

MODEL GOOD MANUFACTURING PRACTICES (GMP) MANUAL FOR WINERIES – 2018



Wine Institute
425 Market St., Ste. 1000
San Francisco, CA 94105

Table of Contents

SECTION 1: INTRODUCTION	3
1.1 HOW TO USE THIS MANUAL	3
1.2 REGULATORY FRAMEWORK.....	3
1.3 DISCLAIMER	4
SECTION 2: GMP NARRATIVE MODELS	4
2.1 Qualified individual – 117.3 and 117.4.....	4
2.2 Personnel - 117.10	5
Employee, Supervisor, Visitor & Contractor Personnel Hygiene.....	5
2.3 Winery and Grounds 117.20	7
Grounds.....	7
Plant Construction and Design.....	8
2.4 Sanitary Operations 117.35.....	9
2.5 Sanitary Facilities and Controls: 117.37	14
2.6 Equipment and Utensils 117.40	16
2.7 Processes and controls 117.80	18
Raw Materials and Other Ingredients	19
Manufacturing Operations	20
2.8 Warehousing and Distribution 117.93	21
2.9 Food Defense 121.5	21
2.10 By-Products Diverted to Animal Food 507.12	21
Additional Resources	23

SECTION 1: INTRODUCTION

This manual provides compliance advice on the current Good Manufacturing Practices (GMP) regulations found in the US Code of Federal Regulations (CFR) under Title 21, Part 117, subparts A and B, and enforced by the US Food and Drug Administration (FDA). These are operational requirements for all food manufacturers and apply to wineries crushing grapes and other fruit, storing, transporting and/or fermenting the juice, and food-packaging wine for commercial, institutional, or consumer consumption.

This manual does not include California government requirements, nor those enforced by the US Alcohol and Tobacco Tax and Trade Bureau (TTB). Processing unfermented juice beverages is not addressed in this manual. FDA Juice HACCP Regulations (21 CFR 120) contains specific requirements for juice in addition to those found in 21 CFR 117, subpart B.

There is some overlap in the GMPs. When overlap occurs, it is a signal that FDA considers the items important enough to break out into details to ensure the safety of food.

The advice given here is intended to be adapted and implemented by individual wineries to meet their specific kinds of operations and facilities.

A written GMP compliance program is strongly advised, but apart from some specific tasks that must be documented (identified within the manual), is not mandatory under FDA regulations.

1.1 HOW TO USE THIS MANUAL

Each of the sections explain the purpose of the GMP, individual elements of each GMP written program, and an explanation of what the winery must do to accomplish the scope and tasks to be completed for each written model program. It is the preference of the winery as to which format they would like to include in their written food safety and operational program. Either format can also be easily modified to fit the needs of an individual winery and its unique operations.

1.2 REGULATORY FRAMEWORK

This manual is intended to provide recommendations for wineries of any size on how to build, and if desired, create a written GMP compliance program that meets the requirements of FDA's revised GMP. Each part of the Manual provides additional detail on how wineries can comply with each section of the revised regulations.

21 CFR Part subpart A – Definitions and Qualifications

117.3 Definition of *Qualified Individual*

117.4 Qualifications of Individuals Who Manufacture, Process, Prepare, or Pack Food

21 CFR Part 117 subpart B – Current Good Manufacturing Practice (cGMPs)

117.10 Personnel	
117.20	Winery and grounds
117.35	Sanitary operations
117.37	Sanitary facilities and controls
117.40	Equipment and utensils
117.80	Processes and controls
117.93	Warehousing and distribution
21 CFR 121.5	Food Defense
21 CFR 507.12	By-products for Animal Food

1.3 DISCLAIMER

This GMP manual is intended to assist wineries with meeting the applicable food safety laws and regulations enforced by the US Food & Drug Administration (FDA). There is no intent or representation by Wine Institute that implementing all of advice in this Manual is an implied or overt guarantee that the winery will be in full compliance with all FDA laws and regulations. It is the responsibility of the winery operators to know what is needed and to be in compliance with the GMP requirements.

SECTION 2: GMP NARRATIVE MODELS

2.1 Qualified individual – 117.3 and 117.4

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Management is responsible for assuring that every individual, including part-time and temporary employees who have assigned tasks in producing, storing, and transporting food are qualified to perform their assigned tasks. Every individual with food responsibilities must receive basic training in the principles of food and personal hygiene, and food safety. The basic principles include the importance of employee health and personal hygiene. For example, employees with real or apparent illness, open sores or wounds must not be assigned duties that might permit contamination of food. Employees must also receive basic training in personal hygiene, such as wearing clean garments and proper hand washing, as appropriate to the food, the facility and the individual's assigned duties.

For every individual with assigned food duties, make a record of training, including supervisors. A training record can be a sign-in sheet for a presentation on basic principles, with additional material for more specialized training. The material presented must be in a language understood by the individual being trained.

2.2 Personnel - 117.10

Employee, Supervisor, Visitor & Contractor Personnel Hygiene

General hygiene training is required for all processing staff, visitors or contractors that will be close to or come into contact with any area in which food, food-contact surfaces, or food, food-packaging is exposed, such as incoming fruit storage and processing, crushed fruit storage, fruit juice storage, fermentation, and bottling/food-packaging. The degree of personal hygiene training required is that which is appropriate to the operations where persons are. For example, cleanliness of hands and garments is more important where fruit, juice or other food is exposed than in areas where there is no exposed food, such as warehouses of finished wine.

“Food-contact surface” is discussed further below in 2.4, Sanitary Operations.

If a manager or supervisor sees an employee or other person that appears to have an illness, open wound, boils, sores, or infected wounds, or another apparent source of pathogen contamination, that person must not be assigned work in any operation that might result in food, food-contact surfaces, or food-packaging becoming contaminated until the condition is corrected. Personnel must be instructed to report health conditions to their supervisors.

Open or infected wounds, and boils that are adequately covered (*e.g.* by an impermeable cover) is an acceptable corrective measure.

Personal cleanliness and clean clothes - appropriate to assigned duties - must be maintained during operations when food is exposed. Storing of outerwear, other clothing unsuitable for a given operation, or other personal belongings must be stored in areas other than where food is exposed or where equipment or utensils are washed. If employee lockers are provided, management is responsible for assuring they do not become a source of contamination. One means to assure lockers are in good order is for management to make periodic inspections for trash, food residue, or pests to be sure they do not become a source of contamination.

Visitors entering any area in which food, food-contact surfaces, or food-packaging is exposed must not contribute to contamination. Visitors must wear appropriate outer garments as decided upon by management. If hair restraints or other measures are used by employees, visitors must be similarly garbed to the extent necessary to protect against allergen cross-contact and against contamination of food before entering processing areas. There will be few areas, if any, in a winery that require these measures. It is management’s responsibility to decide what is needed for a given area.

Hand washing is necessary for all individuals who will be in contact with food, food-contact surfaces, or food-packaging. Hands must be washed immediately after using restrooms, eating, drinking, or smoking, and immediately after hands have become soiled or contaminated, before

resuming work that includes contacting food, food-contact surfaces¹, or food-packaging materials².

Hand washing stations supplying warm potable water must be conveniently located near processing areas. Signs saying hands must be washed should be posted next to hand washing stations. Proper hand washing techniques may be an appropriate topic for employee training. Hand sanitizer stations may be placed near processing lines, but are not a substitute for hand washing. Sanitizers are not as effective in removing microorganisms as proper hand washing.

Anyone entering areas where food, food-contact surfaces, or food-packaging is exposed must not get so close that they may contribute to contamination of exposed food, food-contact surfaces, or food-packaging.

Unsecured jewelry, including earrings, watches, rings, neck chains, bracelets, and exposed piercings, that cannot be adequately sanitized when food is manipulated by hand, must be removed or covered. If covered, the covering must be sanitary and prevent anything from entering the food, food-contact surfaces, and food-packaging. Medical alert bracelets on the wrist or ankle and wedding bands without any attachments are allowed as long as they do not appear to present a risk of contaminating the raw materials, ingredients, food-packaging or finished wine. Winery management may choose to prohibit wearing false nails where food is exposed as a measure to prevent them from contaminating food.

If gloves are used in contact with food, food-contact surfaces, and food-packaging, they must be kept intact and sanitary.

The use of hair and beard nets when working in any area in which food, food-contact surfaces, or food-packaging is exposed, such as raw materials, ingredients, food-packaging and wine

¹ *FDA defines Food-contact surfaces as ‘those surfaces that contact human food and those surfaces from which drainage, or other transfer, 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.’ In addition to those items onto which food is intentionally placed, overhead objects that may drip or allow objects to fall onto food are considered food-contact surfaces.*

If the surface is not one for which food-contact “ordinarily occurs during the normal course of operations,” and is not overhead and likely to allow something to drop, then it is not a food-contact surface. Exteriors of tanks, equipment that is below or apart from actual food-contact, and which does not offer a probable means to contaminate food, are not food-contact surfaces.

² *FDA does not define “food packaging” in Part 117. With regard to wineries, the term is understood by FDA to mean the interior surface of containers and closures that is or will be in contact with wine. These surfaces, and the area in which exposed food-contact surfaces of packaging are held, must be kept clean and not contribute to contamination of the finished food.*

processing areas is recommended, but not required. Management is responsible for assuring finished products are not contaminated.

Eating food, chewing gum, drinking beverages, or using tobacco of any kind must not be allowed in any area where food, food-contact surfaces, and food-packaging is exposed.

2.3 Winery and Grounds 117.20

Grounds

The grounds about a winery that are under the control of the winery must be properly kept and maintained, and, whenever they are applicable, must include:

- Properly storing equipment, removing litter, waste and trash, and cutting weeds or grass within the immediate vicinity of the plant if they might otherwise become an attractant, breeding place, or harborage for pests.
- Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
- Adequately draining areas if they that might otherwise contribute to food contamination by seepage, foot-borne or vehicle-borne filth, or providing a breeding place for pests.
- If there is on-site waste treatment and disposal, the systems must be operated in an adequate manner so that they do not become 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 well maintained, management must take whatever steps are needed, such as trapping, extermination, or other means to exclude pests, dirt, and filth from the winery property that may otherwise become a source of food contamination.

It is up to management to decide what is appropriate. For example, driveways, lanes and areas serving vehicles should be paved, graded, drained and free from pools of standing water. If paving is not practical, dust control measures should be used during processing when food, food-contact surfaces, and packaging is exposed.

Waste material must be stored in suitable covered containers that prevent the waste material from attracting pests. For example, dumpsters and outside storage areas should be located on smooth, non-absorbent surfaces, and have lids that are kept closed except when trash is being added or removed.

Outdoor areas for the unloading and/or crushing of grapes, fruit, or other raw materials should be constructed of smooth concrete or equally impervious material, properly sloped to drain, or equipped with trapped drains of sufficient size to prevent the buildup of liquids.

Unused equipment and pallets should be organized and stored only in designated areas that are maintained so pests are not provided harborage.

If the winery property is bordered by grounds not under the winery's control and not properly maintained as described above, extra care must be exercised inside winery property to exclude pests, dirt, and filth that may be a source of food contamination. The extra steps may include inspection, pest extermination, or other means to prevent food contamination.

Plant Construction and Design

The winery buildings must be suitable in size, construction, and design to permit maintenance and sanitary operations for food-production purposes (*i.e.*, manufacturing, processing, packing, and holding). The facility must provide adequate space for placing of equipment and storage of materials to allow ready access for maintenance, sanitary operations, and the production of safe food. There should be enough space to allow for the segregated storage of ingredients containing allergens (any ingredient containing proteins from eggs, dairy, peanuts, tree nuts, wheat, seafood, shell fish, or soybeans), lubricants, and toxic chemicals.

Drips or condensate from fixtures, ducts and pipes must not be allowed to contaminate food, food-contact surfaces, or food-packaging materials. Aisles or working spaces between equipment and walls should be unobstructed and of adequate width to permit employees to perform their duties without risking contamination of food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

Walls, floors and ceilings must be adequately constructed and maintained. In food, food-contact surfaces, and food-packaging areas, the walls, floors, and ceilings should be light-colored, easily cleanable and constructed of material providing a smooth, impervious, cleanable surface. If concrete is used for floors or walls, its surface should be sealed with a clear or light-colored epoxy-based resin. Paint may be used on walls, but extra care must be taken to ensure peeling or mold growth does not occur.

Where necessary ("necessary" means when there are insects or other pests that might enter), doors, windows, roof openings and other openings that might allow the entry of pests should be self-closing, screened if required for interior ventilation, and kept closed at all times when not needed to be open to allow passage. All openings to the outer air where food is exposed must be effectively protected against entry by pests using one or a combination of the following:

- a. Screens.
- b. Effective electric screen panels.
- c. Fans or air curtains which provide sufficient air velocity to prevent the entrance of insects.
- d. Properly constructed and maintained flaps where it is impractical to use self-closing doors or air curtains.

Lighting, including skylights, located over wine/food preparation facilities and washing areas must be shielded, coated or otherwise shatter-resistant. Hand-washing areas, dressing and locker rooms, toilet facilities, and in all areas where wine is being processed, manufactured, processed, packed, or held, and where equipment or utensils are cleaned need adequate lighting.

To the extent possible, wiring and plumbing should be not be located where condensate and accumulated dust might fall in food, or onto food-contact surfaces, and food-packaging.

FDA recommends, but does not require, that all equipment and pallets of material be stored 18 inches away from any wall to allow for access for cleaning, placing of pest control devices if necessary, and to clean the equipment. What FDA does require is that storage conditions and practices not contribute to contamination.

Ventilation should be controlled to minimize dust, odors and vapors (including steam and noxious fumes) in areas where there might be allergen cross-contact, or that might contaminate food. Locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces. Restrooms should have exhaust fans that vent directly outside of the winery.

Utensil and equipment wash sinks with two or three compartments are recommended, but not required. If used, they should be large enough to accommodate the complete immersion of equipment and utensils. Each sink should be supplied with hot and cold potable running water that can reach the compartments. Employees should be instructed that these utensil and equipment sinks are not for hand-washing.

Whether or not compartmented sinks are used, equipment and utensils must be properly cleaned. Cleaning and sanitizing of utensils and equipment must be done in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

At least one service sink with a floor drain should be provided for the cleaning of mops and for the disposal of mop water or similar liquid wastes. Back-siphon preventers or vacuum breaks are not explicitly required by regulation, but their absence may be cited as an objectionable condition.

2.4 Sanitary Operations 117.35

General Maintenance

Buildings, fixtures, and other physical facilities of the winery must be maintained in a clean and sanitary condition, and as repaired and as clean as is necessary to prevent adulteration. To FDA, “adequate repair” means the roof is not leaking, there are not holes in walls, or major cracks in

floors or walls. The purpose of the regulation is for the structure to be sufficiently repaired and cleaned to prevent adulteration. It does not mean that structures must be in perfect condition, but must, at all times when processing occurs, be in good enough condition to not contribute contamination or adulteration.

Recommended but not required: Depending upon the size and complexity of the winery operation, it may be appropriate to establish a written maintenance program. Doing so will contribute to the safety of ingredients, food-packaging, in-process product and packaged wine.

If a maintenance program is written, it should include a schedule for examination and routine replacement of expendable items (such as air filters), and when needed, work orders for repair or replacement of durable equipment:

- a. Lighting as needed in all areas of the winery.*
- b. Air filter maintenance and replacement schedule.*
- c. Interior and exterior doors and windows are periodically checked to ensure they are tight and solid to prevent entry of pests and unauthorized visitors.*
- d. Hand washing stations.*
- e. Water and wastewater plumbing.*
- f. Electrical circuit breakers, switches and general wiring.*
- g. Water and wastewater treatment equipment.*

Even if no written schedule is prepared, equipment must be clean and sanitary upon start-up. If processing equipment becomes contaminated while in use, then processing needs to stop to allow for cleaning of the equipment. At the end of processing, equipment should be cleaned, as necessary for storage.

Winemaking operations should include routine procedures for:

- a. Examining equipment and utensils before each day's production for possible sources of contamination, including condensate and pests, by the operator.
- b. Examining utensils and food-contact surfaces (including equipment) that have come in contact with the floor, waste, or other insanitary objects.³
- c. Responding to food or wine processing equipment becoming contaminated.⁴
- d. Storing all equipment in a manner to protect against contamination of the product at the end of the processing day, or conclusion of an operating cycle, in such a manner that it will not contribute to contamination later in production.
- e. Sanitizing all utensils, spoons, spatulas, containers, etc. before start-up, at the end of each

³ *Contaminated food or wine processing equipment must be cleaned, sanitized, and inspected before restarting production.*

⁴ *If food or wine processing equipment is contaminated in any form of waste or floor splashing during production, the operator must immediately stop production. The section affected must be cleaned, sanitized, and then inspected before resuming production.*

production batch, and after a thorough cleaning.

Substances Used in Cleaning and Sanitizing, Storage of Toxic Materials

Cleaning compounds and sanitizing agents used for cleaning and sanitizing must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification. Use of EPA approved cleaning and sanitizing agents is satisfactory to meet this requirement.

Only the following toxic materials may be used or stored in a facility where food is processed or exposed:

- a. Those required to maintain clean and sanitary conditions;
- b. Those necessary for use in laboratory testing procedures;
- c. Those necessary for winery and equipment maintenance and operation, such as lubricants; and
- d. Those necessary for use in the winery's operations.

Chemicals for cleaning and sanitizing food-contact surfaces should be segregated from non-food grade or other toxic chemicals.

Toxic cleaning compounds, sanitizing agents, and pesticides must be identified, held, and stored in a manner that avoids contamination of food, food-contact surfaces, or food-packaging materials. A caged storage area or locker with limited access by authorized employees is one way to manage and control use.

Recommended but not required: A master list of all chemicals used in the winery should be maintained and updated as needed, but at least annually. No new chemicals are allowed in the winery unless reviewed by winery management and added to the master list.

All staff authorized to handle hazardous chemicals are to be trained on the proper use, labeling, and storage of hazardous chemicals as part of their annual GMP training as individuals qualified to perform these tasks.

Pest Control

When good housekeeping practices, door and window closures and/or screens, and routine cleaning are insufficient to prevent pest entry, then consider the use of more aggressive measures, such as sticky boards and insect-attracting UV light and/or pheromone traps inside the winery and the use of baited rodent traps outside the winery. Do not allow pesticide use to contaminate food, food-contact surfaces, or food-packaging. Be sure to comply with California

state licensing requirements for pesticide application and use.

Pest control starts with preventing pest entry. External doors, including overhead dock doors in areas where food is exposed, as well as pedestrian or truck access should be constructed and maintained to minimize the entry of dust, vermin and insects by at least one or a combination of the following methods:

- A self-closing device.
- Effective air curtains.
- A fly-proof screen.
- A fly-proof annex.
- Adequate sealing around trucks in docking areas.
- Electric insect control devices, pheromone or other traps and baits that are strategically located so they do attract insect to areas where food, food-contact surfaces, and exposed food-packaging material are present.

If using pest control stations, it is suggested they be checked once every two weeks and a record made of the general amount and specific type of pests caught. A site map that has the identification, location, and type of all sticky boards, interior insect and exterior bait stations and traps plotted on a facility diagram is helpful.

Recommended but not required: If pests are noticed as a problem, a trend analysis should be developed, plotting all of the individual pest control reports on a monthly basis to direct attention to any areas that consistently have pests. It helps to compare against the same month from the prior 2 years to determine if increased pest activity is normal or if a pattern of pest activity is not following the prior patterns for the same month the prior 2 years. Records of this monitoring activity should be maintained for review by designated staff and for future reference.

In the event of ongoing pest problems that the existing system does not appear to address, it is important to respond quickly with additional control measures, such as traps, etc. Be sure the building is in good repair. It may be necessary to hire a professional pest control service if the winery does not have one already under contract.

Share the results of the pest control program with staff. All employees should be encouraged and trained to observe and immediately report any pests in the winery.

Note: Pest control chemicals are toxic substances and must be stored so they will not contaminate food, food-contact-surfaces, and food-packaging. Storing pest control chemicals in a secured area separate from other chemicals used by the winery is advised.

Recommended but not required: Winery management should conduct a quarterly review of the winery layout and structure to ensure that pest activity is not observed internally or externally.

Cleaning, Sanitation and Storage of Food-Contact Surfaces

All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food. All food-contact surfaces must be properly cleaned and sanitized. A written cleaning plan is not required, but clean equipment is required.

Recommended but not required: If appropriate, a written Master Sanitation Schedule that identifies all winemaking equipment and utensils can be useful. General procedures and frequencies for the cleaning, sanitizing and proper storage between uses should be included.

All food-contact surfaces, utensils, and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of food or unintended allergen cross-contact.

IMPORTANT: Overhead surfaces that may drip or shed onto exposed food-contact surfaces are also considered food-contact by FDA.

Recommended but not required: Review existing procedures and consider if building a Master Sanitation Schedule is appropriate. If so, begin by first establishing a list of all winery fruit, juice and wine processing equipment and utensils.

For each piece of equipment and utensil:

- a. Identify the specific cleaning chemical(s), sanitizing chemical, minimum concentration, minimum cleaning and sanitizing solution temperature, and a reference to the Standard Operating Procedure (SOP) for details on the cleaning and sanitizing of each piece of equipment and utensil.*
- b. Identify if the cleaning will be Clean-In-Place (CIP), Clean-Out-of-Place (COP), or manually cleaned.*
- c. Identify the type of record that will capture the details of the CIP, COP and/or manual cleaning.*
- d. Describe the methods used to prepare cleaning solutions. Confirm the correct concentration of cleaning and sanitizing chemicals and check at least once per week.*

After cleaning, all equipment must be stored in a manner to protect against contamination of the product contact surfaces. At the close of an operating season, equipment should be cleaned before storage, and covered or protected from contamination by pests. If covering is not practical, then pre-production cleaning must ensure no contamination remains before using the

equipment.

Start-up Tasks for Food-contact Surfaces:

Utensils and food-contact surfaces (including equipment) that have come in contact with the floor, waste or other insanitary objects need to be cleaned, sanitized, and inspected before resuming operations.

If winemaking equipment becomes contaminated by any form of waste or floor splashing during operational activities, the winemaker must immediately stop operations. The section affected must be cleaned, sanitized, and then inspected before resuming operations.

Sanitation of Non-Food-Contact Surfaces

Non-food-contact surfaces of equipment used in processing must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

2.5 Sanitary Facilities and Controls: 117.37

Water Supply

Each winery must have adequate sanitary facilities and accommodations including water supply, plumbing, sewage disposal, toilet facilities, hand-washing facilities, and rubbish and trash disposal.

Water in wineries for washing of the grape and fruit stock, cleaning and sanitizing product contact and non-product contact surfaces (equipment and utensils), floors, walls, windows, hand washing, and drinking needs to be potable, with the source meeting US EPA Safe Drinking Water and State of California standards. If using a municipal water supply, then no further testing is required.

If individual water supplies (wells or non-municipal sources) and water supply systems for use in food processing and cleaning, need repair or have otherwise become contaminated, they must be disinfected before being returned to use.

Samples of individual water supplies (wells or non-municipal sources) should be taken upon the initial approval of the physical structure, after every six (6) months of use, and when any repair or alteration of the water supply system has been made. Since wineries seldom operate year-round, water testing from non-municipal sources should be performed at the beginning of each processing season. A winery's water sampling and testing should include analysis for total bacterial count and a coliform count.

Plumbing

All plumbing piping, fixtures, and drainage needs to meet the locally enforced sanitary plumbing code. There must be no cross-connection between the safe water supply and any unsafe or questionable water supply. Backflow preventers must be installed when there is the possibility of backflow occurring.

The piping within a facility must be designed to carry adequate quantities of water to locations where it is needed throughout the facility.

Drains must properly carry sewage and liquid disposable waste from the facility. There must be 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. If floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor, the floor should be sloped toward drains near the center of processing areas. Drains should not be located beneath equipment.

Sewage disposal

Sewage must be transported outside the facility by an adequate sewage system, or disposed of by other adequate means. Local water quality ordinances can specify what means are adequate.

Toilet facilities

Each winery must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials. It is expected but not explicitly required that doors to toilet facilities not open directly into areas where food is exposed, and should be self-closing. Doors to toilet facilities that do open directly to where food is exposed are likely to be cited by an FDA Investigator as an objectionable condition.

Hand-washing facilities

Each winery must provide hand-washing facilities that will ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. FDA does not specify what temperatures are suitable, only that it must not be so hot or cold that it will discourage proper handwashing.

Note: Some inspectors may say the regulations require hand washing water to be within a specific temperature range. If so, the regulation is not an FDA regulation for food processing. GMPs for food processing do not include a temperature specification for hand washing.

Convenient means located in or near areas where there is exposed food, food-contact surfaces, or food-packaging surfaces. Hand washing sinks are required in toilet facilities, and should be in lunch/break rooms. If not in lunch/break rooms, employees must be instructed to wash hands following eating, drinking, or smoking. Hand washing sinks are not required in areas where there is no exposed food, food-contact surfaces, and food-packaging.

Rubbish and offal disposal

Rubbish and any offal must be removed, stored, and disposed of in a manner that minimizes the development of odor, minimizes the potential for the waste to attract, harbor, or become a breeding place for pests. Disposal must not cause contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces in proximity to exposed food or food-contact surfaces.

2.6 Equipment and Utensils 117.40

Design and Material

All facility equipment and utensils used in manufacturing, processing, packing, or holding food must be designed and made of suitably durable and cleanable material. The workmanship must be adequately cleanable, and must be adequately maintained to avoid allergen cross-contact and contamination. Repairs must also be suitable and adequately cleanable. Equipment surfaces should be smooth and free from cracks and crevices.

Maintenance priority should be given to items identified posing a risk to food safety, with special attention given to any non-conformities, violations, or objectionable conditions identified by the State of California, FDA, Alcohol and Tobacco Tax and Trade Bureau (TTB), private third-party auditors and/or internal corporate audits. FDA expects food processors to know what needs to be done in their facility, and to promptly correct any condition that is putting food at risk.

Equipment should be made of material that is undamaged by the food being processed, easily cleaned, sanitized, and maintained in good condition. Wooden equipment and utensils, other than aging barrels, is discouraged because wood is a porous material and cannot be completely cleaned.

Seams

In particular, seams and welding repairs must be smooth, continuous, and not become a site where debris, dirt, or product residue will accumulate.

Non-food-contact equipment

Equipment in areas where food is manufactured, processed, packed, or held and that does not come into contact with food, must also be kept in a clean and sanitary condition.

Floor-mounted equipment, unless easily moveable, should be sealed to the floor or elevated to provide distance between the floor and equipment to allow for cleaning underneath.

Recommended but not required: If necessary for efficient operations, the winery maintenance manager should establish an equipment maintenance schedule for processing equipment, and review and repair all items that need periodic attention. If used, this preventive maintenance schedule should address:

- a. Annual or semi-annual review (depending on processing schedules) of all processing equipment and utensils.*
- b. Lubrication schedule (using only food-grade non-allergenic lubricants) for all processing equipment.*
- c. Bearing schedule to check wear and lubrication.*
- d. Valve schedule to check valve operation.*
- e. A review of the causes for disruptions after breakdowns or unplanned line shutdowns occur.*

In the event of an equipment failure during production hours, the crushed fruit, juice or wine should be protected from contamination while remaining in place, removed and stored for later processing, or discarded. If the juice is to be made into wine, then its further processing will minimize or eliminate risks from microbial contamination.

Following repair, food-contact surfaces of the repaired processing equipment should be thoroughly cleaned and sanitized prior to being used for winemaking.

Equipment in areas where wine, juice, food additives, or food-packaging that does not come into contact with food or packaging must be cleanable and kept in a clean and sanitary condition.

Instruments and Controls

If temperature control is needed to prevent a pathogen hazard or decomposition, each freezer and cold storage compartment must be equipped with an indicating thermometer, temperature-measuring device, or temperature-recording device that accurately shows the temperature within the compartment. This requirement for temperature monitoring applies only when a food safety or decomposition risk may exist when temperature is not within a set range.

Instruments and controls are used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions to control or prevent the growth of undesirable microorganisms in food, must be accurate, precise, and adequately maintained, and adequate in number for their intended uses. Proper pH, below 4.6, is important to protect wine from

pathogen contamination.

Compressed Air Systems

Compressed air or other gases (excluding commercially packaged gases such as carbon dioxide, nitrogen, and others) intentionally introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives. If the compressed air will be sprayed on any winemaking equipment, utensils, food-packaging or on the juice or wine itself using compressed air from an on-site compressor, then it should have an oil filter, moisture collector, and a particulate filter prior to use.

2.7 Processes and controls 117.80

General

All operations in the manufacturing, processing, packing, and holding of wine (including receiving, inspecting, transporting, and segregating) must be done using adequate sanitation principles.

For example:

- Product contact surfaces of equipment and utensils should be inspected and identified as clean prior to use.
- Hoses, and in particular, the ends, should be stored off the floor and flushed with potable water before use.
- Debris, unnecessary equipment, and other items not needed in a particular operation should be stored in other areas of the winery.

Appropriate quality control operations must be used to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. An appropriate degree of quality control for wine is to be sure that the final product is fit for consumption. Routine monitoring of the winemaking process is sufficient to meet the intent of this regulation.

Overall sanitation of the winery must be under the supervision of one or more competent individuals assigned the responsibility to maintain sanitation in the facility. Competence can be demonstrated by experience, training, education, or a combination of these.

FDA is evaluating whether allergens used in winemaking need to be declared on the wine label. At present, March 2018, there is no such requirement. If that changes, TTB and FDA will coordinate what label changes might be needed. Until that happens, there are no required changes in the use or labeling of allergens in winemaking.

If any non-alcoholic foods are made in the winery, the winery should maintain a list of all

allergens known to be received, stored, processed, packaged/bottled and/or shipped to customers.

The Big Eight allergens of concern to FDA are:

1. Milk
2. Eggs
3. Fish
4. Crustacean shellfish (e.g., crab, lobster, shrimp)
5. Tree nuts (e.g., almonds, walnuts, pecans)
6. Peanuts
7. Wheat
8. Soybeans

If any allergens are used, they should only be stored in a segregated area of the warehouse, with each different allergen stored in a manner that it will not cross-contact another allergen.

The facility management must exercise care to ensure that processing operations and procedures do not allow allergen cross-contact.

If a non-wine food contains known allergens and other non-wine food is made at the same winery that do not contain allergens, or contains different allergens, management is required to ensure there is no unintentional allergen cross-contact. If food with allergens is processed, packaged or bottled on the same processing equipment as food without allergens, then it is strongly recommended that an allergen processing matrix, including a cleaning schedule, be established, to minimize unintentional allergen cross contact.

Inspect lubricants for possible use of an oil derived from an allergen, such as soy or peanuts. Check with the lubricant manufacturer and determine if the lubricant is highly refined, which is effective in removing allergens.

In the event of an unintentional cross-contact between fruit, crushed fruit, juice, other ingredients, or food-packaging/bottles exposed to an allergen(s), the labeling on the finished non-alcoholic food must either indicate the allergen is present or the food must be discarded.⁵

Simply put, management is responsible for not allowing contamination from any source.

Raw Materials and Other Ingredients

This section is primarily directed toward wine additives, fining agents, and any non-wine foods made at a facility.

Contents of partially used bins, lugs, totes, other types of containers or bags of other ingredients,

⁵ This applies to products other than alcohol that may also be manufactured at the facility.

or food-packaging should be closed or covered, with the lot identifier visible, and properly stored if not completely used. In addition, partial bins, lugs, totes, other types of containers or bags should be emptied as soon as possible.

If food has become contaminated, it must be rejected, or if appropriate, treated or processed to eliminate the contamination. For example, if a batch has been contaminated with lubricating grease, it is adulterated. The winery may decide to discard or divert it to some use other than for human consumption.

If a spill occurs, juice or wine spillage should be cleaned up immediately using procedures appropriate to the location of the spillage.

Note: FDA does not require monitoring of the volumes of wine produced. TTB regulations on monitoring wine volume loss must be followed.

Piping and tank outlets need to be capped or covered when not in use, and cleaned and ready for use. Covers for juice storage and/or fermentation tanks containing juice or wine need to be kept closed while still allowing venting at times when being open is not a necessity for operations.

All raw materials, ingredients, food-packaging, in-process product and finished product other than wine need to be stored off the floor on pallets, barrels, slip-sheets or racks in their designated area (dry or cold storage areas). TTB requirements for storing wine must be followed.

Pallets need to be kept in good repair or discarded. When not in use, pallets should be stored in protected areas to protect them from accumulating bird droppings, attracting pests, or become a pest harborage area.

Outer surfaces of ingredient containers shall be clean before moving to a processing area.

Incoming loads and shipments should be inspected by adequately trained staff prior to unloading to ensure that the goods do not appear to be contaminated.

Incoming material that is accepted and not intended for immediate processing should be stored in pre-designated areas of the winery, appropriate to the storage needs of the material received. This usually means areas that are clean, dry and protected from the outside environment, pests, and contamination.

Manufacturing Operations

Winemaking operations must be conducted and managed in a manner that minimizes the potential for the packaged wine to be contaminated. Equipment, utensils, and food containers must be adequately maintained with appropriate cleaning and sanitizing practices, as necessary. If needed for thorough cleaning, equipment must be taken apart.

Unintentional allergen cross-contact must be avoided.

2.8 Warehousing and Distribution 117.93

The storage environment of the packaged wine, although protected by the bottle, plastic pouch or other types of food-packaging, needs to be clean and sanitary. If the winery uses the same storage area for the packaged wine as is used for ingredients and food-packaging, the packaged wine should be segregated to dedicated areas of the common storage area.

Trailers and railcars should be inspected prior to loading for shipment. If problems are noted that make the container unsuitable, it should be rejected and the owner or operator of the conveyance notified.

2.9 Food Defense 121.5

Wineries are exempt under 21 CFR 121.5(e) from the requirements of the rule on Mitigation Strategies to Prevent Intentional Adulteration, commonly known as the Food Defense Rule. Prudence dictates that measures recommended for food defense may be easily applied in wineries at low cost. Provisions to protect against theft are also useful in deterring attempts at intentional adulteration.

Fences, lights, locks, limited and controlled visitor access, all contribute to food defense. The cost of modest video surveillance is much less costly than it was only a few of years ago. If video surveillance is used, the monitoring should be focused on bulk vessels, whether for fermentation, storage, or aging. The probability of intentional adulteration after final packaging in retail containers is low.

2.10 By-Products Diverted to Animal Food 507.12

By-products of winemaking, such as seeds, stems, and pomace, without any further processing by the winery, may be directed to animal food. The by-products must be held under conditions that will protect against contamination by:

- Holding in appropriate containers and equipment, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
- Holding in a way to protect against contamination from sources such as trash; and
- During holding, identifying the human food by-products as intended for use as animal food.

The by-products must be labeled to identify the by-product by the common or usual name, either on the container or accompanying the shipment as human food by-products for use as animal food. Accompanying documents includes bills of sale or lading, invoices, and receipts.

If the winery is responsible for transporting the human food by-product, or arranges with another party to transport the human food by-products, then the shipping containers (*e.g.* totes, drums, and tubs) and bulk vehicles must be examined prior to use to protect against contamination from the container or vehicle.

Additional Resources

1. **Part 117 subpart B, the GMPs**
 - a. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117&showFR=1&subpartNode=21:2.0.1.1.16.2>
2. **Produce Safety Rule Fact Sheet**
 - a. <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf>
3. **Sanitary Transportation Rule Fact Sheet**
 - a. <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM494118.pdf>
4. **Copies of FDA Inspection Forms (FDA 482 Notice of Inspection & FDA 483 List of Objectionable Conditions)**
 - a. <https://www.fda.gov/downloads/iceci/inspections/iom/ucm127428.pdf>
 - b. <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm500328.pdf>