

Food Safety Plans for Retail Juice and Cider Processors

.....Step by Step



6

A Workbook to Guide You
Through the Planning
Process

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- University of Connecticut
Cooperative Extension System
- Connecticut Department of
Consumer Protection

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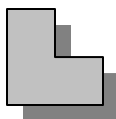
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.....Step by Step

Forward

The Connecticut State Department of Consumer Protection and the University of Connecticut Cooperative Extension System have been working together to bring you the latest information about how to make sure that the cider and juice you produce is as safe as it can be.

Retailers of juice are those who sell directly to the consumer at their own farm stand, a farmer's market or online. Retailers do not need to adopt a HACCP plan and have the option to treat or not to treat their cider to achieve the 5 log reduction of *E. coli* O157:H7 or *cryptosporidium parvum*. (Those who do not achieve a 5 log reduction, i.e., those who sell unpasteurized juice, must have a warning label on the bottle.)

Does this mean that retailers do not have to follow rules and regulations to make their cider safer? No. Cider processors must still comply with certain federal, state and local rules and regulations. Keep in mind that an outbreak of foodborne illness attributed to a retail operation will have a negative impact on all of the cider industry, as well as devastating effects on the processor's operation.

To help retail processors of juice to produce safe cider, we have developed this workbook. The workbook takes the retailer step-by-step through the development of what we call a Food Safety Plan. While much simpler than a HACCP plan, a Food Safety Plan will help you to focus on the steps in your operation that need special attention. It is likely that you are already using many food safety practices in your operation. Formalizing these practices and writing them down as a Food Safety Plan will indicate to regulators and consumers alike that you are committed to producing a safe juice product.

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INTRODUCTION

Food safety is a concern for anyone in the food business. If the juice you produce makes a customer sick, there will be health, legal, and economic consequences for you, your customers, and others in the industry.

While once considered an unlikely cause of foodborne illness, juice related outbreaks in the 1990s alerted processors, regulators and consumers to the fact that fresh juice (especially if unpasteurized) needed a closer look. As a result of these outbreaks and the increased concern about the safety of fresh juice products, the U.S. Food and Drug Administration (FDA) passed the Juice HACCP rule in 2001. This rule requires all juice processors, other than those only selling retail from their farm stand or farmers market, to implement a plan for **Hazard Analysis Critical Control Point or “HACCP.”**

Retailers (juice processors that sell their juice only directly to the public—at a farm store, roadside stand, farmer’s market or on the internet) are **not required** to develop a HACCP plans under federal law, but that does not mean that they shouldn’t seriously consider writing a HACCP plan or at the least, adopt some type of **food safety plan** to help them focus on the safe handling of their product.

Retail operations are usually regulated by state agencies applying state regulations often based upon **FDA’s Model Food Code**, a guidance document that describes appropriate controls that can be applied to reduce juice hazards at the retail level. FDA does require that packaged juice products produced by retail establishments either undergo a treatment designed to ensure an effective 5-log pathogen reduction, (just as juice subject to the HACCP regulation must undergo) or bear a warning label that explains that the juice has not been treated to ensure its safety and that it may contain harmful bacteria that can cause serious illness, especially in children, the elderly and persons with weakened immune systems. Juice not sold in packaged form, such as juice served by the glass at restaurants and juice bars, is not subject to either the HACCP regulation or to the warning label requirement.

Retail juice safety words to know:

- **FDA’s Model Food Code** is a guidance document used by states to develop food safety regulations for retail food operations. You may find information about the Model Food Code at:
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>.
- **Juice Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice** is the US FDA regulation requiring a HACCP plan and implementation for processors of juice (except those who retail juice only). A copy may be found at:
<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006803.htm>.
- **The 5-log reduction** performance standard required by the HACCP regulation means that you must treat your juice (or citrus fruit if using surface treatments) using a process that will achieve at least a 100,000 fold decrease in the number of microorganisms. Juice processors must apply controls (e.g., heat) to achieve the 5-log reduction required by the regulation.

Because retailers do not need to comply with the FDA Juice HACCP rule, and because retailers are still able by regulation to produce unpasteurized fresh juice, it could be argued that juice produced by retailers is more “risky.” If an outbreak should occur that is attributed to a retail producer, it could have a negative impact on all producers of fresh juice and cider.



This workbook is one tool to use when putting together your food safety plan. It provides you with basic information about what you need to include in your plan; how to work through it; how to develop a program that meets the needs of your operation; and how to meet the needs of the regulators that oversee your operation. After each step is described, there are activities or worksheets for you to complete. If you complete the activities or worksheets as you go along, you will have a food safety plan developed by the time you get to the end of the workbook.

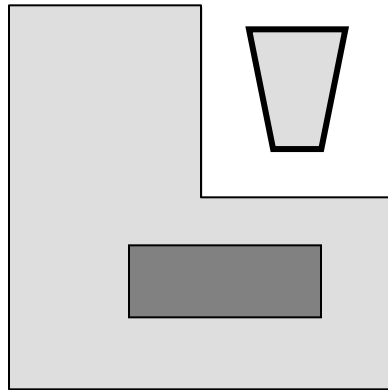
Your food safety plan

Because juice and cider are produced from raw agricultural products, the safety of your final product will depend on how the fruit and juice are handled from time the fruit is in the field or orchard to the time it is purchased by the consumer, especially, if you do not plan to pasteurize your product or treat it with UV light. So, it is important to include the following components in your food safety plan:

- Step 1: Follow Good Agricultural Practices (GAPs)
- Step 2: Follow Good Manufacturing Practices (GMPs)
- Step 3: Develop and Follow A Sanitation Plan
- Step 4: Monitor Key Food Safety Focus Points
- Step 5: Develop a Traceback Plan
- Step 6: Keep Good Records



Food Safety Hazards in Juice and Cider





FOOD SAFETY HAZARDS IN JUICE AND CIDER

History of Foodborne illness and Juice:

Until recently, the fresh fruit and vegetable industries have been relatively untouched by the threat of their products causing foodborne illness. However, in the last 5-8 years there have been several incidents that have involved fruits and vegetables that were up until now considered at low risk for causing foodborne illness. Salmonella has been associated with cantaloupe, *Escherichia coli* O157: H7 with lettuce, and *cyclospora* with raspberries.

Fresh juice-related outbreaks have included cider/apple juice outbreaks occurring in Oklahoma (*E. coli* O157:H7) in 1999, California (*E. coli* O157:H7), Connecticut (*E. coli* O157:H7), and New York (*Cryptosporidia*) in 1996 and in Massachusetts (*E. coli* O157:H7) in 1991 and New Jersey (*Salmonella*).

In addition, orange juice outbreaks have occurred in 1992 (India), 1995 (Florida), 1999 (Australia and U.S.-made in Arizona), 2000 (California). Outbreaks have also been attributed to carrot juice, watermelon juice, mamey juice, lemonade and grapefruit juice. The primary organisms involved in these outbreaks were *Salmonella* and *E. coli* O157:H7.

Foodborne illness

Foodborne illness is caused primarily by microorganisms. Microorganisms that cause disease are found naturally in the environment. Juice contaminated with pathogenic microorganisms usually does not look bad, taste bad, or smell bad. It is impossible to determine whether juice is contaminated with pathogenic (disease causing) microorganisms without microbiological testing. To avoid potential problems it is important to control or eliminate these microorganisms during processing.

Spoilage vs. Contamination (not all microorganisms cause foodborne illness)

It is important to remember that not all biological, physical, and chemical hazards will cause foodborne illness. Some of these hazards are going to spoil the quality of the product, but not affect the safety. They are not pathogenic or disease causing. Examples include:

- bacteria that cause slime formation
- bacteria or yeasts that cause fermentation in fruit juices
- a hair in canned juice (that has been thermally processed)

Pathogenic microorganisms can be transmitted to humans by a number of routes, including air, water, direct person-to person contact and food. Some pathogenic microorganisms can be transmitted to food by animals, or by contact with the soil, or by contact with contaminated surfaces and equipment.

The severity of the foodborne illness depends on the pathogenic microorganism or toxin ingested, the amount of the microorganism or toxin consumed (dose), and the health status of the individual. For individuals who have immunocompromised health conditions (those being treated for cancer or HIV, or who have had organ transplants), or for the aged, children, or pregnant women, foodborne illness may be life-threatening.



Three Types of Food Safety Hazards that affect apple cider

I. Biological Food Safety Hazards

▪ Bacteria

Bacteria are the number one cause of foodborne illness from juice. Foodborne disease causing bacteria cause illness when a consumer drinks juice/cider containing bacteria such as *E. coli* O157:H7 and the bacteria then grow and establish themselves in the human intestinal tract. Bacteria can be destroyed by heating (pasteurization) to a specific temperature for a specific length of time.

Bacteria may be brought into your operation on employees, on raw fruit, on trucks, equipment or boxes used to transport food. The best defense is to assume that bacteria are always there and to control the environment to prevent or minimize their growth and/or contamination.

How Bacteria Grow in Juice:

Bacteria do not survive and grow just anywhere---they need a favorable environment to thrive. Bacteria need moisture, a food source, enough time, and the right temperature and pH to grow and multiply.

Moisture. Bacteria need water to grow. Moisture requirements are different for each species of bacteria. If water is not available in a food product, the bacteria may remain but will not grow and multiply.

Water Activity (Aw) describes the availability of water in food. Most bacteria cannot grow at a water activity of less than 0.91. Juices have an Aw of .97, providing plenty of moisture to allow for the growth of microorganisms.

Food. Bacteria need a source of nutrients to grow and multiply. Carbohydrates provide the main source of energy. Fruit and vegetable juices are excellent sources of these nutrients.

Potentially Hazardous Foods

Potentially hazardous foods (PHF) support the growth of bacteria and are the foods most commonly associated with foodborne illness. Typically they are high in moisture, low in acid (neutral or higher pH), and contain carbohydrates and protein.

Potentially Hazardous Foods (PHF)
Meat, fish, poultry, eggs Dairy products including milk, cream, soft cheeses, ice cream, yogurt, sour cream Cooked rice, macaroni, noodles, cereals Cooked potatoes, vegetables Cut cantaloupe and other melons Garlic in oil mixtures Soy products such as tofu, miso Raw seed sprouts

Most food regulations do not list fresh fruits and vegetables and juices as potentially hazardous foods (except for sprouts and melon). However, recent foodborne illness outbreaks tied to fresh fruits and vegetables and juices challenge our previous notion of what makes a food Potentially Hazardous.



How Bacteria Grow in Juice, cont.

pH. The acidity or alkalinity of a food affects the ability of bacteria to survive and grow. pH is a measure of the acidity or alkalinity of a food. While most bacteria prefer a pH near neutral (pH = 7.0), the bacteria associated with foodborne illness from juice and cider have been known to grow in a pH of as low as 3.5 (acidic). The pH of most fruit juices falls between 2.3 and 3.5, while the pH of apple cider can range from around 3.4-4.0. The pH of tomato juice ranges from 4.1 – 4.2; carrot juice around 6.4; pineapple juice from 3.3-3.5; cranberry juice from 2.3-2.5; orange juice from 3.6-4.3 and lemon juice from 2.2-2.6.

Time. Under favorable conditions (enough moisture and food available with the desired temperature), the multiplication of bacteria by cell division may occur every 20-30 minutes.

Bacteria do not multiply at a constant rate. Figure 1 illustrates the growth curve for a bacteria. Initially the microbial cells grow in size rather than number. This is called the **lag phase**. The next phase is the **log phase** where cells multiply fast. The third phase is called the **stationary phase**. During this phase the number of bacterial cells produced equals the number of cells that are dying; the total number of bacteria remains the same. When the nutrients are depleted, the growth rate decreases. This is the **death phase**.

In a food processing environment, you want to keep the bacteria in the lag phase for as long as possible.

Temperature. Generally bacteria grow and multiply best within the temperature danger zone, 41°-140°F, though there are some bacteria, including *Listeria monocytogenes* that grow at refrigerator temperatures. Bacteria can survive freezing temperatures but cannot grow or multiply at these low temperatures

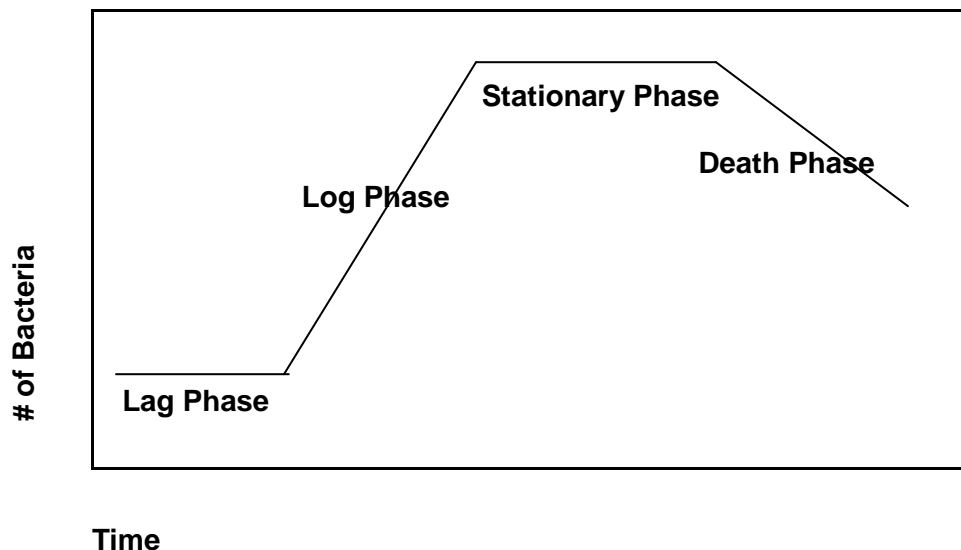


Figure 1. Bacterial growth curve

For foodborne microorganisms to be a potential source of illness from juice/cider, the following conditions must be present:

- The bacteria must be in the juice/cider.
- The bacteria must be able to grow in the juice/cider.
- The temperature must be right for the bacteria to grow and multiply-usually in the temperature danger zone of 41°F to 140°F.



- Enough time must be given for the bacteria to grow and multiply.
- The juice/cider must be consumed or the bacteria must contaminate a utensil, hand or other food that comes into contact with your mouth.
- **Viruses**
Viruses are composed of tiny genetic material (not live) that attach to cells in a live host (human or animal), take over the cell and destroy it. Examples include the Hepatitis A virus and the Norwalk virus.

Viruses use food as a means to move from one place to another. They can be destroyed by heat. Hepatitis A and Norwalk virus are resistant to extreme pH and stable at refrigeration and freezing. They also appear to be resistant to heat and radiation.

Viruses are spread from person to person (often an infected employee) by putting something in the mouth that has been contaminated with the stool of a person with hepatitis A. This type of transmission is called "fecal-oral." For this reason, the virus is more easily spread in areas where there are poor sanitary conditions or where good personal hygiene is not observed. Contaminated irrigation or drinking water may also be a source of viruses.

The most effective control for viruses is preventing contamination of food products in the first place. In other words irrigate crops with water that is not fecal contaminated and establish hygienic employee practices. Good personal hygiene, especially hand washing, and the use of gloves are effective in preventing the spread of viruses.

- **Parasites and Parasitic Protozoa**
Parasites are microorganisms that survive by living on or inside a host (human or animal). They can be found in raw animal foods, raw seafood, or fresh, raw fruits and vegetables. They may also be found in contaminated water. Parasites are transmitted by putting anything into your mouth that has touched the stool (feces) of an infected person or animal.

Heating will completely destroy parasites. Freezing for a specific period of time will also kill parasites. Cryptosporidium is a parasitic protozoa responsible for food safety problems in cider.



Fresh Juice Biological Hazards and Preventive Measures:

BIOLOGICAL HAZARD	POSSIBLE SOURCES	PREVENTIVE MEASURES
<i>E. Coli</i> O157:H7	Rodents, birds, animal feces, contaminated water (Implicated in outbreaks attributed to cider, orange juice)	Good Agricultural Practices (GAPs) , washing and brushing fruit, pasteurization, storage away from rodents, birds, animal feces, do not use drops
<i>Salmonella spp.</i>	Contaminated water, insects, soil, animal feces, infected humans, birds (Implicated in outbreaks attributed to grapefruit juice, watermelon juice, orange juice)	Good Agricultural Practices (GAPs) , washing and brushing fruit, pasteurization, storage away from rodents, birds, animal feces, do not use drops
<i>Listeria monocytogenes</i>	Animal feces, soil, silage	Washing and brushing fruit, pasteurization, storage away from rodents, birds, animal feces, do not use drops, keep production area dry, facility sanitation
<i>Shigella</i>	Contaminated water	Testing for water potability, changing water in wash tanks, chlorination of water in wash tanks, clean, sanitize wash tanks, sluices, pasteurization
<i>Giardia</i>	Contaminated water	Testing for water potability, changing water in wash tanks, chlorination of water in wash tanks, clean, sanitize wash tanks, sluices, pasteurization
<i>Cryptosporidia</i>	Contaminated water (implicated in outbreaks attributed to cider)	Testing for water potability, changing water in wash tanks, chlorination of water in wash tanks, clean, sanitize wash tanks, sluices, pasteurization
Hepatitis A	Employees	hand washing, gloves, personal hygiene, ill employees not at work, pasteurization
Norwalk virus	Employees	hand washing, gloves, personal hygiene, ill employees not at work, pasteurization



2. Chemical Hazards:

Chemical contaminants have the potential to cause foodborne illness or allergic reactions in consumers. Some may cause or promote certain cancers. These contaminants can be naturally present in foods or added to the food during production. Manufacturers must make sure that chemical compounds are used with strict adherence to any existing regulations and/or product specifications.

Chemical hazards can include:

- 1) Intentionally added chemicals
 - preservatives, acids, food additives, sulfiting agents, processing aids
- 2) Unintentionally added chemicals
 - agricultural chemicals: pesticides, herbicides, animal drugs, fertilizers
 - plant chemicals: cleaners, sanitizers, oils, lubricants, paints, pesticides
 - environmental contaminants: lead, cadmium, mercury, arsenic, PCBs
- 3) Naturally occurring chemical hazards
 - mycotoxins or toxins produced by mold, including patulin
 - allergens such as milk proteins (if cider is pasteurized in a dairy plant)

Patulin

Patulin is a mycotoxin that is produced by certain types of molds (*Penicillium*, *Aspergillus* and *Byssochyلامys*) that may grow on apples and pears. Though a direct connection has not been made to humans, patulin has been found to cause a range of health problems in laboratory animals including harm to fetuses (mutagenic), problems with the immune system and bleeding in the brain. There is concern that similar effects may occur in humans, which is why exposure should be kept as low as practically possible. Patulin is most likely to be a problem in apples or pears with bruises, rot or other surface damage. Patulin may be a more serious problem when using drops or apples that have been stored for a longer period of time.

FDA believes that control by processors of patulin levels to an action level of 50mg/kg or below can be achieved principally by inspecting and removing spoiled and/or visually damaged apples pears from the supply fruit used to make juice/cider. FDA **expects** that juice/cider makers **will** sort out rotten and /or damaged apples/pears as part of the cider making process. (In a HACCP plan, it is expected to be a critical control point.) A washer-brusher will also help remove the rot and soft spots that may contribute to patulin formation.

It also makes sense to test cider several times during the season for presence of patulin. This may be especially important if making cider late in the season with stored apples/pears. For more information on patulin, check out these web pages:

- ◆ USFDA CFSAN Office of Plant and Dairy Foods and Beverages, **Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice Products**, September, 2001.
<http://www.fda.gov/Food/FoodbornellnessContaminants/NaturalToxins/ucm212520.htm>
- ◆ USFDA Office of Regulatory Affairs Compliance References CPG-Chapter 5-Food, Colors and Cosmetics, Compliance Policy Guide, Compliance Policy Guidance for FDA Staff, CHAPTER - 5, SUB CHAPTER - 510 Sec. 510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin, October 2001.
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074427.htm>



Fresh Juice Chemical Hazards and Preventive Measures:

INTENTIONALLY-ADDED CHEMICAL HAZARDS	POSSIBLE SOURCES	PREVENTIVE MEASURES
Food chemicals	Preservatives, sulfiting agents, flavor enhancers, color additives, processing aids	Detailed specifications for the raw materials and ingredients; warranty or letter of guarantee from supplier; supplier audits; supplier HACCP plan; testing program, labeling
UNINTENTIONALLY-ADDED CHEMICAL HAZARDS	POSSIBLE SOURCES	PREVENTIVE MEASURES
Environmental contaminants	Lead, zinc, mercury, copper, tin	Check water supply safety; equipment specifications will prevent use of these materials; supplier agreements and letters of guarantee
“Plant” chemicals	Cleaners, sanitizers, paints, oils/lubricants	Identify and list all indirect additives possible; check that each chemical is approved; check that each chemical is properly used; record the use of any restricted chemicals; have written sanitation plan and SSOPs
Agricultural chemicals	Fertilizers, pesticides (insecticides, rodenticides, fungicides, herbicides)	Identify and list all indirect additives possible; supplier agreements and letters of guarantee; testing program.
NATURALLY OCCURRING CHEMICAL HAZARDS	POSSIBLE SOURCES	PREVENTIVE MEASURES
Allergens	Milk processing in a dairy plant that is also pasteurizing or processing juice.	Clean up of facility after milk processing and before juice processing or the use of separate facilities, labeling
Patulin	Moldy, rotten, bruised or otherwise damaged apples or pears—particularly those stored and used late in the season.	Culling/sorting apples/pears before they go into the press; testing program



3. Physical Hazards:

Physical hazards are defined as any materials, not normally found in a food, which can cause illness or injury to the consumer. These can include metal fragments, plastic, glass particles, and jewelry.

Some physical hazards may contribute to the loss of quality of the food product rather than a food safety problem. These hazards may be addressed by your sanitation program. For example: the presence of a small piece of rodent hair in a product to be cooked is not a food safety hazard. However, it will affect the quality and reputation of the product so the possibility of rodent hair contamination should be addressed with a standard operation procedure that prevents the occurrence.

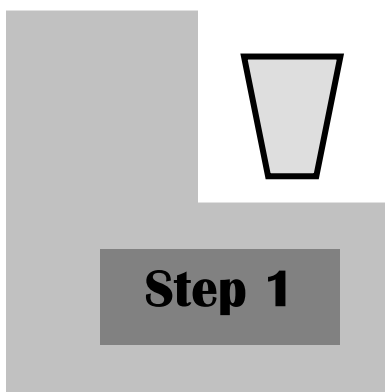
Fresh Juice Physical Hazards and Preventive Measures:

HAZARD	SOURCES	PREVENTION
Hair, gum, jewelry, pens	Employee carelessness	Employee education/training; Supervision
Metal fragments, screws, wire, bolts, blades	Equipment (grinder), raw materials	Magnets, metal detectors, frequent inspection of machinery, filters/screens
Glass	Glass containers, thermometers, light fixtures	Protected light fixtures, establish glass breakage procedures
Stones, gravel	Raw materials	Use of sifters, filters, traps
Plastic	Packaging materials	Suppliers HACCP plan, inspection of materials
Pests	Building, raw ingredients	Extermination, inspection, proper storage
Wood	Building, equipment, pallets	Inspect and maintain premises, eliminate equipment, wooden pallets

Generally, in the juice industry, regulators are most concerned about the presence of metal from the grinder. When developing a food safety plan, it makes sense to consider the integrity of the screens or fillers as a focus point for food safety.



Follow Good Agricultural Practices (GAP)





Step 1 Follow Good Agricultural Practices (GAP)

Disease-causing bacteria, viruses and parasites can be found on raw fruits and vegetables. Since 1987, the number of produce-associated outbreaks has doubled. *Salmonella* on tomatoes and cantaloupe, *E. coli* 0157:H7 on lettuce and in cider, hepatitis A on scallions, and *Cyclospora* on raspberries have raised concerns among regulators, the produce industry and consumers. This trend should concern produce farmers--small operations as well as large—it makes no difference.

Good Agricultural Practices are part of a voluntary food safety program developed by FDA and USDA for fruit and vegetable growers. The goal is to help reduce foodborne illness. The GAP program describes key steps that growers can use to help reduce or minimize contamination of produce by disease-causing organisms. This contamination can occur at any point during the food distribution system—from farm to table.

What is being done?

As part of a national initiative of research, education and outreach in the area of food safety control and prevention, a plan to ensure the safety of imported and domestic fruits and vegetables was announced in 1998. In response to this initiative, the FDA and USDA prepared a guidance document entitled "**Guide to Minimize Microbial Food Safety Hazards of Fresh Fruits and Vegetables**" which addresses Good Agricultural Practices (GAP) from growing/harvesting to transport of fresh (unprocessed) and minimally processed fruits and vegetables that are sold to consumers.

How can you minimize risk?

Soil, rainwater and surface water sources of irrigation water of course, are not sterile and are likely contaminated with microorganisms that cause illness. These microorganisms may also result from the addition of certain fertilizers and poor farm worker hygiene.

The "**Guide to Minimize.....**" outlines recommendations for practices that would minimize microbial contamination of produce and encourages growers (and packers and shippers) to take an active role in minimizing food safety hazards in fresh produce.

The guidelines focus on

- Sources and use of water
- Safe use of manure and biosolids
- Worker health and hygiene
- Availability of clean and working sanitary facilities
- Sanitation in the field (harvesting, irrigation, dealing with wildlife, etc.)
- Packing facility/barn sanitation
- Transportation of fresh produce

Is the "guide" a regulation?

The answer to this question is no. These are recommended practices which have been endorsed and/or adopted by the FDA, USDA and many producer associations. What does this mean to you? It means that the standard way of doing business could, ultimately, be to follow all recommendations in the guide, where applicable. Your customers may want to know if you adhere to the GAP. This could be important to business.



GAP PROGRAM GUIDELINES:

These program guidelines are based on the October 1998 document- *The Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* published by the Food and Drug Administration and USDA.

GAP words to know:

- **Clean** means that produce and food contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris.
- **Contamination** is the unintended presence of harmful substances or conditions in food that can cause illness or injury to people who eat the food.
- **Good Personal Hygiene Practices** are good health habits including bathing, washing hair, wearing clean clothing and shoes and proper hand washing. Also, you and your employees should not work with fresh produce when ill with symptoms including coughing, sneezing, diarrhea or uncovered wounds, lesions and boils.
- **Sanitary** means the food contact surface is clean and free of harmful microorganisms and other contaminants.

I. Water Sources for Irrigation and Drinkable Water (potable water)

- Wells are protected from outside contamination.
- Drinkable water supply and/or wells are tested at least once a year.
- Water source(s) used for washing produce are located the distance required by local/state regulations from the manure storage facility, livestock areas, pesticide storage area and septic system drainage field.
- Water used to clean and/or sanitize produce and for human consumption meets current EPA drinking water standards.
- Records of all water tests on file.
- Backflow prevention devices and/or air gaps are installed at appropriate locations to prevent cross-connections with the potable water supply.
- Good management practices are in place to protect the quality of irrigation water.
- Farm livestock access to ponds and streams used for irrigation is limited.

GAP words to know:

- **Air Gap** is an unobstructed open vertical distance through air that separates an outlet of the potable water supply from a potentially contaminated source like a drain.
- **Backflow** is flow of contaminated water into the potable water supply caused by backpressure.
- **Cross Connection** is any physical link through which contaminants from drains, sewers or waste pipes can enter a potable water supply.
- **EPA Drinking Water Standards** are standards for drinking water established by the EPA. These standards indicate that the water meets specific microbial standards.
- **Potable Water** refers to water that meets the EPA drinking water standards.



II. Good Manure/Bio-solids Management Practices

- Storage and treatment facilities located as far as practical and possible from growing and handling areas.
- Storage and treatment facilities include physical barriers that prevent leakage, run-off or wind spread.
- There is a manure treatment plan in place.
- ***Use of manure in any form during the growing season should be in accordance with USDA and/or state regulations.***
- Equipment that comes in contact with manure/bio-solids in any form is cleaned prior to and during harvest and/or transportation of fresh produce.
- Biosolids are applied in accordance with local regulations/processor instructions.

GAP words to know:

- **Biosolids** are the by-product of human waste treatment by local government that may be used as fertilizer or as a soil amendment. EPA regulations control their use as a soil conditioner because it may contain possible pathogens and heavy metals.
- **Compost** is organic residue, or a mixture of organic residues and soil that have been piled, moistened and allowed to undergo biological decomposition. Mineral fertilizers are sometimes added.
- **Manure** is animal feces not composted or incompletely composted. May contain pathogens like Salmonella and E. coli O15:H7.
- **Manure Slurry** is a mixture of manure and water.

III. In the Fields

- Worker Health and Hygiene
 - Worker food safety training is in place.
 - Workers and supervisors practice good personal hygiene which includes:
 1. Clean clothing, shoes and boots
 2. Daily bathing or showering
 3. No smoking or eating in work area
 4. Hair covered
 5. Wash hands as required
- Limit bare hand contact with fresh produce.
- Field workers have easy access to toilet and hand washing facilities.
- Supervisors are aware of the symptoms of foodborne illnesses.
- Sick employees are sent home or reassigned when appropriate to duties where there is no direct contact with produce or food contact surfaces.
- Sanitary Facilities
 - Toilet facilities and hand washing stations are clean and regularly serviced (soap, water, single use paper towels).
 - Portable toilets are maintained and transported in a manner that prevents wastewater from contaminating fields.
- Sanitation
 - Harvest storage containers are cleaned prior to use.
 - Clean containers are kept covered until used in the field.
 - Harvesting equipment is kept clean and in good working-order.
 - Harvested produce does not come in contact with manure/biosolids, nonpotable water, workers with poor hygiene and/or dirty boots and clothing, dirty packaging or storage containers.
 - Farm livestock, including poultry or pets, are restricted from fields or orchards where crops are grown and harvested.



GAP words to know:

- **Agricultural water** refers to water used in the growing environment including water used for irrigation, cooling, frost protection, or as a carrier for fertilizers and pesticides. Typical sources of agricultural water are rivers, streams, irrigation ditches, ponds, reservoirs, lakes, wells, and municipal supplies.
- **Good Management Practices** refer to general practices to reduce microbial food safety hazards. The term may include both "good agricultural practices" used in growing, harvesting, sorting, packing, and storage operations and "good manufacturing practices" used in sorting, packing, storage, and transportation operations.

IV. In the Packing/ Processing Facility (check with the local regulatory authority to determine if the facility must be licensed and meet regulatory standards).

- Worker Health and Hygiene
 - Worker food safety training in place.
 - Workers practice good personal hygiene
 1. Wear clean clothing and shoes/boots.
 2. Do not smoke or eat in work area.
 3. Hair is covered.
 4. Wash hands as required.
 5. Limit bare-hand contact with fresh produce.
 6. Open wounds covered with a clean bandage and single-use glove
 - Sick employees and those with uncovered open wounds, sores, etc. are sent home or, when appropriate, assigned to other duties having no direct contact with fresh produce or food contact surfaces.
- Sanitary Facilities
 - Restrooms are accessible and well serviced (cleaned regularly and well supplied with water, soap and paper towels)
- Sanitation
 - Approved sanitizers used to sanitize food contact surfaces.
 - Area and equipment **washed** and sanitized at least once a day. (Sanitizing alone is inadequate.)
 - Unused and new packing containers protected from contamination during storage.
 - Pest control system is in place.
 - Produce waste is removed daily.
 - Grounds are maintained in good condition.
- Temperature Control
 - Refrigeration storage units are maintained at the correct temperature.
 - Refrigeration units are not loaded beyond capacity.
 - Ice used for cooling is made of potable water.
- Storage of Harvested Crops
 - Storage areas are clean and free of contamination
 - Storage areas are used exclusively for food crops
 - Produce is stored at least six inches off the floor
- Washing Operations
 - Sanitizer level is monitored.
 - Wash water changed when dirty or after several hours and maintained at temperature of no more than 10 degrees cooler than the produce.
 - Packing lines, conveyer belts and all other food contact surfaces are washed, rinsed and sanitized at the end of the day.



GAP words to know:

- **Food-Contact Surfaces** are those surfaces that may come in contact with fresh produce. They include equipment, such as containers and conveyor belts which may be used in harvesting, post harvesting, and packing operations.
- **Pest** refers to any animal or insect of public health importance including, but not limited to, birds, rodents, cockroaches, flies, and larvae, that may carry pathogens that can contaminate food. (*While technically not “pests” the family pet may also carry pathogens.*)
- **Processing Water** means water used for post-harvest treatment of produce, such as washing, cooling, waxing, and product transport.
- **Sanitizing** means to adequately treat clean food-contact surfaces by a process that is effective in destroying or reducing the numbers of harmful microorganisms without affecting the quality or safety of the food.
- **Sanitizer** is a chemical compound designed to kill microorganisms when used according to manufacturer’s specifications for amount and concentration.
- **Approved Sanitizer** is a sanitizer that has been approved by the FDA and/or the Environmental Protection Agency (EPA) for use on food and/or food contact surfaces.
- **Rinsing** means removing residues, soil, grease, soap and detergents from surfaces by flushing with potable water.
- **Washing** means removing all soil or food residues from surfaces by scrubbing and using potable water and soap.

- Workers loading and transporting produce practice good personal hygiene
- Harvested produce loaded and stored in a manner to minimize physical damage and reduce risk of contamination during transport and to allow for air circulation.
- Vehicles used to transport fresh produce to market are clean and well maintained.
- Vehicles used to transport produce are not used to transport animals or animal products.

VI. Traceback System

- Distribution records are maintained for all produce leaving the farm.

GAP words to know:

Trace-back is the ability to track fresh produce items back to their source including growers, packers and transporters. This may be helpful in identifying and eliminating a potential hazard in the farm to table pathway.

VII. Pick Your Own Operations-Field Sanitation (could also apply to those who give farm tours)

- Pets and farm livestock are not allowed in "pick your own" area
- Toilet facilities and hand washing stations are clean, regularly serviced and maintained in good working order (soap, water and single-use paper towels) and available for customer use.
- Clean containers available are for customer purchase and use.
- Produce picked by customers is not permitted for retail sale.
- Facilities are available for customers to clean hands after coming in contact with farm animals (petting zoo) prior to entering "pick your own" area.
- Customers are not permitted to eat produce in the field as there are insufficient facilities for proper washing.



How can you get more information/education on integrating GAP programs into your business?

Here are some sources of GAP guidelines, practical application and general information.

GAP Guidance

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

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM064574>

Information about GAP Audits

USDA/AMS: Fresh Produce Audit Verification Program

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&page=GAPGHPAuditVerificationProgram>

Audit checklist

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5050869>

Harmonized Audit materials:

<http://www.ams.usda.gov/AMSV1.0/HarmonizedGAP>

GAP education/training/plan writing materials

Cornell National GAP Program education materials:

<http://www.gaps.cornell.edu/>

Penn State University:

<http://foodsafety.psu.edu/gaps/>

AgMatters

<http://www.agmattersllc.com/gap/>



Step 1 Worksheet: GAP check list.
ZZZ Cider Mill
2 Apple Street, Anytown, CT

Date: _____

Starting at the top, read through this check list and check off any practices that you already have as part of your operation's routine. Mark those that don't pertain to your operation as NA (not applicable). Consider any boxes that are not marked as practices you may need to adopt as part of your food safety plan.

On-Farm Water Resources

Water Source

- Recognize the risks associated with your water source.
- Test your water.
 Contact your local or state health department for the names of laboratories licensed to test water.
- Keep records for all water tests.
- Check to see that backflow devices are installed where needed.

Drinking Water Wells

- Conduct an assessment of your drinking water well with this survey:
www.ecn.purdue.edu/SafeWater/farmasyst/surveys/drinkwaterwell.htm
- Develop a well maintenance plan. If you have an older well (30-40 years or older), have the well examined by a water quality expert.
- Check for possible sources of contamination on your property and nearby.
- If you are considering drilling a new well:
 - Follow the states recommended minimum separation distances.
 - Locate your well on ground higher than surrounding pollution sources.
 - If necessary, build soil up around the well so that all surface water drains away from it. Avoid areas that are prone to flooding.
 - Make the well accessible for pump repair, cleaning, testing and inspection.
 - Hire a competent, licensed well driller and pump installer.
 - Obtain a permit to drill a new well

GAPs in the field

Water

- Choose agricultural chemical application methods that are less risky.
- Consider the management/location of farm animals and/or wildlife to minimize water contamination.
- Potable water must be available in the field for workers and "pick your own" patrons to wash their hands and to drink.



Worker Health and Hygiene

- Be aware of any federal, state or local regulations for worker health/hygiene.
- Conduct worker food safety training.
- Encourage workers to start each day in clean clothing.
- Have an employee sick policy in place, allowing workers options if they cannot work with food.
- Know the symptoms of foodborne illness.
- Provide employees with easy access to hand washing facilities or stations with potable water, soap and paper towels.
- Provide employees with easy access to toilet facilities.
- Where applicable, limit bare hand contact with fresh produce.

Manure Management

- Have a manure management plan in place.
- Store manure as far away as practical from areas where fresh produce is grown and handled.
- Where possible, erect physical barriers or wind barriers to prevent runoff and wind drift of manure.
- Actively compost manure.
- If manure is not composted, age the manure to be applied to produce fields for at least six months prior to application.
- Store manure slurry for at least 60 days in the summer and 90 days in the winter before applying to fields.
- Apply manure in the fall or at the end of the season to all planned vegetable ground or fruit acreage, preferably when soils are warm, unsaturated, and cover-cropped.
- If applying manure in the spring (or the start of a season), spread the manure two weeks before planting, preferably to grain or forage crops.
- Incorporate manure immediately after application.
- Avoid growing root and leafy crops in the year that manure is applied to a field.
- DO NOT harvest vegetables or fruits until 120 days after manure application.
- If the 120-day waiting period is not feasible, such as for short season crops like lettuce or leafy greens, apply only properly composted manure.
- Any equipment that comes into contact with manure must be cleaned prior to use for harvesting or transporting fresh produce.

Harvest sanitation

- Wash, rinse and sanitize, *when possible and practical*, all crop containers before harvest.
- When sanitizing, use an approved sanitizer according to the manufacturer's directions for amount and concentration.
- Cover harvest containers to keep crop dust, animals, insects and birds out.
- As much as possible, restrict farm livestock, including poultry and pets, from field or orchards where crops are grown or harvested.
- Clean harvesting equipment each day with potable water.
- Keep harvesting equipment in good working order. Set up a maintenance schedule.
- Train workers to follow good hygiene practices.
- Do not haul produce in equipment that has been used to transport garbage, manure or animals.



GAPs in the Packing House

Water

- Be sure that you have backflow prevention devices installed in your water supply system.
- Potable water must be available for food processing, cleaning and sanitizing, and hand washing.

Worker Health and Hygiene

- Be aware of any federal, state or local regulations for worker health/hygiene.
- Conduct worker food safety training.
- Workers start each day in clean clothing.
- Have an employee sick policy in place, allowing workers options if they cannot work with food.
- Know the symptoms of foodborne illness.
- Provide employees with easy access to hand washing facilities or stations with potable water, soap and paper towels.
- Provide employees with easy access to toilet facilities.
- Where applicable, limit bare hand contact with fresh produce.

Sanitation

- Plumbing fixtures allow for hot and cold running water and mixing of water for cleaning and sanitizing.
- Use food grade containers and store produce covered.
- Have pest control program in place. Screen and seal windows and doors to keep rodents, birds and insects out.
- Packing equipment, containers, utensils and food contact surfaces are made of food grade materials that are easy to clean and sanitize.
- Set up a cleaning and sanitizing schedule for the floor, food contact surfaces, containers, equipment and utensils.
- Keep grounds around the packing house clean, free from items that attract rodents, birds, and insects (garbage, long grass, weeds).
- Packing lines, conveyer belts and all other food contact surfaces are washed, rinsed and sanitized at the end of the day.

Washing operations

- Sanitizer levels are monitored (using test strips).
- Water is changed when dirty or after several hours.
- Wash water is maintained at a temperature no more than 10° cooler than produce.

Storage area sanitation

- Clean and sanitize storage areas on a regularly scheduled basis or as needed.
- Clean and sanitize your produce storage containers before use.
- Store unused containers where they are protected from contamination.
- Inspect the storage area regularly for signs of insect, rodent or bird infestations.
- Cover produce containers and store on shelves that are at least 6" off the floor.
- Train workers to keep storage areas clean.

Temperature control

- Find out which thermometers are appropriate for use in your operation.
- Cool fruits and vegetables quickly after harvesting to maintain quality and minimize the growth of pathogens.
- If you use ice to cool produce, it must be made with potable water.
- Monitor temperature of wash, rinse, and cooling water.



- Be careful not to overload refrigerators or cold rooms beyond their cooling capacity.
- Monitor and record temperature of coolers at least daily.
- Use refrigerated trucks for transport and monitor truck temperature.

Pick-Your-Own operations

Hygiene

- Provide your customers with toilet facilities and toilet paper.
- Provide your customers with hand washing facilities with paper towels, soap and a trash can.
- Post signs encouraging customers to wash their hands.
- Be familiar with symptoms of illness and check to make sure that customers do not have open wounds or lesions.
- If you have an on-farm petting zoo or if customers can come in contact with animals, provide an opportunity for them to wash their hands after touching animals.

Sanitation

- If possible, do not allow pets in the field or orchard. If pets must accompany customers, encourage them to pick up and properly dispose of any pet waste.
- Establish guidelines for customers with children in the field and orchard. Discourage diaper changing in the field.
- Provide trash cans for any customer trash.
- Provide toilet facilities and hand washing facilities that are accessible, clean, and regularly supplied with toilet paper, paper towels, soap, water, and trash can.
- Encourage customers to wash their hands after petting animals and using toilet facilities.
- Use signs and fact sheets to promote hand washing and safe food handling.
- Clean and sanitize the pick your own containers that you provide to customers.
- Do not sell produce that has been picked by customers.
- Do not allow customers to eat produce picked in the field.

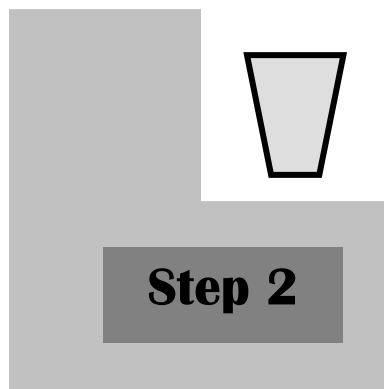
Trace back systems

Trace back systems are in place.

- Records are maintained for all produce leaving the farm.



Follow Good Manufacturing Practices (GMPs)





Step 2

Follow Good Manufacturing Practices (GMPs)

Good Manufacturing Practices as defined by the FDA in 21 CFR part 110 are the minimum sanitary and processing requirements for ALL food companies, regardless of product produced. As a producer of fresh juice products sold at retail, it may be hard to think of yourself as a food processor—in the same category as those who make your breakfast cereal or the cold cuts you make your sandwich with. But in the eyes of regulators, you indeed are considered a food processor and must abide by many of the same rules as the big guys!

GMPs include general statements regarding sanitation, facilities, equipment, processes and controls. The areas of sanitation that FDA suggests be included in a Sanitation Plan all relate to parts of GMP regulation, 21 CFR part 110.

GMPs are prescribed for 4 main areas of food processing:

1. **Personnel Hygiene**
 - ◆ Knowing how and when to wash hands
 - ◆ Understanding the importance of clean uniforms
 - ◆ Proper use of hair and beard nets
 - ◆ Policy on jewelry - minimal is best
 - ◆ Policy on chewing tobacco, smoking, and eating
2. **Building and Facilities**
 - ◆ Hand washing stations
 - ◆ Adequate lighting and ventilation
 - ◆ Storage of ingredients (refrigerated and on pallets)
 - ◆ Separation of raw ingredients from processed foods
 - ◆ Pest management program
3. **Equipment and Utensils**
 - ◆ Easily cleaned and sanitized
 - ◆ Easily maintained
 - ◆ Meet food grade standards
4. **Production and Process Control**
 - ◆ Time/temperature control charts
 - ◆ Records on food ingredients
 - ◆ Lot identification and coding
 - ◆ Product weight controls

A copy of the regulation can be found in the appendix for your convenience. More information about Good Manufacturing Practices may be found on the web at:

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

Step 2 Activity:

It is recommended that you study and refer to this document as you are developing your food safety and sanitation plans.

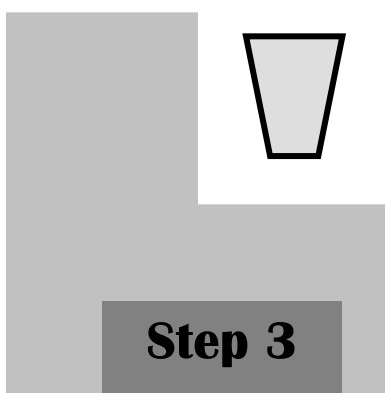


You might find it helpful for both you and your regulators to have a written document describing your process—or “How We Make Juice.” This could include how you grow your fruit (do you use GAPs?), how it is harvested, how it is transported to the juice processing area, how the fruit is received, stored (where, what temperature?), sorted. Describe the process in detail including how fruit is transported to the conveyor, how it is culled, how it is pressed, filtered, held or stored and bottled and labeled.





Develop and Follow A Sanitation Plan





Step 3 Develop and Follow a Sanitation Plan

Though not required by state or federal regulations, developing and implementing a written sanitation plan makes good business sense for retailers of fresh cider and juice. The planning process will help you to better understand and manage your operation.

Sanitation makes sense because sanitation practices directly affect the microbiological, chemical and physical safety of fresh cider and juice. A clean processing environment contributes to the production of a safe food product.

According to existing laws that apply to *every* food processing operation, any food processed under unsanitary conditions is considered *adulterated* because the food may be contaminated with filth, or substances that could make the food unsafe to eat.

The current Good Manufacturing Practice (GMP) regulations (Chapter 21 CFR Part 110) outline basic conditions and practices that must be followed to avoid adulteration (discussed as Step 2). These GMPs have been and continue to be applicable to *all foods*, including cider and juice.

The Food and Drug Administration (FDA) has identified eight key sanitation control procedures that focus on specific parts of the GMP. Developing a plan to control these eight sanitation conditions will go along way to prevent your cider or juice from being adulterated.

Sanitation words to know:

- **Adulteration:** Intentional or unintentional addition of a contaminant to a food, making it unfit for human consumption.
- **Biofilm:** A biofilm is formed when certain bacteria adapt to harsh conditions by changing and sending out tendrils that attach to the surface and to each other. They release a slime layer which protects them. They are not effectively removed by normal cleaning measures and are resistant to many sanitizers.
- **Chlorine:** A chemical used (in the form of hypochlorites) in sanitizing solutions and in flume and fruit wash water.
- **Clean:** Free of visible soil including food residue and dirt.
- **Cleaning agent:** A chemical compound specifically formulated for use on floors, walls, equipment, and food-contact surfaces to aid in the removal of soil.
- **Iodine:** A chemical used in some sanitizing solutions. It can be used only in solutions that have a pH below 5.0.
- **Parts per million:** A unit of measure for concentration of chemical sanitizing solutions.
- **Potable:** Safe to drink—as it applies to the water supply.
- **Quaternary ammonium compounds (Quats):** A non-corrosive sanitizing solution. May be effective in acid and alkaline environments, but may be more selective than other sanitizers.
- **Sanitation:** The creation and maintenance of conditions designed to protect public health.
- **Sanitary:** The number of disease-causing microorganisms has been reduced to safe levels on clean food contact surfaces.
- **Surfactants:** components of cleaning agents that reduce surface tension where the cleaning agent meets the soiled surface, allowing the cleaning agent to penetrate and disperse the soil so that it can easily be rinsed away.



Your sanitation plan should include:

- A **written plan** for sanitation activities that take place daily, weekly and monthly or periodically
- **Sanitation Standard Operating Procedures or SSOPs**, or written step-by-step cleaning and sanitizing procedures for each sanitation operation (e.g., cleaning and sanitizing the cider press or cleaning and sanitizing floor drains).
- **Check lists** for documenting sanitation activities that were accomplished (daily, weekly, monthly or periodically).

A written sanitation plan will help to:

- document your sanitation program,
- communicate your commitment to sanitation to your employees, customers, consumers and regulators,
- organize your sanitation program so that it can be easily reviewed, evaluated and improved if needed, and
- produce a safer, higher quality product.

Training:

After developing your SSOPs, you must *train your employees to follow them*. Supervisors should monitor employees to be sure that they are following the SSOPs. Employee evaluations should be based, in part, on the how the employee carries out these procedures.

A sanitation plan does not need to be difficult or complicated. It can be as simple as writing down what you intend to do, doing what you said you would, and using a checklist to document what you did. This plan will provide evidence of your efforts to regulators---especially if an outbreak is traced back to your product.

Cleaning and Sanitizing: As simple as 1-2-3-4-5-6!

Cleaning removes visible dirt and debris, including dust, food waste, and dirt on the floor. **Sanitizing** reduces illness causing microorganisms to safe levels. (You cannot eliminate microorganisms from a food processing environment--that would be "sterilization.")

It is important to know that you cannot sanitize a food contact surface without cleaning it first. Dirt and food waste can "protect" bacteria from the effects of the sanitizer. In addition, organic matter (food) can make a sanitizer ineffective.

Basic Cleaning-Sanitizing Procedure:

Step 1: Wet mop or wipe up dirt, debris and food waste.

Step 2: Rinse with clean water

Step 3: Wash/scrub with detergent to loosen remaining particles

Step 4: Second rinse with hot water

Step 5: Sanitize with chemical approved for use on food contact surfaces

Step 6: Air dry (If manufacturer recommends rinsing, rinse and then air dry)

Use cleaners and sanitizers that are acceptable to your regulatory authority.

It makes sense to talk to your supplier about your facility, your cleaning and sanitizing needs and any problems you may be having. Talk to several suppliers, if needed, to get the most information before you buy.



Cleaning

Cleaning agents

- Proper cleaning procedures will provide the foundation for an effective sanitation program
- You must always clean first with the appropriate detergent before you sanitize.
- Selection of the right cleaner will depend on:
 - ◆ type of soil
 - ◆ amount of cleaning required
 - ◆ type of surface to be cleaned
 - ◆ type of equipment used for cleaning

Factors Affecting Cleaning

- Concentration of cleaner
- Specificity of cleaner--different cleaners work best on different types of soil (i.e. some cleaners are best for removing grease)
- Time the cleaner is in contact with area to be cleaned
- Degree of foaming
- Temperature of the cleaning solution
- Mechanical action (scrubbing)
- Type and amount of soil
- Water, including hardness

Types of detergents/cleaners

Types of Cleaners	Best Used For
General Purpose—household cleaners and those intended for extensive hand contact	Mild, safe for use on painted or corrodible surfaces; usually not adequate for commercial processing environments; may be used on lightly soiled surfaces, or when there is a long contact time and agitation (scrubbing)
Alkaline	Range from moderately to highly alkaline (caustic); more effective than general purpose cleaners against food soils
Chlorinated (chlorinated alkaline)	More effective than general purpose cleaners against food soils; more effective in loosening protein based soils or for surfaces that are difficult to clean due to their shape or size such as perforated storage crates and waste containers; can be corrosive; do not use on aluminum. <i>They are not to be used in place of sanitizers.</i>
Acid	Best for removing inorganic mineral deposits (scale, lime) and stains associated with hard water.
Enzyme	Less corrosive; soil specific—protein, oil, or carbohydrate-based soils, not effective for general cleaning

**Adapted from information in Sanitation Control Procedures for Processing Fish and Fishery Products, National Seafood HACCP Alliance from Training and Education, 2000.



Sanitizing

Sanitizers

- Chlorine, iodine containing compounds, and quaternary ammonia are the three most commonly used chemical sanitizers.
- When heating is used as a sanitation step, temperature of water has to be maintained not less than 170°F (76.7°C) and not more than 190°F (87.8°C) for a time period of 30 seconds.
- Each sanitizing agent has benefits and disadvantages.
- Use the sanitizer that best fits your needs.

Factors Affecting Sanitizing

- Concentration of sanitizer—adding too much sanitizer can make a toxic and ineffective solution, while too little will make the solution weak and ineffective. Be sure to test when making the solution and regularly during the process to be sure that you are maintaining the proper concentration.
- Consider a plan for sanitizer rotation to prevent buildup of biofilm.
- Specificity of sanitizer--different sanitizers work best on different surfaces.
- Time the sanitizer is in contact with area to be sanitized.
- Temperature of the sanitizing solution.
- Contact with organic material (can reduce effectiveness of sanitizer).

Sanitizer concentrations commonly used in food plants.

Sanitizer	Food Contact Surfaces	Non-food contact surfaces
Chlorine	100-200* ppm**	400 ppm
Iodine	25* ppm	25 ppm
Quats	200 ppm	400-800 ppm
Peroxyacetic acid	200-315* ppm	200-315 ppm

*The higher end of the listed range indicates the maximum concentration permitted without a required rinse (surfaces must drain). [Source: 21 CFR 178.1010]

**See "Words to Know" page 28 for the meaning of ppm.

To measure sanitizer concentration, ask your supplier for sanitizer test strips—you simply dip the strip into your solution and the color will tell you if you have the right concentration.

Adapted from information in Sanitation Control Procedures for Processing Fish and Fishery Products, National Seafood HACCP Alliance for Training and Education, 2000.



Types of Sanitizers

Sanitizer	Forms/Description	Advantages	Disadvantages
Chlorine	Hypochlorites Chlorine gas Organic chlorine, e.g., Chloramines	-Kills most types of microorganisms -Less affected by hard water than some -Does not form films -Effective at low temperatures - Relatively inexpensive -Concentration determined by test strips	-May corrode metals and weaken rubber -Irritating to skin, eyes and throat -Unstable, dissipates quickly -Liquid chlorine loses strength in storage -pH sensitive
Iodophors	Iodine dissolved in surfactant and acid	-Kills most types of microorganisms -Less affected by organic matter than some -Less pH sensitive than chlorine -Concentration determined by test strips -Solution color indicates active sanitizer	-May stain plastics and porous materials -Inactivated above 120°F -Reduced effectiveness at alkaline pH -More expensive than hypochlorites -May be unsuitable for CIP (clean in place) due to foaming
Quaternary Ammonium Compounds	Benzalkonium chloride and related compounds, sometimes called quats or QACs	-Non corrosive -Less affected by organic matter than some -Residual antimicrobial activity if not rinsed -Can be applied as foam for visual control -Effective against <i>Listeria monocytogenes</i> -Effective for odor control -Concentration determined by test strips	-Inactivated by most detergents -May be ineffective against certain organisms -May be inactivated by hard water -Effectiveness varies with formulation -Not as effective at low temp. as some -May be unsuitable for CIP due to foaming
Acid-Ionic	Combination of certain surfactants and acids	-Sanitize and acid rinse in one step -Very stable -Less affected by organic matter than some -Can be applied at high temperature -Not affected by hard water	-Effectiveness varies with microorganism -More expensive than some pH sensitive (use below pH 3.0) -Corrodes some metals -May be unsuitable for CIP due to foaming
Sanitizer	Forms/Description	Advantages	Disadvantages
Peroxy Compounds	Acetic acid and hydrogen peroxide combined to form peroxyacetic acid	-Best against bacteria in biofilms -Kills most types of microorganisms -Relatively stable in use Effective at low temperatures -Meets most discharge requirements -low foaming; suitable for CIP	-More expensive than some -Inactivated by some metals/organics -May corrode some metals -Not as effective as some against yeasts and molds.



Carboxylic Acid	Fatty acids combined with other acids; sometimes called fatty acid sanitizers	<ul style="list-style-type: none"> -Kills most types of bacteria -Sanitize and acid rinse in one step -Low foaming, suitable for CIP -Stable in presence of organic matter -Less affected by hard water than some 	<ul style="list-style-type: none"> -Inactivated by some detergents -pH sensitive (use below pH 3.5) -Less effective than chlorine at low temperature -May damage non-stainless steel materials -Less effective against yeasts and molds than some
Chlorine dioxide	A gas formed onsite and dissolved in solution or by acidification of chlorite and chlorate salts	<ul style="list-style-type: none"> -Kills most type of microorganisms -Stronger oxidizer (sanitizer) than chlorine -Less affected by organic matter than some -Less corrosive than chlorine -Less pH sensitive than some 	<ul style="list-style-type: none"> -Potentially explosive and toxic -Relatively high initial equipment cost
Ozone	A gas formed onsite and dissolved in solution	<ul style="list-style-type: none"> -Kills most type of microorganisms -Stronger oxidizer (sanitizer) than chlorine and chlorine dioxide 	<ul style="list-style-type: none"> Potentially toxic -Inactivated by organic matter (similar to chlorine) -pH sensitive -More expensive than most
Hot Water/Heated Solutions	Water at 170 – 190° F	<ul style="list-style-type: none"> -Kills most types of microorganisms -Penetrates irregular surfaces -Suitable for CIP -Relatively Inexpensive 	<ul style="list-style-type: none"> -May form films or scale on equipment -Burn hazard -Contact time sensitive; inappropriate for general sanitation

Adapted from information in Sanitation Control Procedures for Processing Fish and Fishery Products, National Seafood HACCP Alliance from Training and Education, 2000.



Eight Sanitation Conditions to Include in Your Plan

Sanitation plans are written to meet the needs of *your* operation—it may look different than a plan for a cider maker down the street. All plans should, at minimum, address these eight sanitation conditions:

#1. Safety of process water that comes into contact with juice or juice-contact surfaces, or is used in the manufacture of ice (that may contact juice or fruit).

A major safety concern in any food processing operation is the safety of water. Your sanitation plan must account for the sources and treatment of water that comes into contact with food and food contact surfaces or is used to make ice. The water used in juice processing must be potable or drinkable. There can be no cross-connections between a safe water supply (potable) and non-potable water.

Preventing Cross-Connections in your operation:

Without proper protection devices, something as useful as a hose attached to a faucet has the potential to contaminate the water supply in your processing facility. This can happen when there is a "cross-connection" in your water supply. A **cross-connection** is any physical link through which contaminated water from drains, sewers, waste pipes or dirty water in sinks or buckets can enter a potable water supply.

If a cross-connection is present in the water supply, you may contaminate the water supply if "backflow" occurs. **Backflow** means that the water is flowing in the opposite direction from its normal flow. With the direction of flow reversed, due to a change in pressures, backflow can allow contaminants to enter your potable water system through cross-connections. Backflow contamination due to cross-connections is a serious plumbing problem which can cause sickness and even death.

A potentially hazardous cross-connection occurs every time someone uses a hose sprayer to apply insecticides or allows a faucet hose to sit in contaminated or dirty wash water. Without a **backflow prevention device** between your hose and the faucet, the contents of the hose and anything it is connected to can "flow back" into the piping system and contaminate your drinking water.

The simplest form of backflow prevention is an **air gap**--an unobstructed vertical distance between the faucet, hose or plumbing fixture and the flood level rim of the sink or receptacle. When air gaps exist, it is not possible for contaminants to flow back into the water supply.

You may want to check with your plumber to make sure that your water systems all have the appropriate backflow prevention devices to prevent cross-connections.

#2. Condition and cleanliness of food contact surfaces including utensils, gloves, and outer garments.

This area relates to the design, workmanship, materials, and maintenance of food contact surfaces and the routine, scheduled cleaning and sanitizing of those surfaces. Processing equipment must be easily cleanable; drain easily and not trap food, soil, and bacteria. It must be designed to withstand the environment of its intended use and the action of cleaners and sanitizers. This includes equipment for ice production and storage. At minimum, cleaning and sanitizing of all equipment that contacts food should be done daily. The condition of equipment should be inspected at least monthly.



Include plans for cleaning and sanitizing all food contact surfaces in your sanitation plan. **Food contact surfaces** include brusher/washers, conveyors, fruit presses, press cloths, refrigerator shelves, cutting knives, tables, ice makers/storage bins, and gloves, aprons or other outer garments that contact food. All food processing equipment and utensils must be in working condition and clean prior to processing. In addition, they must be sanitized with the proper type and concentration of sanitizer.

#3. Prevention of cross-contamination from unsanitary(contaminated, dirty) objects to food, food-packaging material and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product.

This area relates to: employee practices to prevent product contamination; physical separation of raw and cooked product; and plant design to prevent contamination.

Cross-contamination is the transfer of biological or chemical contaminants to food products from raw foods, food handlers or the food handling environment.

One of the major sources of cross-contamination is food handlers. Cross contamination can occur when food handlers:

- Do not wash their hands **after** going to the bathroom, handling dirty produce or harvesting bins, handling garbage, touching dirty equipment or food-contact surfaces, coughing or sneezing, scratching their head, and **before** handling food or food-contact surfaces.
- Do not change gloves when they are dirty or ripped.
- Do not wash hands before putting on gloves.
- Wear dirty clothing and/or boots (especially if boots are used in the field prior to entering the processing facility).
- Do not wear hair restraints.
- Have dirty fingernails or long, polished or artificial nails.
- Have hanging jewelry, pens or other personal effects that could fall into food.
- Drink, eat, or smoke on the job.

Hands can be a significant source of pathogenic microorganisms, or even chemical contamination with plant chemicals such as pesticides or cleaning compounds.

The juice processing room should have a hand washing sink, equipped with soap, hot water, paper towels and a trash can.

To effectively control cross-contamination, you need to look at all areas of your operation to make sure that raw products (raw fruit) are not handled, stored or processed in a manner that will allow them to contaminate your ready-to-drink juice products.

Your operation should be set up so that the chances of cross-contamination occurring are reduced. If your juice processing facility is located close to where farm animals live or graze, this means that special attention needs to be paid to preventing the unintentional transport of pathogens from animal facilities or areas where manure is handled to the juice processing facility. If not physically in a separate building, doors between facilities must be air-tight, and should contain screen doors that open out (to minimize flies in the facility). Minimize food handler movement from "dirty or raw" areas (especially sources of contamination from animals) to clean or processing areas. Use foot-baths if possible or change into clean boots when coming into the processing area.

Clean lab coats or aprons (if changing clothing is not practical) and hair restraints can also help to minimize contamination when going into the processing areas.



Toilet facilities should be easily accessible, properly functioning, supplied with sinks, hot water, soap, toilet paper, paper towels and covered trash cans.

#4. Maintenance of hand washing and sanitizing, and toilet facilities

This area relates to the location **and** maintenance of hand washing, sanitizing and toilet facilities as well as the adequacy of sewage disposal.

Cider and juice processing requires some manual handling of fruit. Loading fruit onto conveyors, sorting and culling and other processing activities are usually done by hand.

You should have hand washing facilities in bathrooms and in processing areas. Hand washing sinks in processing areas must be dedicated sinks—used only for hand washing—never for washing fruit or utensils, rinsing mops or other purposes. They should be checked at least daily to make sure that they are clean, in working order and supplied with hot water (43°C or 110°F), soap, disposable paper towels, and a trash can.

You should have a policy and expectation that workers will always wash their hands when entering the processing facility (even if they have just washed them after going to the bathroom). Hand sanitizers are another tool that can be used to reduce the risk of contaminating food or utensils with dirty hands. If you use a hand sanitizer, it must be used **after** washing the hands – **not in place of** hand washing!! Hand wipes and gels are not approved in food processing operations as a substitute for hand washing.

Toilet facilities should also be checked at least once a day to make sure that they have adequate supplies and are clean and in working order. A back flow or blocked toilet can spread fecal contamination throughout the plant—resulting in a plant closing.

#5. Protection of food, food-packaging material, and food-contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical and biological contaminants.

This area covers protection of food, food packaging materials and food contact surfaces from various microbiological, chemical and physical contaminants such as lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and floor splash.

An "**Adulterated Food**" is food that contains any poisonous or harmful substance which may make it unsafe; and has been prepared, packed or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health...

Source: Section 402 of the Food, Drug and Cosmetic Act, items (a) 1, (a)(3), and (a) 4.

You need to be aware of all of the ways that a food can become adulterated so that it is unsafe to eat. You must anticipate and recognize possible sources of contamination. Contamination can occur during receiving, handling, and storage of packaging materials, dry food ingredients, and fruit.



Possible sources of contamination include:**Toxic compounds**

- Use of non-food grade lubricants
- Fuel contamination
- Aerosols and/or dust from non-food areas (garage, barn, etc.) that could contaminate a food contact surface
- Non-food-grade containers, utensils, and equipment

Sanitation words to know:

- **Food grade:** Safe for use in the storage, packaging or processing of food.

Only approved pesticides (insecticides and rodenticides) should be used to control pests in the plant and these compounds should only be applied as stated on the label.

When using chemicals, cleaners, and sanitizers, avoid adulteration through splash or spillage, aerosols and mist. Food, food contact surfaces and packaging materials should be removed or covered before using these chemicals or, when appropriate, cleaned and/or rinsed thoroughly when exposed to these contaminants.

Condensate or pools of water:

Condensation can be a problem in any “wet” processing environment where moisture can collect on walls, overhead fixtures, ceilings or pipes. Contaminated drips or condensate from ceilings, vents or pipes may contain microorganisms, chemical residues, and filth.

- Lack of proper ventilation may cause formation of condensates.
- Pooled or standing water could splash on the product or product contact surfaces, adulterating the product. Splashing can be caused by foot or vehicle traffic through the standing water.

Wherever there is moisture, *Listeria monocytogenes* and other pathogens and spoilage bacteria can grow and multiply. Dripping condensate can contaminate food contact surfaces. Prevent these problems with ventilation, temperature control, and pipe covers.

Source: Sanitation Control Procedures for Processing Fish and Fishery Products, 2000.

#6. Proper labeling, storage, and use of toxic compounds

This area covers labeling, storage and use of toxic compounds. Improper use of toxic compounds is often the cause of product adulteration.

You may use a variety of chemicals in your operation, including cleaners, sanitizers, pesticides (rodenticides or insecticides), machine lubricants, and maybe some food additives. These chemicals must be used carefully to prevent adulteration of your fruit, water, cider and/or food contact surfaces. Be sure to use them according to manufacturer’s instructions—keep them labeled properly, store them in a safe manner, and dispose of them properly. Only those chemicals that are needed for the operation and maintenance of your processing plant should be allowed in the facility.

Labeling: Original containers must show name of manufacturer, instructions for use, appropriate approvals (i.e. EPA registration). If it is necessary to take some of the compound out and put it in a working container, be sure to label it clearly with the name of the product and instructions for use. Do



not use containers that typically hold food products to hold or mix chemicals, cleaning solutions or sanitizers.

Storage: Store toxic compounds in an area of limited access away from food storage, handling or processing areas. This may mean a locked room or cage. Separate cleaning chemicals from pesticides and food grade chemicals and store them away from non-food grade chemicals so that they do not get mixed up.

Use: Follow manufacturer's instructions; keep Material Safety Data Sheets easily accessible—they provide information on safe use of plant chemicals.

- Thoroughly rinse after using any cleaning agent (with potable water).
- Any fumes or odors from the use of cleaning compounds must dissipate before food handling/processing can begin.
- Avoid using hand cleaners, or sanitizers with fragrance or odor.
- Keep medicine and first aid supplies in a place where they will not contaminate food or food-contact surfaces. They must be properly labeled.

#7. Control of employee health conditions that could result in the microbiological contamination of food, food-packaging materials, and food-contact surfaces.

Food handlers who appear to have an illness, infection, wound or other similar condition that might be a source of microbial contamination of food must be excluded from the food handling environment. It is important to regularly observe those who are handling food in your operation and to talk to the employee if illness or infection is suspected. Sick time and illness policies must be set up to allow sick employees to stay home. A food worker diagnosed with an active case of *Salmonella*, *Shigella*, Hepatitis A or *E. coli* O157:H7, must be restricted from food handling areas.

Sometimes it is possible to reassign an employee to a nonfood processing area. However, any time there is suspicion of a virus or other illness that is easily spread to other employees, sending the employee home is the safest alternative.

If there are skin infections or lesions, they can be covered with an impermeable bandage and glove.

Keep in mind that often employees can be carriers of certain pathogens without exhibiting any symptoms. That is why it is so important that food-handlers wash their hands often (especially after using the toilet and before processing or handling food.)

Responsibilities of management:

GMP states, "plant management shall take all reasonable measure and precautions to ensure that no adverse employee health conditions exist that could lead to contamination of product, packaging, or food contact surfaces." Therefore you need to adopt a "culture" of cleanliness and health—

- Develop **written** policies that require reporting, work restrictions and exclusion of employees that have symptoms of illness, infection or communicable diseases.
- Make sure there is a clear understanding that employees will not lose their jobs (or, if possible, their pay) if they have an illness, infection or communicable disease that keeps them from working with food for a period of time.
- Put up posters and provide training that illustrates the connection between personal health and hygiene and food safety.
- Set a good example—do not come to work sick!



Responsibilities of employees:

- Live a healthy lifestyle
- Be aware of the symptoms of illnesses
- Report illness, communicable diseases and infections.
- Wash hands after using the bathroom, coughing, sneezing, etc.

#8. Exclusion of pests from the food plant.

Pests include rodents, birds, insects and, some might contend, family pets! All of these pests (including family pets) must be excluded from the juice processing operation. While there is concern about quality and economic loss from damage done by pests, the problem here is that these pests carry bacteria and parasites that can cause foodborne illness.

- Rodents carry *Salmonella* and parasites
- Birds may be the source of *Salmonella* or *Listeria*
- Flies and cockroaches may transmit *Salmonella*, *Staphylococcus*, *C. perfringens*, *C. botulinum*, *Shigella*, *Streptococcus* and others.

Sanitation words to know:

Harborage: Shelter for pests, vermin or microbiological contaminants such as bacteria.

Pest control operator: An individual who is licensed or certified to provide pest control services, including the use of pesticides.

Your Pest Control Program

Operators should have a pest control program that is well-planned and documented. Pesticides are poisons and they are expensive. You are encouraged to use integrated pest management systems (IPM) to maximize effectiveness and minimize the cost of your pest control program. Whether this is done by the operator or a licensed pest control professional, the operator is responsible to see that the job gets done.

The pest control program should include:

- the elimination of shelter and things that attract pests;
- exclusion of pests from processing and storage facilities, and
- extermination of pests that get into the plant (not including the family pet).

The pest control program should address pest problems affecting:

- **grounds and parking lots surrounding the operation** (areas of harborage including tall grass, weeds, brush and debris; standing water; presence of domestic or feral animals; presence and effectiveness of traps)
- **the building and layout** (window/door seals; no holes in walls; intact screening; drains clean and free of buildup; 6 inch clearance behind and under equipment and storage shelving)
- **machinery, equipment and utensils** (clean, sanitized; cleanable; harborage sites)
- **sanitation** (eliminate trash, clutter; no food, clutter in storage rooms; signs of pests)
- **waste disposal** (collection times frequent; clean and sanitize garbage and waste containers)
- **use of pesticides and other control measures** (be aware of regulations relating to pesticide use)



Regular inspections of these areas of concern should begin with an initial or baseline inspection to identify problems that currently exist. Look for both the pests and signs that pests may be around (nests, droppings, gnaw marks, webs).

Follow regulations regarding pesticide use. The Department of Environmental Protection and similar state agencies are responsible for regulation. They enforce The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Environmental Pesticide Control Act (FEPCA). Hiring a professional, certified pesticide applicator may make sense. You may also become certified as a private applicator—someone who is certified to use restricted use insecticides in the production of an agricultural commodity on property owned or rented by you or your employer.

Source: Sanitation Control Procedures for Processing Fish and Fishery Products, 2000.

Step 3 Activities:

- 1) Develop a sanitation plan for each of the Eight Sanitation conditions.
- 2) Develop SSOP Cleaning Schedule for each
- 3) Develop checklists to match your plan and procedures.



4) Sample Sanitation Plan:

This is one example of a Sanitation Plan that addresses each of the eight sanitation conditions.

Sanitation Plan

ZZZ Cider Mill

2 Apple Street, Anytown, CT

SAFETY OF PROCESS WATER

1A. Water Source

The water source is well water from a drilled well.

Annually:

- A certified external agency will perform an annual inspection of the well, including the well seal.

Quarterly:

- Water sources will be tested (against EPA waster quality standards) quarterly.

Record Keeping:

- File testing results when received.
- Keep records of any inspections and plumbing work.

1B. Cross-connections

Annually:

- A certified external agency will test all in-place backflow prevention devices annually.

Daily:

- Check daily for hose placement and use, keeping hoses from being submerged in wastewater. Include a quick review of water sources and check for system leaks.

Monthly:

- The quality control supervisor will perform a monthly inspection to determine that no cross connections exist between potable water and waste systems.

Record Keeping:

- Daily and monthly sanitation check list
- Annual report of inspector will be filed.

1C. Processing water

Daily:

- The flume tank water is changed daily and chlorine is added at an initial level of 100 ppm. The chlorine level is monitored every 4 hours for active chlorine using a test kit. During active use, chlorine levels are maintained at a detectable residual level.
- The brusher/washer water is sanitized with chlorine dioxide at an initial level of 100 ppm. The chlorine level is monitored prior to start and every 4 hours of operation using a chlorine test kit. During active use, chlorine levels are maintained at a detectable residual level.

Record Keeping:

- Daily sanitation check list to include change of flume water, adding chlorine, chlorine testing, sanitizing brusher/washer, testing water used in brusher washer for chlorine levels



CONDITION AND CLEANLINESS OF FOOD CONTACT SURFACES

2A. Construction of food-contact surfaces and utensils

Monthly, or when needed:

- Presently, all plant equipment and utensils meet current recommended state and federal standards. Prior to replacing any major piece of equipment, we will evaluate the equipment to determine whether replacing the equipment will impact adjacent processing steps. Specifications of all equipment will be reviewed to ensure it is capable of the intended use and can be easily cleaned. The same evaluation will be conducted on materials used in the modification of the physical plant.
- Orders to purchase minor equipment and utensils used in the process will be reviewed by the supervisor. If necessary, the supervisor of the contracted cleaning company will be contacted to consider the impact of present methods of cleaning and sanitizing plant equipment and utensils. The results of these evaluations will be kept on file.
- The supervisor will evaluate the condition of plant equipment and utensils monthly.

Record Keeping:

- Purchasing records
- Monthly sanitation check list

2B. Cleaning and sanitizing food contact surfaces and utensils

Food contact surfaces are 1) cleaned and sanitized at the end of the day's operations; 2) sanitized before the day's operations begin.

Daily:

- During breaks in processing, major solids are physically removed from floors, equipment, and food-contact surfaces. All surfaces are rinsed with cold water. Equipment and food contact surfaces are scrubbed using brushes with a chlorinated alkaline cleaner in warm (120°F) water. All surfaces and floors are rinsed with cold water. Check sanitizers and food contact surfaces. Food-contact surfaces are sanitized with a 100 ppm sodium hypochlorite sanitizer solution. Floors are sanitized with a 400 ppm quaternary ammonium chloride sanitizer. Utensils are cleaned in a deep sink with a chlorinated alkaline cleaner, rinsed in hot water, soaked in a 100-ppm sodium hypochlorite sanitizer for at least 10 minutes, and rinsed in hot water prior to use. The sanitation supervisor checks sanitizers before use and inspects food-contact surfaces to determine if they are clean and sanitized.
- All process lines will be cleaned and sanitized at the end of the day's operation. At the end of the production day, employees will remove any buildup of debris or other materials from the facility. In addition employees will clean and sanitize all equipment, utensils and the facility. A food-grade alkaline detergent will be used for cleaning, followed by a 100 ppm chlorine rinse.

The concentration of the chlorine sanitizer will be checked and recorded before it is used.

- Before the production day begins, the facility, equipment and utensils will be sanitized using a 100 ppm chlorine rinse. The concentration of the chlorine sanitizer will be checked and recorded before it is used. The supervisor will conduct a preoperational sanitary inspection.

Record Keeping:

- Daily sanitation checklist, including chlorine testing results



2C. Gloves and outer garments

Daily:

- ☑ Employees are required to maintain work gloves and aprons in a sanitary and operable condition and, if necessary (if soiled or torn), must replace them. In addition, the quality control representative will check this gear at the beginning of each day's operations.

Record Keeping:

- Daily sanitation check list

PREVENT CROSS-CONTAMINATION

3A.: Employees' hands, gloves, and outer garments

(note: see employee hygiene procedures)

When employed, with follow up as needed:

- ☑ Employees will be trained on how and when to properly wash and sanitize hands. Training will be documented and kept on file.

Daily:

- ☑ Supply of gloves, aprons, hair restraints, boot sanitizers available.
- ☑ Food handlers are washing hands **after** using restroom, handling farm animals, handling garbage, touching dirty equipment or food-contact surfaces, handling raw food ingredients, coughing or sneezing, scratching their head, and **before** handling food or food-contact surfaces.
- ☑ Food handlers come to work with clean clothes, clean hair, clean short fingernails, and no artificial nails or polish.
- ☑ Supervisors, maintenance workers, quality control and production personnel, including those who handle waste, touch the floor or other insanitary objects, must clean and sanitize their hands and gloves before handling product.
- ☑ Workers wear disposable gloves and replace them as needed when dirty or torn.
- ☑ Workers do not eat or smoke in food processing areas.

Record Keeping:

- Employee training records
- Daily sanitation checklist

3B: Utensils and food contact surfaces 4 hours

Daily:

- ☑ Equipment and utensils, will be inspected before each day's production for possible sources of contamination, including condensate and pests, by the supervisor.
- ☑ Utensils and food-contact surfaces (including equipment) that have come in contact with the floor, waste or other insanitary objects will be cleaned, sanitized, and inspected before restarting production.
- ☑ If food processing equipment (conveyor, washer brusher, dump tank, press, etc.) become contaminated by any form of waste or floor splash during production, the supervisor will immediately stop production. The section affected will be cleaned, sanitized and then inspected by a supervisor before production starts again.
- ☑ Plant grounds are in a condition that protects against contamination of food. Sanitation supervisor inspects plant grounds.
- ☑ Waste is removed from processing areas during production. Sanitation supervisor monitors removal of waste.
- ☑ Raw and cooked products are physically separated in coolers.



- ☑ Nonfood-contact surfaces in processing and packaging areas are cleaned daily at the end of the shift.
- ☑ Packaging materials are protected from contamination during storage.

Record Keeping

- Daily sanitation check list
- Monthly sanitation check list

MAINTAIN HAND WASHING AND TOILET FACILITIES

4A: Hand washing sink (in processing room)

Daily:

- ☑ Hand washing sink will be inspected at the beginning of the day. Hand washing sinks will be supplied with hot water, paper towels, soap, and an empty trash receptacle.
- ☑ Hand washing sink will be cleaned and sanitized at the end of the day.

Record Keeping:

- Daily sanitation check list

4B: Restrooms

Daily:

- ☑ Restrooms will be inspected at the beginning of the day. Restrooms will be clean, in working order, and equipped with paper towels, soap, hot water, trash can.
- ☑ Restrooms will be cleaned and sanitized at the end of the day.

Record Keeping

- Daily sanitation check list

PROTECTION OF FOOD FROM ADULTERANTS

Adulterants include lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, metal fragments, condensate, floor splash, and other chemical and physical contaminants. Food, food packaging materials, and food contact surfaces must be protected from adulterants.

Upon Receipt/Monthly/periodically

- ☑ Cleaning compounds, sanitizers, and lubricants used in processing and packaging areas are approved for use in food plants. Receiving manager checks invoices at receiving before food-grade chemicals are stored.
- ☑ There will be a monthly inspection of the ventilation system to ensure adequate ventilation, airflow and air pressure that prevents or inhibits the formation of condensates in the processing and storage areas.

Daily:

- ☑ Pallets will be inspected, cleaned and sanitized prior to use.
- ☑ Food, food-packaging materials and food-contact surfaces are protected from adulteration from biological, chemical and physical contaminants. Safety-type light fixtures are used in processing and packaging areas.
- ☑ The supervisor will inspect the processing area daily during operation for possible sources of contamination, including contaminated drips or condensate, pooled or standing water.
- ☑ If utensils, equipment or other food contact surfaces come into contact with adulterants, they will be cleaned, sanitized, and inspected prior to use. If this occurs during production, production will be stopped and resumed only after cleaning, sanitization and inspection of the affected area.



- ☑ Lubricants, cleaning compounds, pesticides or other plant chemicals will be stored separately outside processing and packaging areas. Non-food grade chemicals are stored separately from food-grade.

Record keeping:

- Daily sanitation check list
- Monthly sanitation check list

PROPER LABELING, STORAGE AND USE OF TOXIC COMPOUNDS

Any toxic compounds allowed in the plant shall be identified, held, used and stored in a manner that protects against contamination of food, food-contact surfaces or packaging materials.

Upon receipt/monthly/periodically:

- ☑ All toxic compounds used in the plant are labeled with the manufacturer's name, use instructions, and the appropriate EPA approval, or have documentation with the necessary information. Receiving manager verifies that this information is present before toxic compounds are stored.
- ☑ All food-grade lubricants will be stored separately from nonfood-grade lubricants and be properly labeled.
- ☑ The maintenance department will store and properly label all non-food grade lubricants within the maintenance area.
- ☑ No fuels will be stored within the facility. All gas fuels (i.e., oxygen and acetylene) shall be stored in portable tanks outside the plant and will be brought inside only when production is stopped. If it becomes necessary to use such fuels during production, employees will raise barriers to ensure that the process is not contaminated. When finished, the area will be thoroughly cleaned, sanitized and inspected before production starts again.

Daily:

- ☑ All cleaning compounds and sanitizing agents used within the processing environment will be clearly identified and stored away from the process area, food storage areas, packaging storage areas, and any other lubricants or chemicals. Only authorized personnel have access to the cage.
- ☑ All manufacturers' instructions and recommendations are followed. Only authorized personnel fill small working containers, such as containers of hand sanitizing compounds.
- ☑ The quality control supervisor will inspect the processing area for possible contamination sources and to make sure toxic compounds are labeled and stored properly.
- ☑ Any toxic compounds transferred to a "working" container will be labeled with name and instructions for using the compound.
- ☑ Any unlabeled containers will be properly discarded.

Record Keeping:

- Daily audit form will be used to document daily inspection findings.
- MSDS sheets for all chemicals provided by cleaning companies, pesticide control company and in-house chemicals will be filed and available for quick reference.

EMPLOYEE HEALTH CONDITIONS

Upon hiring and as needed:

- ☑ As a part of new employee orientation, employees will be told of the illness policy which includes their responsibility to notify the immediate supervisor of any illness or injury that may lead to contamination of any part of the process. They will also be told that they must notify the immediate



supervisor if they have been exposed to a confirmed disease outbreak of *Salmonella* (such as typhoid), hepatitis A or *Shigella*, especially when employees are asymptomatic.

- ☑ Employees will sign a copy of the illness policy to indicate that they have been told this.

Daily:

- ☑ Employees will notify supervisor if they are ill with diarrhea, vomiting, upper respiratory illness, infection or an infected wound. They will also notify supervisor if they have been exposed to a confirmed disease outbreak of *Salmonella* (such as typhoid), hepatitis A or *Shigella*.
- ☑ Employees will be reviewed for signs of health conditions or medical problems daily before operations begin by the supervisor. At any indication of injury or illness that may compromise the process due to contamination, the supervisor will remove that person from the line. If that employee cannot be assigned other duties, he or she will be sent home until the situation is alleviated or a medical authority states that he or she may return to work.

Record Keeping:

- Training records will be kept to indicate notification of employees of illness policy.
- Signed copies of illness policy.
- Observations will be recorded on the daily sanitation check list.

EXCLUSION OF PESTS

A professional pesticide control company is contracted and is responsible for all facets of pest control within the plant as well as the grounds. MSDS's for all pesticides used by the company are on file.

Daily:

- ☑ Supervisor will conduct a daily inspection of the premises for signs of pest infestation including nests, tracks, gnaw marks, webs, etc.

Monthly and as needed:

- ☑ The supervisor will conduct a monthly review of the plant layout and structure to ensure that contamination of any aspect of the process does not occur from internal or external sources.

Record Keeping:

- Observations will be recorded on the daily and monthly sanitation check lists.

For more information about developing an SSOP Plan, look here:

Seafood HACCP Alliance Course, **Sanitation Control Procedures for Processing Fish and Fishery Products**

Available from: Florida Sea Grant College Program, P.O. Box 110409, Gainesville, FL 32611-0409, (352) 392-2801 or online at: <http://seafood.ucdavis.edu/sanitation/scpmanual.htm>
(Seafood HACCP is also an FDA regulatory program—this manual, developed for seafood would be useful for juice/cider processors as well.)

Juice HACCP Training Curriculum, First edition, August 2002. Juice HACCP Alliance



Sample Sanitation Checklists: Daily Sanitation Check List:

ZZZ Cider Mill
2 Apple Street, Anytown, CT

Product:
Batch:
Date:

Sanitation Condition	Pre-Op Time:	4 Hour Time:	Post-Op Time:	Comments and/or Corrections
<p>1) Safety of Water</p> <ul style="list-style-type: none"> No hoses in water No evidence of water system leaks or problems 	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>		
<p>2) Condition and cleanliness of food contact surfaces</p> <ul style="list-style-type: none"> Equipment cleaned and sanitized at the end of the day. Sanitizer strength: Flume tank water is changed daily and chlorine is added. Chlorine strength: Brusher/washer water is sanitized with chlorine dioxide. Sanitizer strength: Boot sanitizer mixed Sanitizer strength: Gloves and aprons clean and in good repair Utensil wash area is clean Sanitizer strength: 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	
<p>3) Prevention of cross-contamination</p> <ul style="list-style-type: none"> Employees in clean clothing, hair restraints, clean hair, etc. Employees wash hands and/or change gloves when dirty or torn or contaminated. Food processing area is clean, free of debris or sources of contamination (condensation, pooled water) Floor drains are cleaned and sanitized at end of the day. Sanitizer strength: Trash and garbage containers are cleaned, sanitized at the end of the day and emptied as needed. Receiving area is clean, free of debris, door is closed. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	

<ul style="list-style-type: none"> • Storage area is clean, no food or packaging materials on the floor. Food and packaging protected from contamination. • Plant grounds are in a condition that protects against contamination of food. • Waste is removed from processing areas during production. Sanitation supervisor monitors removal of waste. • Raw and cooked products are physically separated in coolers. • Nonfood-contact surfaces in processing and packaging areas are cleaned daily at the end of the shift. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>4) Maintenance of hand washing and toilet facilities</p> <ul style="list-style-type: none"> • Hand washing sink is cleaned at the end of the day, equipped with hot water, soap, paper towels, and clean, trash cans • Restrooms are cleaned at the end of the day, toilets and sinks are in working order, supplied with soap, paper towels, toilet paper, hot water, trash can 	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>	
<p>5) Protection from adulterants and 6) Labeling, storage, and use of toxic compounds</p> <ul style="list-style-type: none"> • Food products, ingredients, packaging and food-contact surfaces are protected from contamination • Toxic compounds (including working containers) are properly stored, labeled and used (MSDS sheets and instructions are available) 	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>		
<p>7) Employee health conditions</p> <ul style="list-style-type: none"> • Employees reviewed for signs of illness, wounds—no signs of illness seen 	<input type="checkbox"/>			
<p>8) Exclusion of pests</p> <ul style="list-style-type: none"> • No signs of pests in receiving, storage or processing areas 	<input type="checkbox"/>			



Sample Sanitation Checklists: Monthly Sanitation Check List:

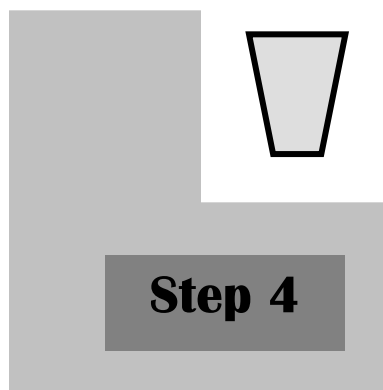
ZZZ Cider Mill
2 Apple Street, Anytown, CT

Product:
Batch:
Date:

Sanitation Condition	Date/time	Satisfactory/ Unsatisfactory	Comments/Corrections
1) Safety of water <ul style="list-style-type: none"> • Water source is safe (twice yearly test) • Test results are on file • No cross-connections in plumbing 			
2) Condition of Food Contact surfaces <ul style="list-style-type: none"> • Processing equipment, utensils, and food contact surfaces in working condition 			
3) Prevention of cross-contamination <ul style="list-style-type: none"> • Ventilation system is inspected for adequate ventilation, airflow and air pressure • Review of layout and structure to ensure that contamination of process does not occur from internal or external sources, including buildings, grounds, waste disposal areas. • . Coolers, including the evaporators, are cleaned annually, or more often if needed. 			



Monitor Key Food Safety Focus Points





Step 4 Monitor Key Food Safety Focus Points

Identifying food safety hazards

If you should decide to develop a HACCP plan, you would need to conduct a **hazard analysis**. A hazard analysis is a process of collecting and evaluating information on hazards associated with your juice product and your juice making process to determine which food safety hazards are reasonably likely to occur. A food safety hazard is any type of physical, chemical or biological contamination that may increase the risk that your juice or cider could make someone sick (see “**Food Safety Hazards in Juice and Cider**”, page 4).

Even though you are not developing a HACCP plan, you must determine and incorporate into your plan the most effective and appropriate prevention or control steps for the food safety hazards likely to affect your product and/or process. We have listed here the hazards you will most likely need to control in your food safety plan.

Some of these hazards may not be present in your process or product—and there may be hazards that are not listed here that you think you should include.

Biological Hazards

Bacteria and parasites most likely to occur in acidic juices (pH 4.6 or less):

- *E. coli* O157:H7
- various *Salmonella* species
- *Cryptosporidium parvum*, a protozoan parasite
- *Listeria monocytogenes*, an illness causing organism ubiquitous in nature

Bacteria/toxins likely to occur in low acid juices (pH greater than 4.6):

[A low acid juice (such as carrot juice or other vegetable juices) that is distributed under refrigeration and not subject to the Low Acid Canned Foods regulation.]

- toxins produced by certain strains of *Clostridium botulinum*

Viruses

- viruses (Norwalk virus, hepatitis A) have been implicated in foodborne illness outbreaks

Chemical Hazards

- Patulin (a mycotoxin that is produced by fungi commonly found on apples and pears)
- Allergens and food intolerance substances added to juice as ingredients (soy protein, sulfites, FD&C Yellow no. 5)
- Pesticide residues
- Lead
- Tin

Physical Hazards

- Glass Fragments
- Metal Fragments



Controlling the identified food safety hazards:

Each of the hazards that are identified for your product must be controlled. Here is a list of controls that can be used to prevent food safety hazards:

Controls for Biological Hazards

The 5-Log Pathogen Reduction

(adapted from the Guidance for Industry, Juice HACCP Hazards and Controls Guidance, First Edition, FDA, 2004,

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072557.htm>)

If you do not want to put a warning label on your product (if packaging, not serving by the cup), you must show that you are achieving a 5-log reduction in the pathogens most likely to affect your juice product (pertinent pathogens).

Hazard control words to know:

Pertinent organism is the most resistant microorganism of public health significance that is likely to occur in the juice and is the pathogen that you must target for the 5-log pathogen reduction treatment. By choosing the most resistant pathogen as your target, you are also treating the product for all other pathogens that are less resistant to the means of treatment. Examples include salmonella for orange juice, *e.coli* O157:H7 for apple cider, and *clostridium botulinum* for low acid juices.

The 5-log pathogen reduction requirement describes the minimum level of pathogen "kill" that your pathogen control measures must consistently achieve. The important thing to understand is that each log of kill is capable of causing a tenfold reduction in the number of organisms of the pathogen that the treatment is designed to kill, i.e., the "pertinent microorganism." A 1-log process would be one that is capable of reducing the level of the pertinent microorganism in the food by 10 fold, e.g., from 100 organisms (of the pathogen) per gram of food to 10 organisms (of the pathogen) per gram of food. A 2-log process further reduces the level of the target pathogen by another factor of 10, i.e., from 10 organisms (of the pathogen) per gram to 1 organism (of the pathogen) per gram of food. Thus, the 5-log performance standard means that you must treat your juice using a process capable of reducing levels of the pertinent pathogen in the juice by at least 100,000-fold ($10 \times 10 \times 10 \times 10 \times 10 = 100,000$).

This is illustrated in the following table:

Initial number of pertinent microorganism bacteria per gram of food	Log reduction	Decrease in pertinent microorganism bacteria levels	Percent of change	Final number of bacteria per gram of food
100,000 (10^5)	1	10-fold	90 %	10,000 (10^4)
100,000 (10^5)	2	$10 \times 10 = 100$ fold	99 %	1,000 (10^3)
100,000 (10^5)	3	$10 \times 10 \times 10 = 1000$ fold	99.9 %	100 (10^2)
100,000 (10^5)	4	$10 \times 10 \times 10 \times 10 = 10,000$ fold	99.99 %	10 (10^1)
100,000 (10^5)	5	$10 \times 10 \times 10 \times 10 \times 10 = 100,000$ fold	99.999 %	1 (10^0)



The initial number of pathogens present in your untreated juice is likely to be far less than 10^5 organisms per gram, i.e., only 10^1 or 10^2 organisms per gram. Applying a 5-log treatment to juice that may contain such levels of pathogens achieves a tolerable level of risk by ensuring that the process is adequate to destroy microorganisms of public health significance or to prevent their growth.

Whatever treatment you use (pasteurization, UV radiation) must consistently achieve at least a 5-log reduction in the "pertinent microorganism."

The Warning Label

The FDA requires that packaged juice products produced by retail establishments that do not undergo a treatment designed to ensure an effective 5-log pathogen reduction bear a warning label that explains that the juice has not been treated to ensure its safety and that it may contain harmful bacteria that can cause serious illness, especially in children, the elderly and persons with weakened immune systems.

Juice not sold in packaged form, such as juice served by the glass at restaurants and juice bars, is not subject to either the HACCP regulation or to the warning label requirement.

Warning label words to know:

The warning label must state: "**WARNING:** This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly and persons with weakened immune systems."

◆ **Controls for Bacteria**

1. Time/temperature control (e.g., proper control of refrigeration and storage time minimizes the growth of pathogen).
2. Thermal treatment (e.g., pasteurization).
3. Cooling and freezing (e.g., cooling and freezing retard the growth of pathogenic bacteria).
4. Addition of preservatives (e.g., preservatives inhibit growth of some pathogenic bacteria).
5. Source control (e.g., the presence or amount of pathogens in raw materials may be controlled by obtaining them from non-contaminated sources –those who use GAP or other food safety programs).
6. UV treatment
7. Pulsed light treatment
8. For fresh citrus juice only: Supplier guarantee for each shipment (only tree-picked fruit was supplied), culling to remove damaged fruit that may have pathogens in edible portion, washing/sanitizing fruit surface, extraction process that minimizes juice/peel contact
9. Warning label on untreated juice (not achieving 5 log reduction)

◆ **Controls for Viruses**

1. All of the methods used for Bacteria and...
2. Personal hygiene (especially hand washing) limits the spread of viruses. This is usually addressed in your sanitation program.

◆ **Controls for Parasites**

1. All of the methods used for Bacteria and...
2. Source control (e.g., preventing the parasite from having access to fruit by using GAPs).
3. Inactivation/removal (e.g., some parasites, such as *Cryptosporidium*, are resistant to chemical disinfection but can be inactivated by heating, drying or freezing).



Controls for Chemical Hazards

1. Source control (e.g., vendor certification and raw material testing).
2. Production control (e.g., proper use and application of food additives).
3. Process control (e.g., proper application of the process such as washing, scrubbing and culling to control patulin).
4. Labeling control (e.g., finished product properly labeled with ingredients and known allergens).
5. Production scheduling (e.g., finished product properly labeled with ingredients and known allergens).

Controls for Physical Hazards

1. Source control (e.g., vendor certification and raw material testing).
2. Production control (e.g., use of magnets, metal detectors, sifter screens)

Patulin

Controls for Patulin *(as described in Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition, US Food and Drug Administration, 2004)*

The potential for high levels of patulin to occur depends on several factors. There is no single factor that will, in all cases, determine whether your apple juice may contain high levels of patulin. The most significant factors are:

- Whether the apples used include fallen fruit - Apple juice made from apples that include fallen fruit is more likely to contain high levels of patulin than juice made from apples harvested to exclude fallen fruit.
- The condition of apples at the time of harvest - Juice made from apples with visible damage (e.g., from birds or insects, mold, or rot), is more likely to contain high levels of patulin than juice made from apples without such visible defects. Proper agricultural control practices by the grower, e.g., insect control, anti-fungal applications when needed, can assist in minimizing mold growth and rot on apples.
- How apples are handled prior to storage - Patulin production can occur during the storage of apples, particularly in apples that are bruised in handling prior to and during storage.
- Storage conditions for apples - Apples stored without proper temperature and atmospheric control of the storage environment are more likely to contain high levels of patulin than apples stored under controlled conditions.
- Monitoring apples during storage for core rot - Patulin production in stored apples can be caused by core rot that is not visible by observation of the exterior of the apple. Lots of apples that are experiencing core rot may be identified by cutting and cross-sectional examination. Eliminating lots of apples with high levels of core rot will reduce patulin levels in the juice.
- Culling or trimming apples prior to juice production - Growth of patulin producing molds is evidenced frequently by the appearance of visible mycelia or rot on the apple. Culling or trimming apples just prior to juice production to eliminate damaged, bruised, moldy, and rotting apples will reduce patulin levels in the juice.

It also makes sense to test cider several times during the season for presence of patulin. This may be especially important if making cider late in the season with stored apples/pears.



Food Safety Focus Points

The process steps that you have identified as the possible source of significant food safety hazards and the preventive measures will be your **Food Safety Focus Points**. This is where you will **prevent or control** the significant food safety hazards.

Commonly, in the production of fresh juice, food safety focus points include process steps where there are time/temperature controls, such as pasteurization (which kills pathogenic organisms) or cooling and refrigeration (which helps prevent the growth of microorganisms). In apple juice or apple cider, the culling step is important to the control of patulin.

It is important to remember that all **Food Safety Focus Points** must be **measurable, observable, and easily monitored**. It is a good idea to keep records on each Focus Point. These records are discussed as Step 6.

The charts below identify the Food Safety Focus Points for several types of juice and processing options. In addition, the Food Safety Hazards are listed along with the preventive measure, the standard for the preventive measure, and how the Focus Point will be monitored.

Food Safety Focus Points for pasteurized apple cider or apple juice:

Food Safety Focus Point	Food Safety Hazard	Preventive Measure Standard	How monitored?
Receiving apples	Patulin	<ul style="list-style-type: none"> ◆ Inspection and culling ◆ Only undamaged apples received 	Observation recorded on checklist
Culling step	Patulin	<ul style="list-style-type: none"> ◆ Inspection and culling ◆ Only undamaged apples are processed 	Observation recorded on checklist
Screening	Metal fragments	<ul style="list-style-type: none"> ◆ Inspect screening prior to processing ◆ Screening is intact 	Checklist
Pasteurization	Pathogens: <i>E. coli</i> O157:H7 and <i>cryptosporidium</i>	<ul style="list-style-type: none"> ◆ Pasteurization ◆ Minimum 160° F for 6 seconds (provides a 5-log reduction) 	Pasteurization log (time/temperature/flow rate)

Food Safety Focus Points for cider using UV light to treat your juice:

Food Safety Focus Point	Food Safety Hazard	Preventive Measure Standard	How monitored?
Receiving apples	Patulin	<ul style="list-style-type: none"> ◆ Inspection and culling ◆ Only undamaged apples received 	Observation/checklist
Culling step	Patulin	<ul style="list-style-type: none"> ◆ Inspection and culling ◆ Only undamaged apples are processed 	Observation/checklist
Screening	Metal fragments	<ul style="list-style-type: none"> ◆ Inspect screening prior to processing ◆ Screening is intact 	Checklist
UV treatment	Pathogens: <i>E. coli</i> O157:H7 and <i>cryptosporidium</i>	<ul style="list-style-type: none"> ◆ UV treatment ◆ Standard determined by manufacturer 	Printout of UV process log



Food Safety Focus Points for cider that is not pasteurized:

Food Safety Focus Point	Food Safety Hazard	Preventive Measure Standard	How monitored?
Receiving apples	Pathogens: <i>E. coli</i> O157:H7 and <i>cryptosporidium</i>	<ul style="list-style-type: none"> ◆ Good Agricultural Practices, ◆ No drops used 	Letters of guarantee from supplier
Receiving apples	Patulin	<ul style="list-style-type: none"> ◆ Inspection and culling ◆ Only undamaged apples are processed 	observation
Culling step	Patulin	<ul style="list-style-type: none"> ◆ Inspection and culling ◆ Only undamaged apples are processed 	observation
Screening	Metal fragments	<ul style="list-style-type: none"> ◆ Inspect screening prior to processing ◆ Screening is intact 	Checklist
Application of warning label	Pathogens: <i>E. coli</i> O157:H7 and <i>cryptosporidium</i>	<ul style="list-style-type: none"> ◆ Warning label ◆ Warning label applied 	Visual observation
Cold storage	Pathogens (especially in unpasteurized cider)	<ul style="list-style-type: none"> ◆ Temperature control ◆ Cooler temperature, 41°F 	Monitor cooler temperatures

Food Safety Focus Points for orange juice:

Food Safety Focus Point	Food Safety Hazard	Preventive Measure Standard	How monitored?
Receiving oranges	<i>Salmonella</i>	<ul style="list-style-type: none"> ◆ Supplier agreement specifying that only tree-picked fruit will be supplied ◆ No drops, tree-picked only 	Letter of guarantee
Culling step	<i>Salmonella</i>	<ul style="list-style-type: none"> ◆ Cull visually damaged fruit, (punctures, splitting, cuts, rot, mold in peel) ◆ Only undamaged fruit is processed 	observation
Sanitize	<i>Salmonella</i>	<ul style="list-style-type: none"> ◆ Sanitized wash used to achieve portion of cumulative 5-log pathogen reduction ◆ All fruit sanitized with sanitizer wash (concentration: Minimum of 200ppm of available chlorine; 30 seconds contact time) 	Observation Free available chlorine tested
Brush/Wash	<i>Salmonella</i>	<ul style="list-style-type: none"> ◆ Sanitized wash used with brusher used to achieve portion of cumulative 5-log pathogen reduction ◆ All fruit goes through brusher/washer 	Observation



Step 4 Worksheet:
Identify and document your food safety focus points.

ZZZ Cider Mill
2 Apple Street, Anytown, CT

Product:
Batch:
Date:

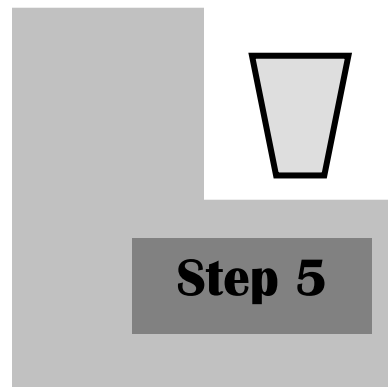
Food Safety Focus Points

Process Step/ Food Safety Focus Point	Food Safety Hazard	<ul style="list-style-type: none"> • Preventive Measure • Standard 	How monitored?





Develop a Traceback Plan





Step 5

Develop a Traceback Plan

(adapted from, FDA Guide to Minimize Microbial Contamination of Fresh Fruits and Vegetables)

Traceback is the ability to track food items, back to their source (processors, growers, packers, etc.). The ability to identify the source of a product through traceback can serve as an important complement to a food safety plan.

How regulators use traceback to solve foodborne illness outbreak investigations

Once an outbreak is suspected, public health officials begin by trying to identify common food items consumed during the time the consumer was likely to be infected by the pathogen. If they can implicate a particular food product and hazard analysis shows that other contributing causes were not to blame (for example, cross-contamination, ill food workers, other sources of infectious agent, etc.), health officials try finding out:

- Where the product was sold or prepared
- Identifying information, including product types, packaging, labeling, and lot numbers, if applicable
- When the product was purchased or prepared, and determine receiving, stock rotation, inventory, handling and shipping procedures

Depending on the pathogen involved, and the suspected food source, there can be wide variations in the reliability of the data obtained from such studies. If lot numbers/grower identifications are not commonly used or recorded on receipt/shipping records, investigators must rely on record review and interviews.

This method increases the time and resources necessary to trace an implicated product back to its source. Further, review of records that may not be complete and interviews with people whose memories may be imperfect make it more difficult to narrow down the cause(s) of an outbreak.

Challenges facing the juice industry

Fresh juice with a relatively short shelf life may be gone by the time an outbreak is reported, making it extremely difficult to identify the item causing foodborne illness. If an implicated source (for example, a field or packing or bottling facility) is identified, the source of contamination may no longer be present when investigators arrive on the scene. Outbreak investigations can be difficult – no one wants to make false accusations. The whole process can be costly in terms of dollars spent and reputations damaged.

Advantages of an effective traceback system

Despite the best of efforts by food industry operators, food may never be completely free of microbial hazards. However, an effective traceback system, even if only some items carry identification, can give investigators clues that may lead to a specific region, bottling company, packing facility, even field, rather than an entire commodity group. Narrowing the potential scope of an outbreak could lessen the economic burden on those industry operators not responsible for the problem.

From a public health perspective, improving the speed and accuracy of tracing implicated food items back to their source may help limit the population at risk in an outbreak. Rapid and effective traceback can also minimize the unnecessary expenditure of valuable public health resources and reduce consumer anxiety. In other words, it is good for all involved.



Develop an effective traceback plan for your operation

Retailers who process juice should examine current practices and develop procedures to track individual containers from the farm to the consumer. At a minimum, an effective traceback system should have documentation to indicate the source of a product and a mechanism for marking or identifying the product that can follow the product from the farm to the consumer. Documentation should include:

- a. Processing date,
- b. Batch or lot identification (if used in addition to processing date)
- b. Operation (farm, retail store and/or processor) identification

Some operators will choose to identify a batch as one days' production. Smaller operators may identify one weeks' production. Larger operations may identify more specifically. The batch identification parameters are important—they can impact on the size of your recall. A smaller batch (1/2 day or 1 load of fruit) will limit the recall to fewer bottles or units.

Some industry trade groups are developing technologies (such as bar codes, stamps, stickers, tags, etc.) to identify the source of food products and software to assist retailers in providing more accurate traceback to the processor.



Step 5 Worksheet

Operation: XXX Cider Mill
Product: Unpasteurized apple cider
Traceback Plan

1. Identify size/specifications of batch or lot.

- Consider if you want to identify your batch as one day's production, one half day's production, a week's production?
- If you are making more than one type of cider (some mixed with pear juice) how will that be identified differently from 100% apple cider?

Define "batch" size here: _____

2. Identify code.

- Date only (00/00/00)?
- Date and Number of batch?
- Color of cap?

Describe code here: _____

3. How will code be attached to the bottle?

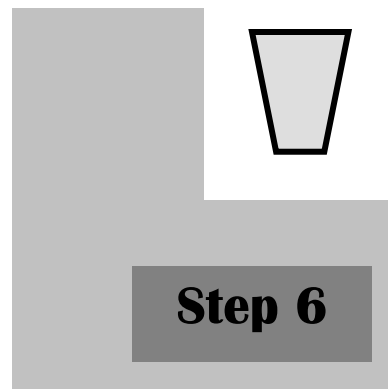
- Stamp on bottle (by hand)
- Stamp on bottle (by machine)
- Stamp on label (by hand)
- Stamp on label (by machine)
- Stamp on cap (by hand)
- Stamp on cap (by machine)
- Identifying sticker on bottle

Describe how code will be attached here: _____





Keep Good Records





Step 6 Keep Good Records

While not required by any regulation, keeping accurate food safety records just makes good business sense. Records provide the permanent written evidence that you process your juice in a manner that is consistent with accepted safe food handling practices. Should your juice be the subject of a foodborne illness outbreak investigation, records can show that you are making every reasonable effort to produce a safe product.

Include the following records in your Food Safety files:

- 1) A description of your process and procedures for making juice (optional)
- 2) Your Sanitation Plan and daily, weekly, monthly check sheets
- 3) The Food Safety Focus Points and preventive measures
 - Any records to show that you have monitored your food safety focus points.
 - Pasteurization records for each batch processed
 - Refrigerator/cooler daily temperature records
 - Records re: culling and inspecting for patulin prevention (notation that only undamaged fruit was processed)
 - Any patulin testing records you may have
 - Any calibration records for appropriate equipment (thermometers, pasteurizers)
- 4) A copy of your traceback plan including a description of product codes and batching or lotting procedures.

It is best if each record includes:

- The name and location of the processor
- The date and time of the activity the record reflects
- A signature or the initials of person performing the operation or keeping the record
- The identity of the product and the production code, lot and/or batch

It makes sense to keep all records from each batch or lot together (whether you define a batch as a days production, a weeks production or more specifically.)

You should keep records for refrigerated products for one year from the processing date.

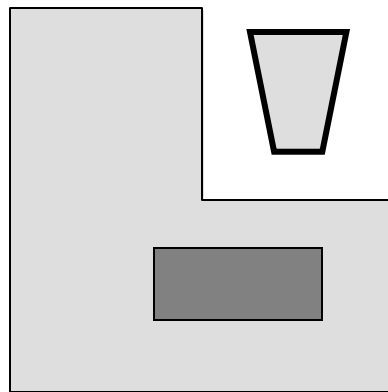


Step 6 Worksheet

- 1) Develop a list of all of the records you need to monitor food safety in your operation.
- 2) Develop a form for each of the records you need (use samples in this workbook as a guide).
- 3) Make a master list of each record and where each record is located – file, room, drawer, etc.



APPENDIX





Appendix #1

GOOD MANUFACTURING PRACTICES

[Code of Federal Regulations]

[Title 21, Volume 2]

[Revised as of April 1, 2003]

From the U.S. Government Printing Office via GPO Access

TITLE 21--FOOD AND DRUGS**CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES****PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR
HOLDING HUMAN FOOD****Subpart A--General Provisions****Sec. 110.3 Definitions.**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- (a) Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.
- (b) Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- (f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- (g) Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ``Food-contact surfaces`` includes utensils and food-contact surfaces of equipment.
- (h) Lot means the food produced during a period of time indicated by a specific code.
- (i) Microorganisms means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term ``undesirable microorganisms`` includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective ``microbial`` instead of using an adjectival phrase containing the word microorganism.
- (j) Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
- (k) Plant means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- (l) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
- (m) Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
- (n) Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (aw). An aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable



microorganisms.

(o) Sanitize means to adequately treat 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.

(p) Shall is used to state mandatory requirements.

(q) Should is used to state recommended or advisory procedures or identify recommended equipment.

(r) Water activity (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Subpart A--General Provisions

Sec. 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated

(1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food;

or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

Subpart A--General Provisions

Sec. 110.10 Personnel.

The plant management shall take all 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, 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.

(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.

(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 workstation, and at any other time when the hands may have become soiled or contaminated.

(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.

(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.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(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.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

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

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Subpart A--General Provisions

Sec. 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B--Buildings and Facilities

Sec. 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.
- (2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
- (3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
- (3) 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.

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.

(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:

- (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.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

- (i) Using protective coverings.
- (ii) Controlling areas over and around the vessels to eliminate harborages for pests.
- (iii) Checking on a regular basis for pests and pest infestation.
- (iv) Skimming the fermentation vessels, as necessary.

(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; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(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.

(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.

(7) Provide, where necessary, adequate screening or other protection against pests.

Subpart B--Buildings and Facilities

Sec. 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.

(b) Substances used in cleaning and sanitizing; storage of toxic materials.

(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.

(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.

(b) 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.

(c) 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.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall 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 shall be cleaned and sanitized as necessary.

(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.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

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

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Subpart B--Buildings and Facilities

Sec. 110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

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.

(b) Plumbing. 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.

(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 disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

- (1) Maintaining the facilities in a sanitary condition.
- (2) Keeping the facilities in good repair at all times.
- (3) Providing self-closing doors.
- (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).

(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:

- (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.
- (2) Effective hand-cleaning and sanitizing preparations.
- (3) Sanitary towel service or suitable drying devices.
- (4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
- (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or 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.
- (6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(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.

Subpart C--Equipment

Sec. 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.

(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.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.



(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.

(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.

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

Subpart D [Reserved]

Subpart E--Production and Process Controls

Sec. 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles.

Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) Raw materials and other ingredients.

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

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with



this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(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.

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

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

(b) Manufacturing operations.

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act.

Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 °F (7.2°C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140°F (60°C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(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.

(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.

(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.

(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.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breadings, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

- (i) Using ingredients free of contamination.
- (ii) Employing adequate heat processes where applicable.
- (iii) Using adequate time and temperature controls.
- (iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
- (v) Cooling to an adequate temperature during manufacturing.
- (vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

- (i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
- (ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
- (iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.
- (iv) Providing physical protection from contamination, particularly airborne contamination.
- (v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

- (i) Monitoring the aw of food.
- (ii) Controlling the soluble solids-water ratio in finished food.
- (iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the aw of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more



of the following practices:

- (i) Monitoring the pH of raw materials, food in process, and finished food.
 - (ii) Controlling the amount of acid or acidified food added to low-acid food.
- (16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.
- (17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

[51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

Subpart E--Production and Process Controls

Sec. 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.

Subpart F [Reserved]

Subpart G--Defect Action Levels

Sec. 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

- (a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
- (b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
- (c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
- (d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.
- (e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[51 FR 24475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]



