The Foundation of Food Safety:

A Current Good Manufacturing Practices Education

WELCOME!

- If you are viewing this slide you are one of the many food production employees around the country who have the vital role of feeding the millions of hungry mouths that make up our country.
- While you may not realize it, in your daily actions you can have a great impact to the well being of your fellow Americans.

Quick Food Safety Stats

- An estimated **48 MILLION** people suffer from foodborne illness a year
- **128,000** hospitalizations
- **3,000** deaths

Source: (CDC ,2020)

Pretty Serious Right?

- The safety of those who consume food that we produce is not something to take lightly
- In fact, there rules and regulations from the US Federal Government regarding food safety. They are found in what is called the Code of Federal Regulations.

Code Of Federal Regulations and Food Safety

- Within the Code of Federal Regulations is a very large and important section, Title 21: Food and Drug Administration.
- Within this part are the rules and regulations that the Food and Drug Administration (FDA) uses to ensure the products our nation consumes are made, stored, and transported in a way that does not endanger the health of the public.

21 CFR PART 117 SUBPART B

- Feel free to read the above title out loud.
- This stands for TITLE: 21, Code of Federal Regulations Part:117, Subpart B
- Still sounds pretty unfamiliar?

Regulations

- While you may not realize it, you adhere to this specific subset of regulations every day you come to work.
- These regulations make up something which most of you may be familiar with: Current Good manufacturing Practices.

CURRENT GOOD MANUFACTURING PRACTICES

- While the name may make it seem this is a recent invention, Current Good Manufacturing Practices were actually created in the past decade.
- While this may be fairly recent, there was a build up of events and changes in our world that led to the need for their creation

Source: (Bottemiller,2013)

Global Changes in Our World

- Since the turn of the century we have seen rapid changes in the world as we know it. Global food commerce has been rising, creating a truly international market place. With the increase in global trade and travel distance of products, there is a greater need to ensure the safety of these products and verify they are in a wholesome nature fit for consumption. Additionally, after the tragic events of Sept 11th, the possibility of terrorism within our nation's food supply became a very real threat.

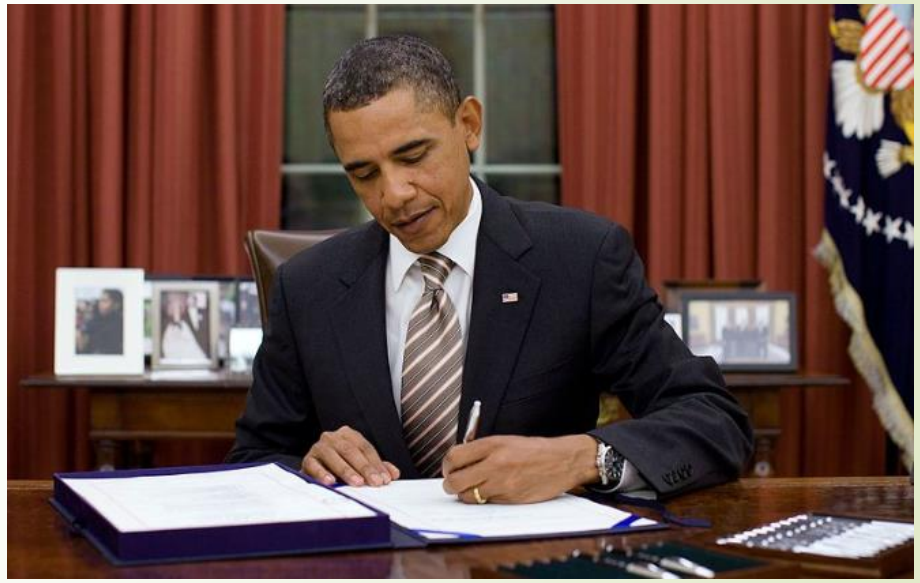
Source: (Bottemiller,2013)

Food Safety Modernization Act

- In recognition of the need to modernize our nation's ability to respond to and eliminate food safety threats, Congress passed the aptly named:

Food Safety Modernization Act

- This was then signed into law by President Obama on January 4th, 2011.



President Obama signing Food Modernization Act

Source: (Bottemiller,2013)

Food Safety Modernization Act

- This piece of legislation truly changed the world of our nation's food suppliers and importers
- A specific requirement that is very relevant to this class is that the FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply

Source: (Bottemiller,2013)

Food Safety Modernization Act

- These requirements led to the creation of our Current Good Manufacturing Practices!
- All of these practices are based upon scientific reasoning and their adherence by each and every one of you helps ensure that we produce wholesome food products for our family and friends to eat.

Current Good Manufacturing Practices

- In the coming slides, we will go over specific items from these regulations that apply to your every day work life.
- Many of these items you are practicing every day
- Please feel free to ask any questions, or give examples as to how you and your coworkers adhere to the practices.

First and Most Important…YOU!

Subpart B--Current Good Manufacturing Practice

Sec. 117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, 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, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.*, by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

117.10 – Personnel (Disease Control)

- Before you walk in the door, you have a huge impact on the health and safety of others. If you feel ill, it is a simple decision: Do Not Come to Work!
- We all know that we can get someone sick from a cough or sneeze, but did you know that can transmit to food as well?

Take Care of Yourself and Your Customer

- Two common examples of human to food transmitted illness:
- Hepatitis A virus – Shellfish and salads are most often linked to outbreaks, although other foods have also been involved
- Norovirus - most common cause of illness from contaminated food.

Source: (FDA,2019)

Notify Management

- The last sentence in the text from earlier is the most important: **“Personnel must be instructed to report such health conditions to their supervisors.”**
- Ultimately we all have personal stake in this and will naturally try to choose the best decision for everyone. But it is very important to notify your supervisor. Elevating to a manger helps to not only ensure the right decisions will be made for your personal work status, but also the health and safety of your coworkers and your customers.

First and Most Important…YOU…Part II

- Now that we covered our personal health and it's importance to food safety, we need to consider our work itself
- There are a number of subparts to this section (nine to be precise) and with good reason, there are a large number of ways we can introduce physical or biological hazards to food products. We will highlight main points of this section that specifically relevant to you.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

117.10 – Personnel (Cleanliness)

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

Cross contamination prevention is a critical task in many food processing facilities. Here are two prevalent examples:

- Raw vs. Cooked
- Allergen

Raw vs. Cooked Contamination

- To the right are cook time temperatures to produce safe prepared meat. In facilities where we are processing raw meat into cooked, ready to eat product these are critical. But why and what does this have to do with cross contamination?

Food	Type	Internal Temperature (°F)
Ground meat and meat mixtures	Beef, pork, veal, lamb	160
	Turkey, chicken	165
Fresh beef, veal, lamb	Steaks, roasts, chops **Rest time: 3 minutes**	145
Poultry	All Poultry (breasts, whole bird, legs, thighs, wings, ground poultry, giblets, and stuffing)	165
Pork and ham	Fresh pork, including fresh ham **Rest time: 3 minutes**	145
	Precooked ham (to reheat) **Note:** Reheat cooked hams packaged in USDA-inspected plants to 140°F	165

Source: (HHS, 2019)

Raw vs. Cooked Contamination

- Simply put, cooking is still the best way to kill pathogenic organisms in food.
- Reaching required temperatures ensures that if the bacteria is present (such as Salmonella in chicken or E. Coli in beef) that we can still deliver safe product.
- It is imperative that as we produce product, we do every thing we can to prevent even the tiniest traces of raw meat contacting product that will not be treated.

Source: (Stanley, 1998)

Allergen Contamination

- According to the FDA, over 160 foods can cause allergic reactions, however, the law only identifies the most eight common. Any ingredient that contains protein derived from one or more of them, are designated as “major food allergens'

- **Milk**
- **Eggs**
- **Fish (e.g., bass, flounder, cod)**
- **Crustacean shellfish (e.g., crab, lobster, shrimp)**
- **Tree nuts (e.g., almonds, walnuts, pecans)**
- **Peanuts**
- **Wheat**
- **Soybeans**

Source: (FDA, 2020)

Allergen Contamination

- IMPORTANT TO NOTE:

  Many food companies go well beyond the "standard" eight allergens listed on the previous slide. Please ensure you abide by your company's required allergen segregation program and not just what is shown in this presentation.

Source: (FDA, 2020)

Quick Allergic Reaction Facts

- If a person with food allergies consumes a food to which they are allergic, a life-threatening reaction called anaphylaxis can occur. The severity depends upon the person and the exposure amount, but each year it poses a significant problem in the United States.

- 30,000 emergency room visits
- 2,000 hospitalizations
- 150 deaths

Source: (FDA, 2020)

How Do We Keep Customers Safe?

- So how do we prevent this potential contamination and ensure the safety of our consumers? There are several subsections that can help us!

Before You Do Anything…

- First and foremost, we need to wash out hands before hitting the production floor every time.

(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.

Allergens: A Small Margin for Error

- While we may enjoy eating peanut butter on a break, an exposure of just 24 parts per million could potentially harm someone who is allergic.
- Consider if you had leftover remnants on your fingers. You then go back to the floor, skip washing your hands, and proceed to bag product that is ready to ship.
- Those remnants can easily transfer from your hands to your product.

Source: (Morisset et all, 2003)

Glove Care

- Well what if I wear gloves? We of course still need to treat our gloves in a very careful manner!

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

Glove Care

- Gloves may be standard PPE in your facility. That being said, we need to be extremely mindful as to where we have been and what we have done with our gloves.
- Additionally, we need to keep in mind the need to replace gloves if they become worn. The last thing a customer wants to experience is a piece of plastic in their food!

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

A Scenario to Ponder

- Consider this. You are working at your station when a coworker walks by letting you know break is in 15 minutes. As you turn back to your station you knock off some product that was left on your table. Being the responsible employee that you are, you grab a broom, sweep up and go back to work. Perfect example right?

A Scenario to Ponder

- Unfortunately not. While maintaining sanitary floor conditions is always a priority, so are you!
- Always remember to change your gloves and wash hands as frequently as needed. Even if it is only for a short period, touching non sanitary surfaces (such as a broom) can easily compromise the integrity of your product.

BREAK!

- Please take a 10 minute break at this point

Your Facility!

- We all take pride in where we work. We want it to look good, tidy and be presentable.
- Did you know that something as basic as that is actually a specific cGMP requirement?

(a) *Grounds.* The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

117.20 Plant and Grounds (Part A)

- While most of this section does not typically fall under your personal responsibility. There are numerous items that you can easily alert maintenance, janitorial, or your manager of if they occur to keep your customers safe.

Keep it Clean!

- It is most certainly a requirement to keep trash where it should be, in the trash! If you notice that the cleaning crew is falling behind in their rounds, please make sure you escalate.
- Additionally, if you see that the area around your facility is starting to look a little behind with lawn care, please escalate as well.
- Why are these items so important? PESTS.

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

Why are Pests a Threat?

- It is a pretty fair assumption that no one wants to work in an environment, let alone eat food from, an environment with pests. But why is it so important?
- We all know that rodents, flies and cockroaches have no place in our facility. But besides the fact that they are unpopular animals, they also can carry very dangerous pathogens such as Salmonella, Listeria and E. coli.
- If one of these pests made its way into ingredients, machinery, or finished product it would compromise the safety of our consumers.

Source: (National Pest Management Association,2020)

Outside the Facility

- Additionally, again consider outside your facility.
- While you may have the cleanest facility inside, if trash and waste is in the parking lot or grounds, or there are overgrown areas of the yard, you will face an extremely uphill battle to keep pests out from the outside
- Remember, only eat in authorized areas, place trash in proper receptacles, and always escalate issues if they arise

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

Another Scenario To Ponder

- You pull into the parking lot on a rainy day. The grass is trim and short, the parking lot spotless, not even a cigarette butt on the ground. You walk on the sidewalk towards the door. There's a small puddle forming that you step through as you walk into the door and are on your way to a productive day at work.

  Everything is as it should be correct?

Another Scenario To Ponder

- Unfortunately no it is not.
- Collecting/standing water poses a significant food safety threat and foot traffic through it can significantly spread filth and foodborne pathogens that go along with it.

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

(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.

Source: (FDA,2020)

Listeria: A Serious Threat

- Consider just one pathogen alone, *L. monocytogenes*
- It is naturally prevalent in the soil and water, can tolerate both acidic and salty conditions, and both high and low temperatures.
- In one particular case, it was found to persist more than 10 years in a food processing plant

Source: (FDA,2020)

Listeria: A Serious Threat

- If it is so prevalent naturally, its not that big of a deal right?
- Wrong. According to the FDA, hospitalization rate is 94%, out of annual 1600 cases.
- So remember, if you see something that is out of place, escalate! Even a simple item such as fixing a clogged drain could be the difference in keeping someone out of the hospital.

Source: (FDA,2020)

117.20 Plant and Grounds (Part B)

- We are going to now take this one step further and consider this. Does your facility or department have a design/layout that helps you keep your food safe?

- It may come as a surprise, but the design itself is part of cGMP adherence

(b) *Plant construction and design.* The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (*i.e.*, manufacturing, processing, packing, and holding). The plant must:

Your Facility's Layout

- We need to consider the need to lay out equipment allowing for ease of cleaning
- Ensure design prevents dripping or condensate from touching piping or fixtures.
- Provide adequate lighting
- Keep in mind potential for cross contamination in production:
  - Allergens
  - Raw vs. Cooked

117.35 Sanitary Operations

- We have discussed personnel and building/grounds, now an item many of you are familiar with: Operations
- This section covers multiple smaller items that we will categorize as following:

  -General maintenance
  -Pest control
  -Sanitation of food contact and non contact surfaces
  -Storage and handling of cleaned portable equipment and utensils

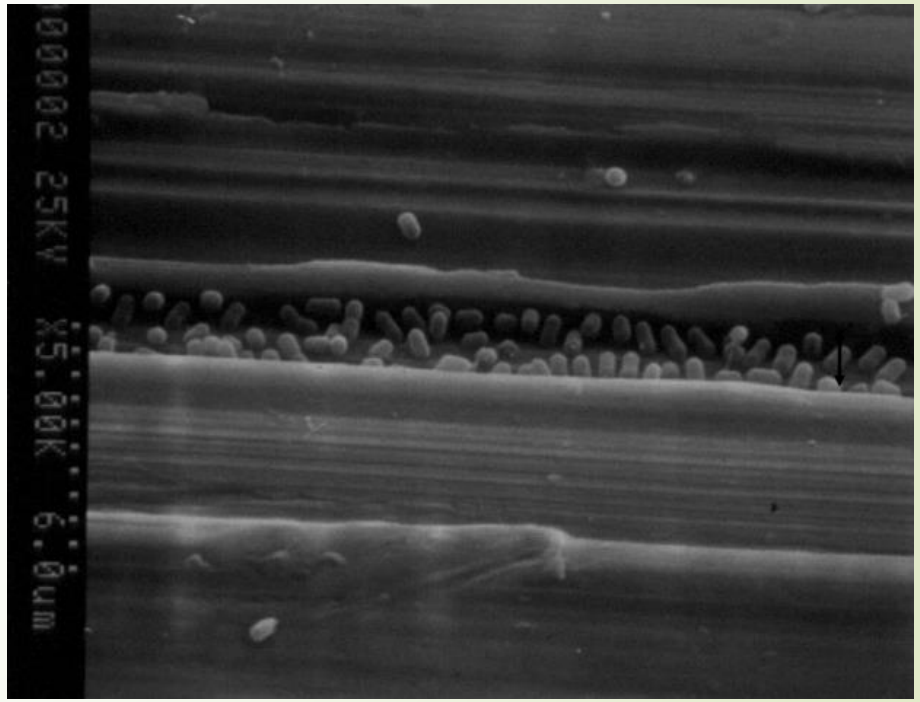
General Upkeep

- As previously mentioned, it is important to report any items that have fallen in disrepair or need attention
- Harborage points for bacteria can easily be created by a small hole in a wall or a pipe that drips leading to collecting water.

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

Attention to Detail Needed

- Even a small scratch on a piece of stainless steel can lead to potentially large risks. To the right is a picture of Listeria on such a scratch



Source: (Henderson,2017)

117.35 Sanitary Operations(Pest Control)

- As mentioned in previous slides 117.20 (Plants and Grounds) pests pose a various serious threat to food safety
- It is a requirement (as stated below) that we take active measures to exclude pests from the facility. Make sure to always report any sightings to do your part

(c) *Pest control.* Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting 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 must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

117.35 Sanitary Operations (Food contact Surfaces)

- When it comes to the surfaces actually touching product, be it a utensil or part of the processing line, it is required we take an active role in ensuring cleanliness.
- As previously mentioned, cross contamination poses a serious threat to the safety of customers. Even when they are not being used, they should be kept sanitary.

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

(f) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

Quick Cleaning Info

- Use the correct temperature when using cleaning solutions, per manufacturing instructions. General temperatures below.

General Guidelines for the Effective Use of Chlorine, Iodine, and Quats

	Chlorine		Iodine	Quats
Water temperature	≥100°F (38°C)	≥75°F (24°C)	68°F (20°C)	75°F (24°C)
Water pH	≤10	≤8	≤5 or as per manufacturer's recommendation	As per manufacturer's recommendation
Water hardness	As per manufacturer's recommendation		As per manufacturer's recommendation	≤500 ppm or as per manufacturer's recommendation
Sanitizer concentration	50–99 ppm	50–99 ppm	12.5–25 ppm	As per manufacturer's recommendation
Sanitizer contact time	≥7 sec	≥7 sec	≥30 sec	≥30 sec

Source: (Educational Foundation (National Restaurant Association),2018)

Your Safety Is Always First

- Depending upon the product your facility makes, your cleaning process may involve a large variety of cleaning agents.
- It is extremely important for your safety as well as the safety as others that they remain properly labeled and identified.

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

Why is Labeling Important?

- Depending upon what cleaning agents are being used, the concentration necessary might vary dramatically and mixing may pose severe risks. For your safety, your coworkers safety, and your customers safety, make sure you are educated prior to using cleaning agents.

- Warning workers not to mix cleaning products that contain bleach and ammonia;
- Making sure that workers know which cleaning chemicals must be diluted and how to correctly dilute the cleaners they are using;
- Thoroughly reviewing and training workers on the use, storage and emergency spill procedures for cleaning chemicals;

Source: (OSHA, 2012)

Food Contact Surfaces- Wet Cleaning

- Wet processing poses its own special circumstances and due to this, the cGMP's outline specific guidance for it which is shown below.
- But why?

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

WATER!

- According to the FDA, most foods have a water activity above 0.95 and that will provide sufficient moisture to support the growth of bacteria, yeasts, and mold
- So if we consider that the process is inherently wet, it is of course at a much higher risk for potential bacterial growth and therefore food safety risk

Source: (FDA,1984)

117.35 Sanitary Operations (Non Food contact Surfaces)

- If the product is not directly touching a surface it is not as much a worry right? Not so, unfortunately
- Regardless of whether the product directly touches a surface or not, the risk of cross contamination is very possible.

(e) *Sanitation of non-food-contact surfaces.* Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

Yet Another Scenario

- Let's consider this scenario. You are working on a blend stand mixing a batch of product. After you finish dumping one set of ingredients, you throw away your pair of disposable gloves in the proper waste bin and document lot numbers for your ingredients on a nearby table. You then wash your hands, put on a fresh pair of gloves, sanitize them and go back to work.
- An excellent example of food safety right?

Yet Another Scenario

- Absolutely! **You** did do everything right.
- However, lets consider that table you wrote your documentation on. When you are completing your paperwork, your sleeves are on the table. Those sleeves could then possibly touch product as you go back to dumping product.
- Remember the slide previously about a tiny scratch in stainless steel holding listeria. If the table isn't cleaned on a regular basis, that could very easily be present and introduced into product

117.37 Sanitary Facilities and Controls

- We have gone over numerous items that are not directly tied to the production work itself and this topic also continues the theme of every action impacting food safety.
- This subsection specifically states each plant must be equipped with adequate sanitary facilities and accommodations including: Water Supply, Plumbing, Sewage disposal, Handwashing and rubbish/offal disposal.
- While some of these items may surprise you, they all impact the safety of our product.

Your Water Supply

- We have mentioned water numerous times throughout this presentation. It is crucial to cleanliness, but also can harbor numerous risks to food safety.

(a) *Water supply.* The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must 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.

Water: A Potential Pathogen Reservoir

- While cleaning, it is crucial to only use water that is safe and sanitary. To the right is a list of commonly recognized waterborne infections that can be transferred to food

- Norovirus Infection (aka Norwalk virus, calicivirus, viral gastroenteritis)
- Shigellosis (Shigella)
- Giardiasis (Giardia)
- Escherichia coli O157:H7 Infection (E. coli O157) and Hemolytic Uremic Syndrome (HUS)
- Cyclosporiasis (Cyclospora spp.)
- Salmonellosis (Salmonella)

Source: (Minnesota Department Of Health,2019)

Be Mindful of Your Water Source

- So what can you personally do to prevent this?
- Only use water that is designated for production use, not all hoses are necessarily intended for use on food contact surfaces and may not undergo necessary filtration.
- If you are unsure of a source, please make sure to alert leadership

Source: (CDC, 2009)

117.37 Sanitary Facilities and Controls (Plumbing)

- While you are going through your normal work day focusing on food safety, you may put your focus to your actions on the production floor, however, a huge impact can come from items far away form there: the restroom and plumbing.

(b) *Plumbing.* Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(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.

(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.

(c) *Sewage disposal.* Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

Restrooms and Food Safety

- It is an absolute necessity that your site has properly functioning plumbing to ensure human waste and wastewater is properly removed.
- First and foremost, feces are common reservoirs for foodborne pathogens. *E. coli,* Norovirus, *Salmonella, Hepatitis A, Shigella* are all food pathogens found in feces of those infected.
- Not only do we need to ensure that toilets function but also that the restrooms are being properly maintained to ensure fecal matter does not potentially transfer to any surface.
- If you see any deficiency in your facility's restroom alert the responsible party immediately to ensure it is addressed.

Source: (HHS, 2019)

Pooling Water and Drain Issues

- As previously mentioned earlier in the presentation, prevention of pooling water is crucial as well.
- In the course of your daily tasks, immediately notify responsible parties of drains or sinks that may be backed up or not able to properly carry away wastewater.
- For example, Listeria monocytogenes is very prevalent in drains. A simple small backup while performing a washdown could lead to a pathogen that was once confined to a small location being spread through an entire facility if only a few people walk through the pooling water

Source: (Appels & Kooijmans, 2017)

A Familiar Topic

- Now for an item we should all be very familiar with: Handwashing

(e) *Hand-washing facilities.* Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

Wash your Hands!

- It is absolutely critical that your facility provides you with the necessary access to proper handwashing. The CDC puts it simply and best:

  "Improving food worker handwashing practices is critical to preventing outbreaks of diseases like norovirus, *Campylobacter*, *Salmonella*, and *E. coli*."

Source: (CDC,2020)

How to Wash Your Hands

- We have previously mentioned that feces are a reservoir of food pathogens. Proper hand washing is a critical way to ensure the spread of these pathogens is contained.
- Your facility should provide you with the ability to follow the proper steps of handwashing, listed to the right

1. **Wet** your hands with clean, running water (warm or cold), turn off the tap and apply soap.
2. **Lather** your hands by rubbing them together with the soap. Be sure to lather the backs of your hands, between your fingers and under your nails.
3. **Scrub** your hands for at least 20 seconds. Need a timer? Hum the "Happy Birthday" song from beginning to end twice.
4. **Rinse** your hands well under clean, running water.
5. **Dry** your hands using a clean towel.

Source: (CDC,2020)

Handwashing Facts

- Outside the food production world, there are undeniable results from simply educating the population.

According to the CDC, handwashing education in the community:

- Reduces the number of people who get sick with diarrhea by 23-40%
- Reduces diarrheal illness in people with weakened immune systems by 58%
- Reduces respiratory illnesses, like colds, in the general population by 16-21%
- Reduces absenteeism due to gastrointestinal illness in schoolchildren by 29-57%

Source: (CDC,2020)

BREAK!

- Please take a 10 minute break at this point

117.40 Equipment and Utensils

- We have covered yourselves, surfaces, and your building. Now to cover something else you use every day and that is crucial to a safe product: your equipment and utensils.

(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

Cross Contamination Prevention

- If you are using equipment or a utensil for the production, processing or holding of food it must be able to be cleaned to prevent cross contamination.
- Remember our example of the scratch in the table housing Listeria? Now think of the potential for harm if we processed product through a piece of equipment where it contacted that bacteria consistently. It is critical that all parts are able to be cleaned thoroughly to meet food safety requirements. If you notice that a piece of equipment or utensil consistently is accumulating product or contamination, make sure to make someone aware.

Cross Contamination

- This is also something to consider for storage as well. If an item is cleaned but not properly stored, it provides just as much potential for harm. Remember, with allergens it is literally parts per million worth of contamination that can be the difference between life or death.

Possible sources of cross contamination with foods

During food processing:
• Shared manufacturing and packaging lines • When food is transported • When food is stored
During point of purchase:
• Food sold in bulk cases where shared utensils are used to hand out (e.g. bay-maries) • Deli foods
During food preparation:
• Shared use of any equipment/machinery without proper cleaning (e.g. knvies, blenders, cutting boards, frying pans, barbeques, deep fryers etc) • Food service (kitchen/waiter) staff not changing gloves when preparing an allergen-free meal
Due to where foods are placed:
• When different foods are stored near each other there is a higher risk of cross contamination/mixing (e.g. buffets, juice bars, pick'n'mix shops).

Source: (Queensland Government,2017)

Your Equipment Itself

- Last, consider what the items you are using to process product are made of themselves. If you notice that they are not food grade or up to the task you are using them for, reconsider and escalate to someone who can assist in getting you the proper tools.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

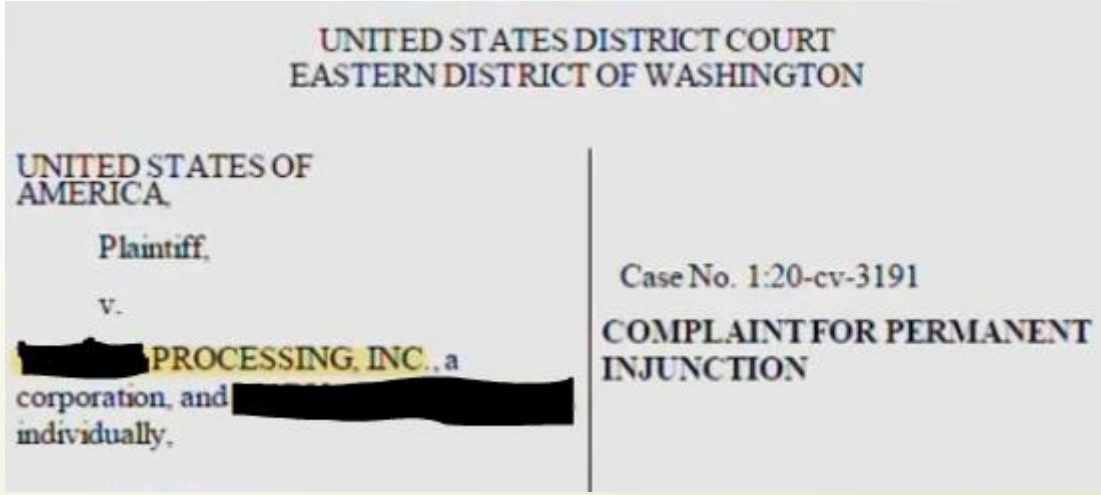
(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

117.80 Processes and Controls

- Congrats! We are at the last section we will cover.
- While we have gone over numerous scenarios regarding operations, this section is specifically dedicated to those sanitary principles that guide our food manufacturing

Your Ingredients

- Logically, first is the material that makes up our product itself.
- It is the moral and legal responsibility of food manufacturers to ensure that they use ingredients from reputable sources.
- For example in November 2020, a juice producer in Washington state was sued by the federal government for their failure to ensure their raw materials used in their product were safe. Specifically, they cited spoiled fruit being used in their product, in some cases even with mold noticeably growing on it.



UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA,

Plaintiff,

v.

[redacted] PROCESSING, INC., a corporation, and [redacted] individually,

Case No. 1:20-cv-3191

COMPLAINT FOR PERMANENT INJUNCTION

Source: (Goodell,2020)

Your Ingredients

- This unfortunate incident is a perfect example of a failure to follow the exact text of cGMPs (listed below).
- The spoiled fruit can be a host of a myriad of microorganisms (2) and the mold growing on the product could potentially lead to toxins (3)

(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

Source: (Goodell,2020)

Potential Reservoirs For Bacteria

- Here are a few examples of potential hosts for dangerous bacteria

Foodborne Illnesses (Bacterial)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods
Campylobacter jejuni	2–5 days	Diarrhea, cramps, fever, and vomiting; diarrhea may be bloody.	2–10 days	Raw and undercooked poultry, unpasturized milk, contaminated water.
Bacillus anthracis	2 days to weeks	Nausea, vomiting, malaise, bloody diarrhea, acute	Weeks	Insufficiently cooked contaminated meat.
Enterohemorrhagic *E. coli* (EHEC) including *E. coli* O157:H7 and other Shiga toxin-producing *E. coli* (STEC)	1–8 days	Severe diarrhea that is often bloody, abdominal pain and vomiting. Usually, little or no fever is present. More common in children <4 years.	5–10 days	Undercooked beef especially hamburger, unpasteurized milk and juice, raw fruits and vegetables (eg. sprouts), salami (rarely), and contaminated water.

Source: (CDC,2004)

Potential Reservoirs For Bacteria

- A lot of bacteria with some scary illnesses right?

Foodborne Illnesses (Bacterial)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods
Listeria monocytogenes	9–48 hrs for gastrointestinal symptoms, 2–6 weeks for invasive disease	Fever, muscle aches, and nausea or diarrhea. Pregnant women may have mild flu-like illness, and infection can lead to premature delivery or stillbirth. Elderly or immunocompromised patients may have bacteremia or meningitis.	Variable	Fresh soft cheeses, unpasteurized milk, inadequately pasteurized milk, ready-to-eat deli meats, hot dogs.
	At birth and infancy	Infants infected from mother at risk for sepsis or meningitis.		
Salmonella spp.	1–3 days	Diarrhea, fever, abdominal cramps, vomiting. *S.* Typhi and *S.* Paratyphi produce typhoid with insidious onset characterized by fever, headache, constipation, malaise, chills, and myalgia; diarrhea is uncommon, and vomiting is not usually severe.	4–7 days	Contaminated eggs, poultry, unpasteurized milk or juice, cheese, contaminated raw fruits and vegetables (alfalfa sprouts, melons). *S.* Typhi epidemics are often related to fecal contamination of water supplies or street-vended foods.
Shigella spp.	24–48 hrs	Abdominal cramps, fever, and diarrhea. Stools may contain blood and mucus.	4–7 days	Food or water contaminated with human fecal material. Usually person-to-person spread, fecal–oral transmission. Ready-to-eat foods touched by infected food workers, eg, raw vegetables, salads, sandwiches.

Source: (CDC,2004)

Please Remember

- The point to take home, is that it is crucial to inspect ingredients we use and make sure they are properly kept at the right temperatures and as well as cleaned prior to use if needed. If something does not look right, escalate immediately!

(b) *Raw materials and other ingredients.* (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

A Consistent Topic: Cross Contamination

- By this point every one should be very familiar with the concept of cross contamination. It certainly is applied here as well! It is crucial to keep incoming ingredients separate from those that have been processed and to make sure we do not potentially contaminate: be it with allergens, other ingredients, product or other adulterants!

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

(6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

Product Integrity

- Now to the production of the product itself
- Every step needs to be taken to make sure that the ability of foodborne pathogens to grow is reduced, be it eliminating cross contamination, cleaning etc.
- You will see in section 3 a reference to temperatures for holding to prevent food adulteration. What is a safe temperature and why is it safe?

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

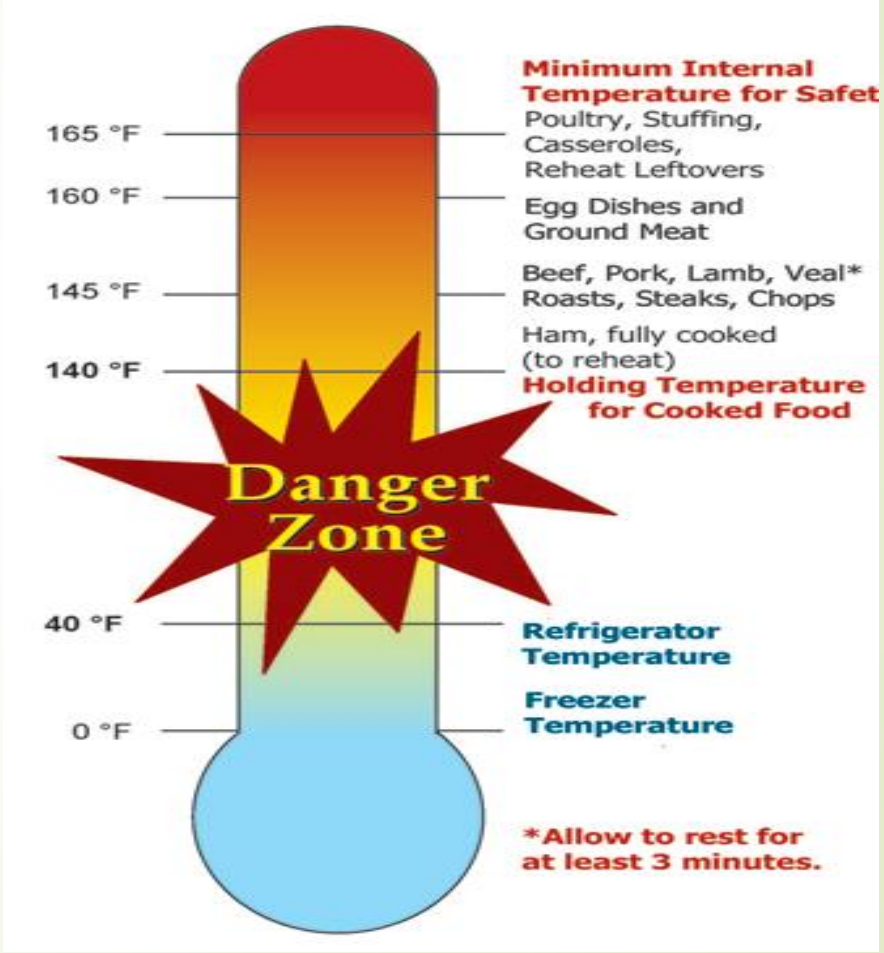
THE DANGER ZONE

- Depending upon the product your facility produces, temperature control might be absolutely critical to the safety of your customers.
- Certain product being at room temperature can cause bacteria to grow to dangerous levels that can cause illness
- So what are the temperatures for this zone?

Source: (USDA,2017)

THE DANGER ZONE

- Bacteria can experience growth rapidly in between 40 °F and 140°F, and double in as little as 20 minutes!



Source: (USDA, 2017)

How to Stay Out of the Danger Zone

- First and foremost, keep items cold—at or below 40 °F. Place food in containers on ice if not in refrigerated areas.
- Try to keep in mind how long you have had product out of normal work flow. Avoid leaving items out when you go to break.
- Stay observant and speak up! If you feel your department is a little warmer than usual that can have a big impact on bacterial growth, notify those responsible

Source: (USDA, 2017)

A Real Life Scenario

- Cross contamination has been on more slides than any other topic but it is literally a matter of life and death.
- Here is a recent example that perfectly illustrates the importance:

  Between May 16 and June 14, 2019, nine confirmed outbreak cases of listeriosis were identified in England. Seven patients died from National Health Service (NHS) Trusts.
- Listeria monocytogenes from unopened packs of cooked meats was detected by an external laboratory through routine testing. An isolate from this was confirmed as the outbreak. One of the last confirmed patients consumed a cheese sandwich, which was produced by the supplier.
- But wait a second. A cheese sandwich is just that, a cheese sandwich. How does a bacteria from meat end up where there is none?

Source: (Whitworth,2020)

Answer: **CROSS CONTAMINATION**

- Findings showed failures at the sandwich manufactures site in following proper cleaning procedures to prevent cross contamination.
- It may seem unnecessary at times, but cleaning a slicer between using cheese and meat could have at least saved the life of one individual in this case, if not more.
- These routine cleanings between products, ingredients or batches help reduce risk and prevent outbreaks from becoming even larger. Remember to follow your company's policy when it comes to cleaning procedure.

Source: (Whitworth,2020)

Ingredient Segregation

- Keeping different ingredients separated and away from anything that may be used in another process when processing is also critical.
- Remember the small amounts it takes for allergens to potentially harm? If all of an ingredient/packaging is not being used and will ultimately be returned to storage its critical it is not contaminated.

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

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

Physical Contaminants

- When we consume a food product, we expect it to be exactly that, food.
- Unfortunately, if a process is not adequately controlled, what is referred to as physical contaminants or extraneous material can be introduced.
- Common examples of physical contaminants in food include: hair, fingernails, bandages, jewelry, broken glass, staples, plastic wrap, packaging, dirt, pests/pest dropping

(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

Source: (Canadian Institute of Food Safety,2019)

Prevention

- So how do we prevent physical contamination?
- Keep jewelry to a minimum. A plain wedding band is often the extent of all that is allowed in a processing operation.
- Use of hairnets and beard nets
- Wear brightly colored bandages (preferably metal detectable) that can be easily seen if they fall off.
- Ensure all at risk product properly passed metal detector inspection
- Establishment and adherence to a pest control program, some of which was detailed earlier.

Source: (Canadian Institute of Food Safety,2019)

KNOWLEDGE CHECK

CONGRATULATIONS! This ends the presentation portion. Take a time to review your notes and we will now begin a knowledge check to ensure your understanding

KNOWLEDGE CHECK

TRUE OR FALSE:

While it is possible for food to become contaminated from other sources, it is not possible for it to be directly contaminated by sick personnel.

KNOWLEDGE CHECK

FALSE

If you are sick you can directly transmit it to food. Hepatitis A and Norovirus are two very common viral illnesses that can be transmitted. If you are feeling ill, do not come to work and do your part to notify workplace management.

KNOWLEDGE CHECK

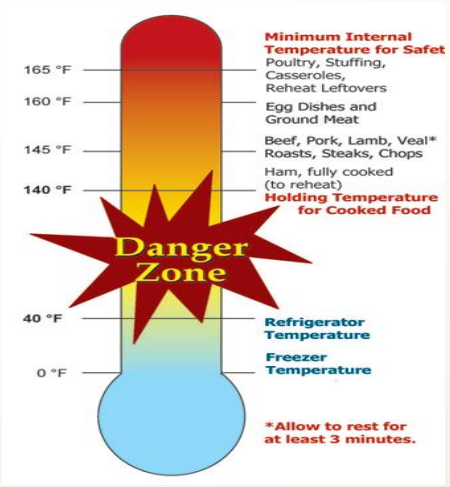
At which of the following temperatures is it acceptable to store raw poultry?

A. 45 F
B. 34 F
C. 55 F
D. 100 F

KNOWLEDGE CHECK

ANSWER: B. 34 F

Remember, always avoid the temperature danger zone.



KNOWLEDGE CHECK

Which of the following is a food safety concern and should be escalated to those responsible?

A. Overgrown shrubs against the facility
B. A spot on the production floor where water pools
C. A sewage back up in the bathroom
D. All of the above

KNOWLEDGE CHECK

ANSWER: D. ALL OF THE ABOVE

Every issue listed is a food safety concern that can lead to pest or bacteria being introduced to the production environment.

KNOWLEDGE CHECK

Which of the following actions would require you to change gloves?

A. Handling of allergens
B. Switching from raw to cooked meat products
C. Throwing away the trash
D. All of the above

KNOWLEDGE CHECK

ANSWER: D. ALL OF THE ABOVE

Every action listed would require a glove change. The key to food safety is to eliminate as much cross contamination as possible.

KNOWLEDGE CHECK

You are going to the production floor where you will be putting on gloves. Do you still need to wash your hands?

A. Yes
B. No

KNOWLEDGE CHECK

ANSWER: YES

It is absolutely critical that you wash your hands every time you hit the production floor to minimize microbial contamination.

KNOWLEDGE CHECK

How long is it necessary to scrub your hands in the process of washing?

A. It is not required
B. 5 seconds
C. 15 seconds
D. 20 seconds

KNOWLEDGE CHECK

ANSWER: D. 20 SECONDS

The longer you scrub the better, however, 20 seconds meets minimal requirements. The act of scrubbing helps remove bacteria especially in harder to access areas such as under finger nails.

KNOWLEDGE CHECK

What is the lowest amount of peanut butter listed that could affect someone who is allergic?

A. 1 gram
B. 240 parts per million
C. 100 parts per million
D. 24 parts per million

KNOWLEDGE CHECK

ANSWER: D. 24 parts per million

However, ideally we want to achieve zero residual allergens. Allergen sensitivities can vary greatly, the safest amount is none.

KNOWLEDGE CHECK

Why do we want to prevent the introduction of pests to a food production facility?

A. They are gross
B. People don't like them
C. They can carry very dangerous pathogens such as Salmonella, Listeria and E. coli
D. They aren't on the ingredients list

KNOWLEDGE CHECK

ANSWER: C. They can carry very dangerous pathogens such as Salmonella, Listeria and E. coli

While the other items may be true, pests can carry very dangerous illnesses like the ones previously mentioned. That is why it is critical to report any sightings to the appropriate personnel.

KNOWLEDGE CHECK

TRUE OR FALSE:

While it is important that we clean surfaces that touch food product, non food contact surfaces do not need to be cleaned.

KNOWLEDGE CHECK

FALSE

If non food contact surfaces are dirty and harboring foodborne pathogens, they can easily spread to clean food contact surfaces through cross contamination.