance for tomatoes, melons and leafy greens; obtained at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlant/Products/default.htm>

¹³ Code of Federal Regulations, Title 21: Food and Drugs, Part 1 – General Enforcement Regulations, Subpart J-Establishment, Maintenance, and Availability of Records, General Provision 1.327(a). Accessible at: <http://ecfr.gpoaccess.gov/cgi/t/text.txt?c=ecfr&sid=8c363ccfd19538d82bf2578bbd91599&rgn=div6&view=text&node=21:1.0.1.1.1.8&idno=21>

- Maintain and retain records for monitoring activities as well as corrective actions taken that include information such as the date and time, name of person(s) who completed the record, the activity being monitored in the documentation, and the methods and timelines of corrective actions.
- Maintain documents and records on-site or off-site or electronically. Documents should be available for inspection within a reasonable period of time.
- Retain records for a minimum of two years or as required by current regulations.

Product Traceability

Product traceability refers to the ability to follow the physical movement of potatoes both from their original source, through intermediate sources to their final recipient and tracking them in reverse from the final recipient back to their original source. Though not a preventive measure, effective product tracing systems are an important element of a potato grower's comprehensive food safety program, therefore:

- Establish a traceability and recall program that enables reconciliation of potatoes delivered to recipients (one step forward).¹⁴ Maintain documents that link the product with the source or production inputs such as soil amendments, seed potatoes, agricultural chemicals, etc. (one step backward). Examples of such records include labels with product-identifying information, invoices, inventory records, bills-of-lading, and shipping/receiving records.

Documentation List:

- Food safety related programs and SOPs

¹⁴ Excludes direct to consumer sales.

SECTION III: STORAGE UNIT OPERATIONS

INTRODUCTION

Proper storage of raw fresh potatoes will minimize the risk of microbiological, chemical and physical contamination. Operators should be aware of and operate in accordance with all relevant laws and regulations. The topics of worker hygienic practices and equipment use and sanitation are addressed in Section I: General Practices and are applicable to this section as well.

12.0 GROUND MAINTENANCE

The grounds around a potato storage facility should be kept in a condition that will control, reduce, or minimize the risk of food contamination. Grounds maintenance includes, but is not limited to:

- Proper storage of equipment, removal of litter and waste, and cutting weeds or grass within the immediate vicinity of the buildings or structures that may constitute an attractant, breeding place, or harborage for pests.^{xv}
- Evaluating adjacent land use to ensure that it does not pose a significant risk of product cross-contamination.^{xvi}

13.0 FACILITY CONSTRUCTION

Storage facilities should be constructed in a manner to minimize potential contamination of stored raw fresh potatoes and should include:

- Facility and equipment structures and surfaces (floors, walls, ceilings, doors, frames, hatches, etc.) constructed in a manner that facilitates cleaning and sanitation and do not serve as harborage for contaminants or pests.^{xvii}
- Air intakes that are not located near potential sources of contamination.^{xviii}
- Lights equipped with shatter-proof bulbs or protective coverings to prevent broken glass and fixture material from contaminating the potatoes.^{xix}

14.0 SANITATION AND MAINTENANCE

Measures to prevent microbiological, chemical and physical contamination of potatoes while in storage are crucial components of a food safety plan. To comply with appropriate food safety management in potato storage facilities, the best practices are:

- On an annual basis, before harvesting activities begin, the bulk storage facility should be completely examined, cleaned and repaired as needed and operated so as to establish an appropriate storage environment before the first potato is introduced.
- Establish a SOP for inspecting the storage facility prior to use to ensure that:
 - The equipment is safe and ready for use.
 - Pest control measures are in place and functioning.

- Food safety protocols are being followed.
- Document inspection observations and any corrective actions taken to address observed deficiencies.
- Establish a SSOP for facility cleaning prior to storing potatoes that includes the following recommendations:
 - Thoroughly clean the storage area and equipment (both portable and fixed equipment).^{xx}
 - Identify, hold, and store cleaning and sanitizing chemicals in a manner that protects against contamination.^{xxi}
 - Keep SDS on file for each cleaning and sanitizing chemical.

Documentation List:

- SOP for facility inspection prior to use
- SSOP for facility cleaning prior to use
- SDS for cleaning and/or disinfecting chemicals used in facility

15.0 PEST CONTROL

Effective measures should be taken to exclude pests from the storage facility and to protect the potatoes against pest contamination while on the premises. Storage facilities may be dormant between uses and should be appropriately protected from pest infestations during these periods of dormancy. However, if pests gain access to the facility when not in use, appropriate pest removal and / or exclusion measures should occur before storing potatoes. The best practices for pest control are:

- Each storage facility should have a written pest control program to exclude animals and pests from the storage facility when potatoes are present.^{xxii} The program should include policies and procedures that cover:
 - Outdoor storage of equipment and materials.
 - Factors enhancing pest harborage.
 - A pest log that includes inspection dates, inspection reports and steps taken to eliminate problems.
- Maps containing the locations of pest traps should be available for review.
- Domestic animals should be prohibited from the storage facility.^{xxiii}
- Open doors, windows, vents, fans, and similar features should be adequately controlled to prevent pest entry when potatoes are present.
- Only bait-less pest control devices should be used inside a potato storage facility. Use all traps, bait, and pesticides for pest control in and / or around a potato storage facility in accordance with local, state, and federal regulations.
- Traps should be inspected routinely and any corrective actions (e.g., cleaning out traps, replacing damaged traps) should be documented.

- Whether pest control is performed internally or by a third-party pest control company, the following documents should be maintained and available for review:
 - A copy of any required license and training records.
 - If applicable, a copy of the applicator's insurance certificate.
 - A schedule of the applicator's activities and actions.
 - A pest control log that includes dates of inspection, inspection reports, and any corrective actions taken.
 - A record of chemicals used and associated SDS.

Documentation List:

- SOP for a pest control program
- Record of pest control chemicals used
- Pest control license(s)
- Pest control applicator's insurance certificate
- Pest control chemical application/activities log
- Trap and bait station location maps
- Trap and bait station inspection logs
- SDS for pest control chemicals

16.0 ENVIRONMENTAL CONDITIONS

Temperature, humidity, air movement, and light exposure are the most important environmental factors affecting potatoes in storage. Temperature requirements are determined by the intended use of the potatoes. There are specific relative humidity requirements for storing potatoes. Humidifiers are typically used in storage facilities to add water to the air. It is important to assess the quality of the water used for humidification as it may be a source for microbiological or chemical contamination. To reduce the risk of contamination in storage facilities:

- Harvested potatoes should be stored separately from market-ready potatoes, equipment, fuels, agricultural chemicals and market-ready packaging materials.^{xxiv}
- Only potable water should be used to produce humidity.
- Any substance used to treat the water should be approved by the U.S. EPA or FDA for use on food and monitored to verify correct concentration. Monitoring activities should be documented.

Documentation list:

- Water test records
- Water monitoring activities

17.0 TRANSPORTATION OF POTATOES

When potatoes are transported from the storage facility, transportation conditions should be managed to minimize the risk of contamination. Food contact surfaces in transportation vehicles that are not properly maintained are potential sources of potato contamination. The best practices to ensure vehicles are not a contamination source are:

- Develop a SOP that describes the best practices to ensure transport vehicles are not a contamination source. These best practices include, but are not limited to:
 - Visually inspect the transportation vehicle to ensure it is clean, functional, and free of objectionable odors, leaks, and any foreign materials.
 - If trailers are used for hauling items other than potatoes, establish procedures to ensure that transport trailers will not potentially contaminate potatoes.
 - During loading, steps should be taken to minimize potential physical damage to potatoes.
 - Bulk field trailers should be protected during transport.

Documentation List:

- Transport trailer inspection log
- Transportation SOP

18.0 DOCUMENTATION AND RECORDKEEPING¹⁵

As a food safety practice, it is essential that companies involved in potato storage document and retain operating and best practice compliance records along with product tracing documentation. It also is important to note that subject to certain exceptions, existing FDA regulations such as Title 21 of the Code of Federal Regulations (CFR) - part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the U.S. However, currently farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.¹⁶

Operational Records

Record maintenance and retention is essential for evaluating actual potato farming practices and packing operations. Records are more reliable than memory and can help identify inconsistencies in operating procedures and practices where corrective actions or employee training may be needed. Furthermore, in the event of a foodborne illness outbreak traced to a particular farm or facility, adequate documentation and records could help identify or rule out the cause of the outbreak and / or contributing factors. The best practices for maintaining operational records are:

¹⁵ The basis for this section is the best practices outlined by the FDA in their draft commodity specific guidance for tomatoes, melons and leafy greens; obtained at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlant/Products/default.htm>

¹⁶ Code of Federal Regulations, Title 21: Food and Drugs, Part 1 – General Enforcement Regulations, Subpart J-Establishment, Maintenance, and Availability of Records, General Provision 1.327(a). Accessible at: <http://ecfr.gpoaccess.gov/cgi/t/text?idx=ecfr&sid=8c363ccfd19538d82bf2578bbd91599&rgn=div6&view=text&noc=21:1.0.1.1.1.8&idnc=21>

- Develop and maintain written food safety programs and SOPs for practices related to storage that are a part of the company's overall food safety plan.
- Maintain and retain records for monitoring, testing, and verification activities as well as corrective actions taken that include information such as the date and time, name of person(s) who completed the record, the activity being monitored in the documentation, and the methods and timelines of corrective actions.
- Records should be reviewed by a qualified individual on a routine basis to ensure that records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about correction actions.
- Maintain documents and records on-site or off-site or electronically. Documents should be available for inspection within a reasonable period of time.
- Retain records for a minimum of two years or as required by current regulations.

Product Traceability

Product traceability refers to the ability to follow the physical movement of potatoes both from their original source, through intermediate sources to their final recipient and tracking them in reverse from the final recipient back to their original source. Provisions of the 2002 Bioterrorism Act require that shippers have the ability to identify the immediate previous source of the product, immediate subsequent recipient of the product and the transporters. Commingling of product may occur at the storage facility and operators should have product tracing systems in place to be in compliance with the Act. Though not a preventive measure, effective product tracing systems are an important element of a comprehensive food safety program, therefore:

- Establish a traceability and recall program that enables reconciliation of potatoes to source (one step backward) and to recipients (one step forward).¹⁷ Examples of such records include labels with product-identifying information, invoices, inventory records, bills-of-lading, and shipping/receiving records.
- Store potatoes in a manner that ensures traceability.

Documentation List:

- Food safety related programs and SOPs
- Product tracing records

¹⁷ Excludes direct to consumer sales.

SECTION IV: PACKINGHOUSE UNIT OPERATIONS

INTRODUCTION

A well designed and managed packinghouse with a robust food safety program can greatly reduce the risk of chemical, physical, and microbiological contamination, while inadequate or inconsistent food safety practices can increase this risk. Conditions in each packinghouse may vary due to location, environment, the volume and type of potatoes handled, local regulations and other variables, and multiple strategies may be employed for effectively dealing with individual packinghouse hazards. However, the overall goal of any effective packinghouse food safety program is to minimize the risk of contamination.

19.0 RECEIVING

When raw fresh potatoes are received at the packing facility it is critical that all essential field information is appropriately maintained and transferred to packinghouse operations for traceability purposes, therefore:

- Establish a policy to ensure and document that potato suppliers follow GAPs outlined in this guidance document.
- Maintain a current list of approved raw material suppliers for all incoming materials and packaging, and establish a SOP for approving new suppliers.
- Establish a procedure for inspecting and accepting or rejecting incoming loads of potatoes containing foreign materials such as glass, rodent droppings, feces, etc.^{xxxv}
- Notify the potato producer if contamination is observed, and take corrective action (e.g., sort, grade, remove contamination, refuse product, etc.).
- Establish procedures to ensure potatoes are held in designated areas and handled under proper conditions.^{xxxvi}
- Inventory control practices and the rationale for those practices should be documented.
- Incoming documentation should provide sufficient information to facilitate product traceability; develop a SOP to maintain that documentation.

Documentation List:

- Current list of approved raw material suppliers
- A SOP for approving new raw material suppliers
- Supplier documentation indicating GAP compliance
- Inventory control practices
- Product traceability SOP

20.0 SORTING AND GRADING

In the packinghouse harvested potatoes should be sorted and graded in a manner that minimizes sources of potential microbiological, chemical and physical contamination. The best practices include:

- Separation of marketable potatoes from foreign materials (e.g., stones) and crop debris (e.g., stems and leaves) during sorting and grading.^{xxvii}
- If foreign material control devices are used, they should be regularly inspected and maintained (i.e., calibrated, if appropriate) and included in a preventive maintenance schedule.
- Foreign materials, culls and debris should be discarded in a manner so as to not attract pests such as insects and rodents.^{xxviii}
- Potatoes that may have become contaminated should be discarded.^{xxix}

Documentation List:

- Foreign material control device maintenance SOP
- Foreign material control device calibration SOP
- Foreign material control device maintenance and calibration logs

21.0 POST-HARVEST WATER USE

Post-harvest water use varies by intended purpose and by practice. For example, water may be recirculated and used along the packing line or used for cooling when the temperature is high during harvesting. With water that comes in contact with potatoes and food contact surfaces, it is important to assess the quality of the water as it may be a source for microbiological or chemical contamination.

Disinfectants, when used with water of adequate quality, may help minimize the survivability or prevent further growth of pathogens if they are present in the wash water. Potato packers should consider options for disinfectants and wash systems that are most appropriate for their operation. The effectiveness of a disinfectant and the amount that should be used depends on the type of product and the treatment conditions, such as water temperature, acidity (pH), water hardness, contact time, amount and rate of product throughput, water to product ratio, amount of organic material, and the resistance of pathogens to the particular disinfectant. General recommendations for post-harvest water use and best practices for monitoring and assessing water quality include:

General Recommendations

- A water system description should be prepared and documented. The description may include maps, photographs, drawings or other means to communicate the location of water source(s), permanent fixtures such as wells, gates, reservoirs, valves, returns, backflow prevention and other above-ground features and the flow of the water system (including holding systems, reservoirs or any water captured for re-use).
- The water supply should be sufficient for the operations intended, derived from an adequate source and provide running water at a suitable temperature and under pressure as needed in

all areas where required for packing potatoes, cleaning equipment, or employee sanitary facilities.^{xxx}

- A documented scheduled assessment of the water system including delivery equipment should be performed routinely and should verify that:
 - The water delivery and wastewater disposal systems are maintained so that they do not pose a risk of contamination for potatoes, water supplies or equipment.
 - All water lines that are susceptible to contamination from backflow are equipped with backflow prevention devices.^{xxxi}
 - The equipment designed to assist in maintaining water quality (i.e., chlorine injectors, filtration systems, and backflow devices) are functioning properly.
- An initial assessment of the washing process that takes into consideration the type of wash system, type of sanitizer(s) used and water quality should be conducted. Document the preventive controls and / or corrective action taken to address the hazards. Update the assessments as changes are made to the system.

Water Quality

- Water that is used in the packing line and / or to cool potatoes should not pose a risk of contamination. Test source water at least annually taking samples as close to the point of use as possible.^{xxxi}
- If the water used to wash, rinse, or cool potatoes is re-circulated, then procedures should be established to determine when and how often water should be refreshed or completely changed out.^{xxxi}
- If water is used to flume and wash potatoes that are destined for fresh market, a final rinse with water that meets the U.S. EPA's microbial standards for potable water should be applied to potatoes.¹⁸ Water may be treated to achieve microbial standards of potable water.
- If disinfectants are used in water to wash or rinse potatoes, only disinfectants registered or approved by the U.S. EPA, FDA or prevailing regulatory agency for their specific intended use should be used.
- Follow the manufacturer's directions for mixing the disinfectant chemicals to obtain effective concentrations; a manufacturer's suggested or allowable level for use in washing and cooling water should not be exceeded.
- If an abnormal event occurs to cause contamination of water, the packer should not use water until corrective action has eliminated the contaminant and testing indicates the water is safe to use.
- Any water additive used to wash potatoes should be food-grade and compliant with federal, state or local regulations for the intended use.¹⁹

¹⁸ US EPA National Primary Drinking Water Regulations: <http://water.epa.gov/drink/contaminants/>

¹⁹ 21 CFR 173.315: <http://ecf.gpoaccess.gov/cgi0/0xv/text;idx?ecf&sid=61dec36ff0885a1e8977c26d21bf3b9&rgn=div8&view=text&node=21:3.0.1.1.4.4.1.3&idno=21>

- All water monitoring equipment should be adequately maintained and periodically calibrated. Maintain a log of maintenance and calibration events.
- If cisterns, tanks, or containers are used to store water, they should be:
 - Cleaned and sanitized before each season or at least once a year.
 - Free of rust.
 - All cleaning and sanitizing verification activities should be documented.

Documentation List:

- Water system description
- Water system assessment
- Washing process assessment
- Water use SOP
- Re-circulated water use SOP
- Monitoring log(s)
- Water test results
- Equipment calibration SOP
- Equipment maintenance and calibration log
- Cleaning/sanitizing verification documents

22.0 PRODUCT CONTACT CONTAINERS AND PACKING MATERIALS

After storage, potatoes are transported to a packinghouse for further washing, sorting, and packing. Product contact containers and packing materials may be a source of microbiological, chemical or physical contamination if they are not handled and stored in a sanitary manner, therefore:

- Establish written policies for containers and packing materials that address the following:
 - Use of product contact containers and packing materials that follow state and federal regulations for food contact materials.
 - Visual inspection of all incoming product contact containers and packing materials to ensure that they are clean, intact and free of any foreign materials prior to use.^{xxxiv}
 - Storage of product contact containers and packing materials on clean pallets in a controlled area that is protected against potential contamination at all times.^{xxxv} An adequate inspection buffer should be maintained between rows, walls and the ceilings and stored containers.
- Product contact containers should not be used for other non-product contact purposes unless containers are clearly marked or labeled for that purpose.
- Any reusable product contact container should be in good condition and included in a regular cleaning and sanitation schedule.

- Compressed air that has contact with packaging materials during packing should be treated in such a way that potatoes are not contaminated with unlawful indirect food additives.^{xxxvi}
- Pallets and slip sheets should be inspected prior to use for conditions that may be a source of potential contamination. Damaged pallets and slip sheets should not be used.
- Inspection and cleaning/sanitizing activities should be documented.

Documentation List:

- SOP for inspection, use, and storage of product contact containers and packing materials
- SOP for inspection, use, and storage of pallets and slip sheets
- SSOP for cleaning reusable product contact containers

23.0 PACKINGHOUSE FACILITIES DESIGN, CONSTRUCTION, AND MAINTENANCE

Packinghouse facilities and equipment should be designed, constructed, and maintained to facilitate cleaning and sanitation. A well designed and managed packinghouse and its corresponding food safety program can minimize the risk of microbial contamination. The grounds around the packinghouse should be kept in a condition that will control, reduce, or minimize the risk of potatoes becoming contaminated.

Even though a packinghouse is not considered a manufacturing or processing facility, the recommendation in this document is that potato packing operations follow the requirements for buildings and grounds, packing and holding of foods, equipment and utensils, sanitary facilities and controls, and sanitary operations as provided for under the Code of Federal Regulations, Title 21 as appropriate to the facility. Facilities and staging areas should be designed to facilitate maintenance and good sanitation practices to control the potential for contamination throughout receiving, packing, and shipping operations. General recommendations for facilities include:

- Facility and equipment structures and surfaces (floors, walls, ceilings, doors, frames, hatches, etc.) should be constructed and installed in a manner that facilitates cleaning and sanitation and does not serve as harborage for contaminants or pests.^{xxxvii}
- The building should provide sufficient space for such placement of equipment and storage of materials as is necessary to maintain sanitary operations and prevent contamination.^{xxxviii}
- The plumbing should be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the facility.^{xxxix}
- The building structure should be such that pests can be excluded from gaining entrance to the facility.^{xl}
- Fixtures, ducts, pipes and overhead structures should be installed and maintained so that foreign materials, drips and condensation do not fall on product, food contact surfaces, or packing materials.^{xli}
- Packing line equipment should only be used for purposes for which it was designed.
- Air intakes should not be located near potential sources of contamination.^{xlii}

- Floors should be sloped to drains, and kept in good repair to provide adequate drainage and prevent accumulation of water.^{xiii}
- Floor drains should be designed to be accessible for cleaning and capable of preventing pest entry.
- Food contact surfaces should be constructed of materials appropriate for potato packing and the packinghouse environment that are not corroded, nontoxic, and that can be readily cleaned and sanitized and do not serve as harborage of microbial pathogens.^{xiv}
- Lighting in all areas should be sufficient for cleaning, sanitation, repairs, etc.^{xv}
- A written glass control policy should be documented, including a glass register.
- Lights should be equipped with shatter-proof bulbs or have protective coverings to prevent broken glass from contaminating potatoes.^{xvi}
- A designated area for employees to store personal items, take breaks, and eat that is separate from a production area should be provided.^{xvii}
- Temporary repairs should not pose a risk of contamination.

For maintaining the grounds around a facility, the best practices are:

- Properly store equipment, remove litter and waste, and cut weeds or grass within the immediate vicinity of the buildings or structures so the grounds are not an attractant, breeding place, or harborage for pests.^{xviii}
- Maintain roads, yards, and parking lots so that they do not constitute a source of contamination in areas where potatoes are exposed.^{xix}
- Adequately drain areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.ⁱ
- Evaluate adjacent land use to ensure that it does not pose a significant risk of product contamination.ⁱⁱ

For toilets and hand washing station construction and design, the best practices are:

- Toilet facilities and hand washing stations, numbers and locations should be in compliance with applicable local, state, and federal regulations. (See OSHA requirements for sanitation applicable to packing facilities)²⁰
- Worker hygiene facility locations should maximize accessibility and use while minimizing the potential for the facility to serve as a source of contamination.
- Toilet facilities and hand washing stations should be constructed of materials that can be readily cleaned and sanitized.
- Ideally toilet facilities should not open directly into areas where product is located.ⁱⁱⁱ

²⁰ OSHA. Sanitation 1910.141

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

- Hand washing stations should be located so as not to pose a risk of cross-contamination. Ideally hand washing stations should be located where employee hand washing can be observed.^{liii}
- Hand washing stations and toilet facilities should be constructed with properly designed drainage systems.^{liiv}
- If the toilets and hand washing stations have any openings to the outside (e.g., windows, vents, etc.), these openings should have proper protection to exclude vermin.^{liiv}

Documentation List:

- Glass control policy
- Water test records
- Back flow test records

24.0 PACKINGHOUSE SANITARY OPERATIONS

Contamination by location and / or flow of humans, product, equipment, and air can be prevented with adequate food safety controls, operating practices, and facility design. A packinghouse should be designed so that potatoes arriving from the field never cross paths nor are they commingled with finished product. Operators should be aware of and operate in accordance with all relevant laws and regulations that describe facility sanitation practices. Recommendations for facilities include:

- Each facility should have a work flow diagram and should perform a hazard analysis for packing operations. This analysis should be documented and available for review. If the operator changes a process (e.g., adds new equipment), then the analysis should be revisited.
- There should be a clear separation of incoming and market-ready potatoes to minimize the potential for cross-contamination.^{livi}
- Establish a procedure for inspecting and accepting or rejecting incoming chemicals and process aids. All chemicals used in packing operations should be used and labeled in accordance with the manufacturer's instructions and with relevant federal, state, and local government regulations. SDS for all chemicals used in the packing facility should be on file and readily accessible.^{livi}
- Trash, leaves, trim, culls, and other waste materials in production areas should be placed in appropriate receptacles and removed from the produce handling areas at a sufficient frequency to prevent the materials from becoming a source of contamination or pest attractant.^{liiii}
- Trash in nonproduction areas should be placed in appropriate receptacles with lids and removed from the facility on a regularly scheduled basis.^{liii}
- Outside garbage receptacles / dumpsters should be covered and located away from packing facility entrances and the surrounding areas should be free of debris.^{liii}

- Label receptacles clearly to indicate their intended use (e.g., trash, recyclable materials or product that might be re-worked). Employees should be trained to recognize and use material receptacles appropriately.
- Operate and maintain sewage and gray water systems so as not to cause direct or indirect product contamination.^{ixi}
- Prevent potential wastewater spillage from contaminating any food handling area by barriers, drains or a sufficient distance between these areas.^{ixii}
- Appropriate measures should be taken to dispose of waste water.
- All packinghouse tools should be clearly designated according to their intended use. Denote tools only used for food contact and those that may contact non-food surfaces (e.g. used for general cleaning).
- Appropriate signage should be displayed throughout the packinghouse to remind employees to adhere to company food safety policies (e.g., use of equipment, hygiene, etc.).^{ixiii}

Equipment maintenance

Equipment used during packing operations should be maintained to prevent contamination of potatoes. The best practices described below outline appropriate equipment preventive maintenance to minimize and control the potential introduction of physical, chemical, and microbiological contaminants in the packinghouse environment.

- Companies should have a written policy regarding acceptable use, preventive maintenance, and repair of equipment.^{ixiv}
- Prior to use in the facility, equipment should be visually inspected and determined to be clean, in good repair and free of foreign materials.
- All maintenance should be conducted in a manner that does not pose a risk of contamination.
- After maintenance activities, clean and, if necessary, sanitize equipment before use with or in proximity to potatoes.
- Equipment lubrication should be managed so as to not contaminate food products.^{ixv} Food grade lubricants should be used on packing equipment where there is a risk of contamination. Food-grade and non-food-grade lubricants are to be stored separately.
- Old, unused equipment should be removed from the packing areas and stored in a manner that does not present a food safety hazard.
- Prepare a written SOP outlining the method and frequency of calibrating monitoring and verification instrumentation.^{ixvi}
- All instrument calibration, equipment inspection and maintenance activities should be documented.

Pest control

Packing facilities should be appropriately protected from pest infestations. All animals including mammals, birds, reptiles, and insects, are potential sources of contamination in produce

environments because they harbor, or could be a vector for, a variety of pathogenic agents. Appropriate cleaning, sanitation, and pest removal / exclusion measures should occur before operations commence. Effective measures should be taken to exclude pests from the packinghouse areas and to protect against pest contamination and should include the following:

- Each packing facility should have a written pest control program.^{ixvii} The program should include policies and procedures that cover the following:
 - Outdoor storage of equipment and materials.
 - Factors enhancing pest harborage.
 - Maps locating pest traps both inside and outside of the facility.
 - A pest log that includes dates of inspection, inspection reports and steps taken to eliminate problems
- Domestic animals should be prohibited in the packinghouse.^{ixviii}
- Open windows, vents, fans, and similar features should be adequately protected to prevent pest entry.^{ixx}
- Only non-toxic bait and pest control devices are to be used inside a packinghouse. Use all pesticides, traps, bait, and chemicals for pest control in and around a packinghouse in accordance with local, state, and federal regulations.
- An adequate inspection buffer should be maintained on both the inside and outside perimeters of the physical facility (e.g., pallets, raw product and equipment may not be stored flush against the wall of the facility).
- When rodent traps are deployed around the inside of the facility and / or bait stations along the outside perimeter of the facility, detailed maps demonstrating the location of each trap and / or bait station should be available for review. Traps and bait stations should be inspected routinely and any corrective actions (e.g., cleaning out traps, replacing damaged traps) should be documented.
- Whether pest control is performed internally or by a third-party pest control company, the following documents should be maintained and available for review:
 - A copy of any required applicator's license and/or training records.
 - An insurance certificate for the applicator.
 - A schedule of the applicator's activities and actions.
 - A record of the chemicals used.

Documentation List:

- Flow diagram of packinghouse operations
- Hazard analysis for the packinghouse
- Equipment use, maintenance, and repair policy
- Equipment preventive maintenance and calibration SOP

- Equipment calibration, maintenance and repair log
- SOP for pest control program
- Record of pest control chemicals used
- Pest control applicator's license(s)
- Pest control applicator's insurance certificate
- Pest control chemical application / activities log
- Trap and bait station location maps
- Trap and bait station inspection logs

25.0 PACKINGHOUSE FACILITY SANITATION

Buildings, fixtures, and equipment should be maintained in a clean condition and kept in repair sufficient to prevent food from becoming adulterated. Without appropriate cleaning practices, packinghouse facilities and equipment may be a source of microbial, chemical, or physical contamination. Cleaning and sanitizing of facilities and equipment should be conducted in a manner that protects against contamination of potatoes, food contact surfaces, or packaging materials. Operators should be aware of and operate in accordance with all relevant laws and regulations with regard to handling all cleaning and sanitizing chemicals used in the packing operation.

Toilet and hand washing stations should be clean, sanitary, and properly maintained for the worker's health, safety, and comfort. Inadequately supplied or improperly maintained restrooms and hand washing facilities may lead to direct or indirect contamination of the potatoes and water sources used on potatoes.

For general facility sanitation, the best practices are:

- A master cleaning schedule (and sanitizing schedule, where appropriate) and related SSOPs should be established for all food and non-food contact surfaces in the facility that may be a source of contamination. The schedule and SSOPs should clearly identify cleaning frequencies, cleaning agents and sanitizers to be used, cleaning methods, precautions, etc.¹³³
- An inspection of the packing facility should be conducted prior to use to verify that maintenance, cleaning and sanitation has been satisfactorily completed, the equipment is safe and ready for use, pest control measures are in place and functioning, and all food safety protocols are being followed.
- Personnel with cleaning and sanitation duties should be trained in the following:
 - The principles and methods required for effective cleaning and sanitation, especially as they relate to food safety.
 - Cleaning and sanitizing of the equipment and facility in accordance with the SSOP.
 - Use of cleaning equipment.
 - Use of appropriate personal protective equipment.
 - Safe use, handling, and storage of cleaning and sanitizing chemicals.

- Cleaning equipment and tools should be kept clean and in good condition.
- Potable water should be used for cleaning the facility interior, equipment, containers, etc.
- Establish a procedure for inspecting and accepting or rejecting incoming sanitation chemicals and supplies.^{lxxi}
- Cleaning compounds and other chemicals used in a potato packing operation should be approved for their intended use.²¹
- A secure, vented storage area should be used for storing facility cleaning and sanitizing chemicals and tools that is located away from product areas and product packaging storage areas.^{lxxii}
- All chemicals used in cleaning operations should be used and labeled in accordance with the manufacturers' instructions and in accordance with relevant federal, state, and local government regulations.
- All facility inspection, maintenance, cleaning and sanitizing, activities should be documented.

For equipment cleaning and sanitation, the best practices are:

- Packinghouse facility equipment should be inspected for cleanliness before packing operations begin each day.
- A cleaning schedule and written SSOP should be developed for all packing equipment and should clearly indicate the following:^{lxxiii}
 - A description of the equipment.
 - Cleaning frequency (e.g., daily, weekly, monthly or seasonally).
 - Cleaning methods (e.g., wash, sanitize and rinse if necessary).
- If any equipment includes filters, these should be routinely inspected and changed according to the manufacturers' instructions.
- Cleaning and sanitizing of equipment should be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.^{lxxiv}
- All equipment cleaning, and sanitizing activities should be documented.

For toilets and hand washing station sanitation, the best practices are:

- Establish SSOPs and schedule for toilet and hand washing facilities cleaning and sanitation including a checklist of facility supplies.
- Maintain written documentation of service and maintenance of toilet and hand washing facilities that demonstrates compliance with applicable worker health and safety regulations.

²¹ Appropriate chemical use can be verified in the NSF International's White Book™ - Nonfood Compounds Listings Directory available at <http://www.nsf.org/usda/fl-listings.asp>

For toilet and hand washing station waste disposal, the best practices are:

- Maintain a written waste collection service schedule.
- Dispose toilet and hand washing station waste according to applicable laws and regulations and in a manner that does not contaminate the packinghouse facility.
- Dispose used hand washing water in a manner that does not result in unsanitary conditions or contamination of the packinghouse facility.
- Dispose used paper towels and other trash in trash container.
- Dispose used toilet paper in the toilet.

Documentation List:

- Pre-operative sanitation inspection logs
- Employee training records
- Service and maintenance logs for sanitary facilities
- Waste collection service schedule
- Master cleaning schedule

26.0 COLD STORAGE AND WAREHOUSING OF MARKET-READY POTATOES

Cold storage and / or a warehouse are often the last areas that house potatoes in a packing facility before they are shipped to the next point of the supply chain. To maintain the integrity of the finished product before it exits the facility, the conditions and sanitation programs of these facilities should include the following best practices:

- Storage of market-ready potatoes should be under conditions that will protect them from physical, chemical, and microbiological contamination as well as product and container deterioration.^{lxxv}
- Market-ready potatoes should be stored with appropriate temperature levels.
- Cold storage refrigeration units should be inspected on a regular basis and kept in good operating condition.
- Temperature monitoring devices should be placed in the warmest area of the refrigerator unit and calibrated on a regular basis.^{lxxvi}
- The storage area should be included in scheduled cleaning and sanitation operations. If finished product is present during cleaning of floors or drains, ensure that water does not splash on products.^{lxxvii}
- Forklifts and other pallet moving equipment should be cleaned on a regular basis.^{lxxviii}
- Market-ready potatoes should be stored away from the walls in the warehouse / storage area.
- The storage area should be included in the facility pest control program.^{lxxix}

27.0 DOCUMENTATION AND RECORDKEEPING ²²

As a food safety practice, it is essential that companies involved in potato packing document and retain operating and best practice compliance records along with product tracing documentation. It also is important to note that subject to certain exceptions, existing FDA regulations such as Title 21 of the Code of Federal Regulations (CFR) - part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the U.S. However, currently farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.²³

In addition, facilities that manufacture, process, pack or hold food for consumption in the U.S. are subject to record keeping practices as specified under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (2002 Bioterrorism Act). The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including packaging. These records must include identifying information regarding the food. The regulation requires, among other things, that records maintained by non-transporters include an “adequate description” of the food, including brand name and specific variety. The recommendations below complement, but do not supersede, existing recordkeeping requirements in 21 CFR - part 1, subpart J.

Operational Records

Record maintenance and retention is essential for evaluating actual potato packing operations. Records are more reliable than memory and can help identify inconsistencies in operating procedures and practices where corrective actions or employee training may be needed. Furthermore, in the event of a foodborne illness outbreak traced to a particular facility, adequate documentation and records could help identify or rule out the cause of the outbreak and / or contributing factors. The best practices for maintaining operational records are:

- Develop and maintain written food safety programs and SOPs for practices such as product handling, facility and equipment cleaning and sanitation, equipment calibration (method and frequency), and employee training programs that are a part of the company’s overall food safety plan.
- Maintain and retain records for monitoring and corrective actions taken that include information such as the date and time, name of person(s) who completed the record, the activity being monitored in the documentation, and the methods and timelines of corrective actions.
- Records should be reviewed by a qualified individual on a routine basis to ensure that records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about correction actions.

²² The basis for this section is the best practices outlined by the FDA in their draft commodity specific guidance for tomatoes, melons and leafy greens; obtained at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/default.htm>

²³ Code of Federal Regulations, Title 21: Food and Drugs, Part 1 – General Enforcement Regulations, Subpart J-Establishment, Maintenance, and Availability of Records, General Provision 1.327(a). Accessible at: <http://www.ecfr.gov/cgi-bin/text-idx?ecf&sid=8c363ccfd19538d82bf2578bbd91599&rgn=div6&view=text&node=21:1.0.1.1.1.8&sidno=21>

- Maintain documents and records on-site or off-site or electronically. Documents should be available for inspection within a reasonable period of time.
- Retain records for a minimum of two years or as required by current regulations.

Product Traceability and Recall Program

Product traceability refers to the ability to follow the physical movement of potatoes both from their original source, through intermediate sources to their final recipient and tracking them in reverse from the final recipient back to their original source. Provisions of the 2002 Bioterrorism Act require that shippers have the ability to identify the immediate previous source of the product, immediate subsequent recipient of the product and the transporters. Commingling of product may occur at the packing facility and operators should have product tracing systems in place to be in compliance with the Act. Though not a preventive measure, effective product tracing systems are an important element of a comprehensive food safety program, therefore:

- Establish a traceability program that enables reconciliation of potatoes to the source (one step backward) and to recipients (one step forward).²⁴ Examples of such records include labels with product-identifying information, invoices, inventory records, bills-of-lading, and shipping/receiving records.
- Store potatoes in a manner that ensures traceability.
- Perform a trace back and trace forward exercise at least annually. This exercise should achieve accurate traceability within 4 hours or as required by applicable regulation.
- Establish a documented recall program with written procedures that includes:
 - A designated recall team with team members' 24-hour, seven-days-a-week contact information.
 - A mock recall exercise performed annually by facility using the company's written recall program.
 - 24-hour, seven days a week contact information for customer contacts
 - Contact list of key regulatory officials (federal and state) that need to be notified if a recall is warranted.
 - Contact list for commodity organizations and trade association experts that might be called upon to provide technical help if needed.
 - Procedures for notifying the public about a hazard when appropriate to protect public health.
 - Procedures for verifying that the recall was carried out.
 - Procedures for the disposal of recalled potatoes.^{1xxx}
- Include information on the product label that allows for effective traceability. Label details could include:
 - Grower or farm / ranch identification

²⁴ Excludes direct to consumer sales.

- Lot number
- Packinghouse identification
- Harvest / Pack date
- Field or block identification
- Quantities

Documentation List:

- Food safety related programs and SOPs
- Product tracing records
- Recall program with contact information for recall team members, customers, regulatory officials, etc.
- Trace exercise records
- Mock recall exercise records

28.0 TRANSPORTATION OF POTATOES

Potatoes may be transported from packing facilities by numerous modes of transportation. Transportation conditions should be managed to minimize the risk of contamination. To minimize the potential for contamination, the cargo area of vehicles transporting potatoes in market-ready packaging materials should be clean and in good condition. The best practices to ensure transport vehicles are not a source of contamination are:

- Develop a SOP that describes the best practices to ensure transport vehicles are not a contamination source.^{xxxxi} These best practices include, but are not limited to:
 - Visually inspect the transportation vehicle to ensure it is clean, functional, and free of objectionable odors, leaks, and any foreign materials.
 - If trailers are used for hauling items other than potatoes, establish procedures to ensure that transport trailers will not potentially contaminate potatoes.
 - During loading, steps should be taken to minimize potential physical damage to potatoes.
- Apply truck seals to all trailers / shipping units containing finished product.

Documentation List:

- Transport vehicle inspection checklist

ADDITIONAL RESOURCES

- Bioterrorism Act of 2002.
(<http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm>)
- FDA - Food Facility Registration
(<http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm>)
- FDA - Prior notice of imported food shipments
(<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm>)
- *Food Security Guidelines and Questionnaire for Fresh Fruits and Vegetables*, United Fresh Produce Association, 2001. (<http://www2.unitedfresh.org/forms/store/ProductFormPublic/>)
- *Guide to Federal Food Safety and Security Inspections: Guidance on Preparing for and Successfully Directing Regulatory Inspections by FDA and other Food Authorities*, United Fresh Produce Association, 2005.
(<http://www2.unitedfresh.org/forms/store/ProductFormPublic/>)
- *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, U.S. Food and Drug Administration, 1998.
(<http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlantProducts/UCM169112.pdf>)
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GLOSSARY

Terms are defined in this glossary based on their use in the context of this document. These definitions may not represent the term as it may be used in a different context.

active ingredient	An ingredient of an agricultural chemical that controls the targeted pest.
adjacent	Refers to areas across from or beside a field or facility where potatoes are grown or handled.
adulterated food	Food that is manufactured under such conditions that it is unfit for food. The main federal law governing adulterated potatoes is the Federal Food, Drug, and Cosmetic Act, which defines in very specific terms how “adulterated” applies to regulated food. ²⁵
agricultural activities	Livestock and crop production, processing activities, etc.
agricultural chemicals	A subset of pest control products used to control crop pests such as insects, diseases, and weeds (e.g., crop protection chemicals such as herbicides, fungicides and insecticides). These can be used on seed potatoes, and during the production, storage and packing of potatoes.
agricultural water	Water used for irrigation and for the application of agricultural chemicals and commercial fertilizers.
agronomic or agricultural inputs	Includes chemicals, microbiological controls, pollinators, commercial fertilizers, compost, cover crops/green manure, manure (livestock waste), mulch and other row cover materials, other by-products, soil amendments and pulp sludge used to produce a crop.
bait	Anything intended to attract or kill pests.
biosolids	The material, predominantly organic in nature, resulting from treatment of municipal sewage and septic system waste.
building	Any structure where potatoes are handled and/or stored or where market-ready packaging materials, agricultural chemicals, commercial fertilizers, etc. are stored (e.g., packinghouse, storage areas, etc.).
bulk	Harvested potatoes that are not contained in market-ready packaging materials.

²⁵ Sec. 402 of the Federal Food, Drug and Cosmetic Act, as amended 21 U.S.C. § 342 Adulterated food (<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIV-sec342.pdf>)

calibration	Determination of the accuracy of an instrument, usually by measurement of its variation from a standard, to ascertain necessary correction factors.
cargo area	The part of the vehicle that is intended to transport potatoes (e.g., wagon, trailer, box).
certified applicator	A licensed or certified individual, who has successfully completed a voluntary or mandatory certification course, paid the certification fee and may apply agricultural chemicals.
chlorine	A chemical element that is widely used for disinfection, water purification and cleaning.
cistern	A container for collecting or holding water (e.g., well water held in a tank, delivered commercial water, a tank for capturing rainwater).
clean	When food or food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris. ²⁶
cleaning	The removal of visible soil (e.g., organic and inorganic material) from objects and surfaces; normally accomplished manually or mechanically using water with detergents or enzymatic products. ²⁷
cleaning agents	Products used to remove food, soil, rust stains, minerals, or other deposits. ²⁸
coliforms	Gram-negative, non-spore forming, rod-shaped bacteria that ferment lactose to gas. They are frequently used as indicators of process control, but exist broadly in nature.
commercial fertilizers	Substances (e.g. calcium) containing one or more recognized plant nutrients that are designated for use in promoting plant growth.
compost	Solid mature product resulting from a managed process of bio-oxidation of a solid heterogeneous organic substrate including a thermophilic phase.
compost tea	A liquid solution made by steeping compost (produced properly by a managed process that includes a thermophilic phase) in water. It is used as both a fertilizer and a spray to control plant disease.

²⁶ FDA. 1998. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf>

²⁷ CDC. 2008. Disinfection Guidelines. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

²⁸ Clemson University, Clemson Extension, FoodSafetySite.com. 2008. <http://www.foodsafety.com/educators/competencies/foodservice/cleaning/cas1.html>

contamination	Infection or pollution with microbiological, chemical or physical substances.
control	Means to manage the condition of an operation in order to be consistent with established criteria, and to follow correct procedures.
control measure	Any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. ²⁹
corrective action	A recognized or approved activity to address a problem.
cross-contamination	The transfer of microorganisms, such as bacteria and viruses, from a contaminated surface or media to a previously uncontaminated surface or media.
<i>E. coli</i>	<i>Escherichia coli</i> are common bacteria that live in the lower intestines of animals (including humans). Though generally not harmful, the presence of generic <i>E. coli</i> is frequently used as an indicator of fecal contamination.
environmental assessment	An evaluation of the growing environment taking into consideration factors including topography, hydrology, geographical features, climatic conditions, land history, near-by land use, agricultural water, and domestic animal and wildlife presence to evaluate any safety risks that may affect the potential for a product to be contaminated. Environmental assessments may be conducted prior to planting, during production, and immediately prior to harvest. ³⁰
facilities	Buildings and other physical structures used for or in connection with the harvesting, washing, sorting, storage, packaging, labeling, holding, or transport of fresh produce.
final rinse (during packing)	Water used in the final step of the cleaning process and the water used to apply agricultural chemicals at the final rinse stage before potatoes are packed into market-ready packaging materials (i.e. high volume spray or drench).
flooding	The flowing or overflowing of a field with water outside a grower's control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of potatoes in that field.
food contact surface	Those surfaces that contact human food and those surfaces from which drainage onto the food or onto surface that contact the food ordinarily occurs during the normal course of operations; includes utensils and

²⁹ FAO. 1997. Codex Alimentarius: HACCP System and Guidelines for its Application; Annex to CAC/RCP-1 (1969), Rev.3.

³⁰ FDA. 2009. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlan/Products/acml74200.htm>

	equipment surfaces. ³¹
food safety assessment	A standardized procedure that predicts the likelihood of harm resulting from exposure to chemical, microbial, and physical agents in the diet.
foreign materials	Anything other than a potato tuber that is present in a potato field.
glycoalkaloids	Naturally occurring chemicals found in potatoes that may cause illness in humans at high levels (primary compounds are α -solanine and α -chaconine). Potato cultivars/varieties are bred for low levels of glycoalkaloids. Levels may increase if tubers are exposed to light during the growing period, harvest, storage or transportation.
Good Agricultural Practices (GAPs)	General steps, measures or procedures that control the operational conditions within a production facility promoting an environment favorable to the production of safe food.
grading	Categorizing or separating potatoes by size, color or quality (i.e., into pre-determined grades).
hazard	A microbiological, chemical or physical agent that is reasonably likely to cause human illness or injury in the absence of control.
human pathogen	Microorganism capable of causing disease or injury to people. This is different from plant pathogens which may cause disease to plants.
lot	A unit of market-ready potatoes harvested or packed during a specified period of time or according to a specific ID.
lot number or ID	Any combination of letters OR numbers, or letters AND numbers, by which a unit of market-ready potatoes can be traced and identified in the packer's records (e.g., skid, block, box).
manure	Any animal excrement (e.g., cow, sheep, horse, pig, chicken, etc.), with or without bedding, that has not been composted and is used to fertilize the soil. Includes excrement (aged excrement).
market-ready potatoes	Includes potatoes that are ready for sale (e.g., to a processor, packinghouse, retail, roadside stand). Once packed, the potatoes will go directly to food service, retail (including retail wholesaler / broker / distribution center) or directly to the end consumer.

³¹ CFR. 2009. Code of Federal Regulations, Title 21 Part 110.3 Definitions
<http://www.accessdata.fda.gov/scripts/cdrh/cdhrs/cfdn/cfsearch.cfm?cfrpart=110>

market-ready packaging materials	Describes two types of packaging materials used with ready-to-sell potatoes. PRIMARY materials come into direct contact with potatoes (e.g., bags, baskets) and SECONDARY materials (e.g., masters, dividers) may be reused and do not come into direct contact with potatoes.
microorganism	Yeasts, molds, bacteria, and viruses. Includes, but is not limited to, species having public health significance.
packaging material	Any item that is used in holding and transporting finished potatoes during storage and shipment.
packinghouse	A facility where raw agricultural commodities are washed, trimmed or sorted and packed in commercial containers, e.g., cartons or totes.
pathogen	A disease causing agent such as a virus, parasite, or bacteria.
pest	Any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
pooled water	An accumulation of standing water; not free-flowing.
potable water	Water that meets the standards for drinking purposes of the state or local authority having jurisdiction or water that meets the quality standards prescribed by the U.S. Environmental Protection Agency's National Interim Primary Drinking Water Regulations, published in 40 CFR Part 141. ³²
premises	Includes production site(s), building(s) and immediate surrounding land.
product contact container	Containers used to hold potatoes that are ready for shipping.
raw agricultural commodity	Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. ³³
raw fresh potato	A potato in its unpeeled natural form or state; also referred to as table or table-stock potatoes.
recall	Means for an operation to remove from sale or use, or to correct, a marketed product (i.e., that has been sold or distributed) that may have an impact on food safety.
re-circulated water	Water that is being reused.

³² OSHA. 1987. Field Sanitation – 1928.110.

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10959

³³ Sec. 201 (r) of the Federal Food, Drug and Cosmetic Act., as amended, 21 U.S.C. § 321 (r)

(<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/EDCAct/EDCActChaptersandIIIShortTitleandDefinitions/ucm086297.htm>)

Registered Food Facility	Facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States under FFDCa section 415(a); exempt industries include farms, retail food establishments, restaurants, nonprofit food establishments, fishing vessels, and facilities regulated exclusively by the USDA.
Reportable Food Registry	An electronic portal for Registered Food Facilities to report when there is reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals; a requirement for Registered Food Facilities.
risk	A function of the probability of an adverse effect and the severity of that effect, consequential to a hazard or hazards in food.
<i>Salmonella</i> spp.	A rod-shaped, motile bacterium – nonmotile exceptions are <i>S. gallinarum</i> and <i>S. pullorum</i> – non-spore-forming and Gram-negative organism that cause illness (salmonellosis) in humans. Environmental sources include water, soil, insects, manufacturing surfaces, animal feces, and raw meats, poultry or seafood.
sanitize	To adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
sanitizer or sanitizing agent	An agent that reduces microbiological contamination to levels conforming to local health regulations. ²⁸
Sanitation Standard Operating Procedures (SSOPs)	A set of written instructions that addresses sanitation conditions and practices before, during, and after processing including but not limited to water quality, food contact surfaces, cross-contamination, pest control, employee hygiene and health, maintenance of hand washing and toilet facilities, etc.
seed potato	A tuber or any part of a tuber used for propagation purposes.
sewage sludge	Includes all biosolids.
soil amendment	Elements added to the soil, such as compost, peat moss, or fertilizer, to improve its capacity to support plant life.
Standard Operating Procedures (SOPs)	A set of written instructions detailing all steps and activities required in performing a given task or in reaction to a given event; the purpose of which is promote quality by minimizing variation and facilitating consistency.
storage	Keeping potatoes in a pre-determined and controlled location or any location where potatoes are kept for a period of days to months (e.g.,

	atmosphere controlled or modified; cooled, dry, contained location).
surface water	Water at or above the land surface. ³⁴
traceability	Permits the source of the potatoes to be identified and maintained at any stage in the supply/distribution system.
ultraviolet index (UV index)	A measure of the solar ultraviolet intensity at the earth's surface; indicates the day's exposure to ultraviolet rays. The UV index is measured around noon for a one-hour period and rated on a scale of 0-15.
wash water	Water used during the cleaning process (e.g., in dump tanks, pits, sprays, drums) to remove organic and other material from potatoes.
waste	Refers to any item or material requiring disposal (i.e., garbage).
waste water	Water that has been used and contains dissolved or suspended waste materials. ³⁵
water distribution system	All pipes, pumps, valves, storage tanks, reservoirs, meters, fittings, hydraulic appurtenances, and other components used to carry water from its primary source to other areas of the property, building, etc.

³⁴ United States Department of the Interior - Bureau of Reclamation. Glossary and Acronyms: Pursuant to the Biological Assessment. <http://www.usbr.gov/lc/region/g2000/assess/glossary.htm>

³⁵ EPA's glossary of climate change terms (<http://www.epa.gov/climatechange/glossary.html#W>)

APPENDIX I. FIELD MANAGEMENT – ASSESSMENT OF ENVIRONMENTAL CONDITIONS

Issue	Assessment Considerations	Potential Mitigation Measures
<p>Adjacent land use (raw manure piles/lagoons, livestock, landfills, sewage treatment, chemical plants, etc.)</p>	<p>In evaluating risk from physical, chemical, and microbiological hazards to potatoes, factors to consider include:</p> <ul style="list-style-type: none"> • Topography – potential contaminants may be uphill or downhill from potato fields • Opportunity for water run off through or from a potential contamination source • Presence of fencing and other physical barriers such as: <ul style="list-style-type: none"> ○ Berms and ditches to divert runoff. ○ Covering on pile to prevent wind dispersion. ○ Vegetated strips to filter potential contaminants. • Opportunity for transfer of foreign material to fields 	<ul style="list-style-type: none"> • If possible, move potential hazard (e.g., manure piles, livestock) to a location that does not pose a risk to a mature potato crop. • Erect barriers (e.g. diversion ditches, fences, storage pits, windbreaks, etc.) or buffers (e.g. sod strips, grass waterways, etc.) to prevent contamination from run off or wind dispersion of potential hazard.
<p>Animal activity in the field (wild or domestic)</p>	<p>There should be monitoring of the growing fields prior to each growing season.</p> <p><u>Routine monitoring may include notation of:</u></p> <p>Observation of animals in the field</p> <ul style="list-style-type: none"> • Frequency of sightings • Type of animal(s) – domestic and wild • Approximate number of animals • Location of animals – i.e., proximity to growing field, water source or other relevant factors <ul style="list-style-type: none"> • Temporal patterns of animal presence – i.e., morning, afternoon, evening <p>Downed fences Animal tracks in production block Animal feces or urine in production block Eaten plants in production block</p>	<ul style="list-style-type: none"> • Assess the extent of animal activity and impact on the potato crop. • If there is evidence of feces in the production block, measures should be taken to ensure that potatoes are not contaminated by animal feces during harvest. • Prior to taking action that may affect animals, producers should consult with wildlife and / or domestic animal experts as appropriate. • Prior to taking action that may affect natural resources, producers should check local, state, and federal regulations that protect riparian habitat, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors. • Evidence of fecal contamination and corrective actions should be documented and available for verification for a period of 2 years.

Issue	Assessment Considerations	Potential Mitigation Measures
Flooding	<p>In evaluating potential risk to potatoes, factors to consider include:⁷⁶</p> <ul style="list-style-type: none"> • Potential source(s) of flood waters – fresh water, salt water, ground water, surface water, etc. • Potential upstream contributors of human pathogens or chemicals (e.g., industrial source, livestock holding/grazing areas, etc.) • Field management since flooding occurred (i.e. planting of rotational crops, working of the soil). 	<ul style="list-style-type: none"> • Soils from formerly flooded production ground should be allowed to dry sufficiently and reworked prior to planting potatoes. • Create barriers between potential flood water sources and production land (e.g., levees, berms, etc.).
Documentation	Records should be retained for at least 2 years.	

Referenced Regulations

ⁱ 110.80 Processes and controls

Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function.

ⁱⁱ 110.10 Personnel

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

ⁱⁱⁱ 110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

^{iv} 110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

- (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
- (2) Maintaining adequate personal cleanliness.

^v 110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

^{vi} 110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

^{vii} 110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

^{viii} 110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

¹⁰ 110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

¹¹ 110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

¹² 110.10 Personnel

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness... or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

¹³ 110.10 Personnel

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an ... , open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

¹⁴ 110.37 Sanitary facilities and controls

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

- (2) Effective hand-cleaning and sanitizing preparations.
- (3) Sanitary towel service or suitable drying devices.

¹⁵ 110.37 Sanitary facilities and controls

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing: (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

¹⁶ 110.20 Plant and grounds

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

¹⁷ 110.20 Plant and grounds

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

110.20 Plant Grounds

(b) Plant construction and design... The plant and facilities shall: (4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair;

110.20 Plant Grounds

(b) Plant construction and design... The plant and facilities shall: (6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

110.20 Plant Grounds

(b) Plant construction and design... The plant and facilities shall: (5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

110.35 Sanitary Operations

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

110.35 Sanitary Operations

(b)(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

110.35 Sanitary Operations

(c) Pest control. No pests shall be allowed in any area of a food plant... Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

110.35 Sanitary Operations

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials.

110.80 Processes and controls

(b)(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

110.80 Processes and controls

(a)(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration.

110.80 Processes and controls

(a)(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

xxx 110.80 Processes and controls

(b)(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

xxx 110.37 Sanitary facilities and controls

(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

xxx 110.80 Processes and controls

(b)(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

xxx 110.37 Sanitary facilities and controls.

(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

xxx 110.37 Sanitary facilities and controls.

(b) Plumbing shall be of adequate size and design and adequately installed and maintained to: (5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

xxx 110.80 Processes and controls

(a)(1) ... Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality.

xxx 110.80 Processes and controls

(a)(1) ... Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.

xxx 110.80 Processes and controls

(a)(1) ... Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

xxx 110.80 Processes and controls

(b)(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

xxx 110.40 Equipment and utensils

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

110.20 Plant and grounds

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes.

AND 110.40 Equipment and Utensils

- (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.
- (b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

110.20 Plant and grounds

(b) The plant and facilities shall: (1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

110.37 Sanitary facilities and controls

- (b) Plumbing shall be of adequate size and design and adequately installed and maintained to:
- (1) Carry sufficient quantities of water to required locations throughout the plant.

110.35 Sanitary operations

(c) Pest control. No pests shall be allowed in any area of a food plant... Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials

110.20 Plant and grounds

(b) The plant and facilities shall: (4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials;

110.20 Plant and grounds

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

110.37 Sanitary facilities and controls

(b) Plumbing shall be of adequate size and design and adequately installed and maintained to: (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

110.40 Equipment and Utensils

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be

made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

110.20 Plant and grounds

(b) The plant and facilities shall: (5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

110.20 Plant and grounds

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

110.10 Personnel

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

110.20 Plant and grounds

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to: (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

110.20 Plant and grounds

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to: (2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

110.20 Plant and grounds

(a)(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

110.20 Plant and grounds

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

110.37 Sanitary facilities and controls

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by: (4) Providing doors that do not open into areas where

food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

¹⁰⁸ 110.37 Sanitary facilities and controls

(c) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing: (1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

¹⁰⁹ 110.37 Sanitary facilities and controls

(b) Plumbing shall be of adequate size and design and adequately installed and maintained to: (2) Properly convey sewage and liquid disposable waste from the plant.

¹¹⁰ 110.20 Plant and grounds

(b) Plant construction and design. The plant and facilities shall: (7) Provide, where necessary, adequate screening or other protection against pests.

¹¹¹ 110.80 Processes and controls

(b)(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food.

¹¹² 110.35 Sanitary operations

(b)(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- (i) Those required to maintain clean and sanitary conditions;
- (ii) Those necessary for use in laboratory testing procedures;
- (iii) Those necessary for plant and equipment maintenance and operation; and
- (iv) Those necessary for use in the plant's operations.

¹¹³ 110.37 Sanitary facilities and controls

(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

¹¹⁴ 110.37 Sanitary facilities and controls

(c)(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

¹¹⁵ 110.20 Plant and grounds

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to: (4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

¹¹⁶ 110.37 Sanitary facilities and controls

(b) Plumbing shall be of adequate size and design and adequately installed and maintained to: (2) Properly convey sewage and liquid disposable waste from the plant.

¹⁰⁰¹ **110.37 Sanitary facilities and controls**

(b) Plumbing shall be of adequate size and design and adequately installed and maintained to: (2) Properly convey sewage and liquid disposable waste from the plant.

¹⁰⁰¹ **110.37 Sanitary facilities and controls**

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing: (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

¹⁰⁰¹ **110.40 Equipment and utensils**

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces... Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

¹⁰⁰¹ **110.40 Equipment and utensils**

(a) ... The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants... Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

¹⁰⁰¹ **110.40 Equipment and utensils**

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

¹⁰⁰¹ **110.35 Sanitary operations**

(c) Pest control. No pests shall be allowed in any area of a food plant... Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

¹⁰⁰¹ **110.35 Sanitary operations**

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials.

¹⁰⁰¹ **110.20 Plant and grounds**

(b) Plant construction and design. The plant and facilities shall: (7) Provide, where necessary, adequate screening or other protection against pests.

AND

110.35 Sanitary operations

(c) Pest control. No pests shall be allowed in any area of a food plant... Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

¹⁰⁰¹ **110.35 Sanitary operations**

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(d)(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

110.35 Sanitary operations

(b)(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- (i) Those required to maintain clean and sanitary conditions;
- (ii) Those necessary for use in laboratory testing procedures;
- (iii) Those necessary for plant and equipment maintenance and operation; and

110.35 Sanitary operations

(b)(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

110.35 Sanitary operations

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

110.35 Sanitary operations

(a) General maintenance...Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

110.93 Warehousing and distribution

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

110.40 Equipment and utensils

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

110.35 Sanitary operations

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

110.35 Sanitary operations

(d)(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

110.35 Sanitary operations

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or

food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

¹⁰⁰⁰ **110.80 Processes and controls**

(b)(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

¹⁰⁰⁰ **110.93 Warehousing and distribution**

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.