



# Good Manufacturing Practices (GMPs) For Michigan Apple Cider

Amended: April 9, 2006

**Primary Principle:** This document has been developed to define Good Manufacturing Practices (GMPs) within the state of Michigan for the purpose of manufacturing both fresh and treated apple cider that is safe and of the highest quality. It is intended only as a guide to understand how to apply current science and general food regulation in a cider-production setting. Strict adherence to these GMPs cannot guarantee hazard-free cider, however their implementation will serve to reduce the possibility that cider will become contaminated during the manufacturing process.

These GMPs were developed through collaboration by the Michigan cider industry, the Michigan Apple Committee, the Michigan Department of Agriculture, and Michigan State University Extension. Based on the most current available research, they will necessarily be revised as new information becomes available from researchers and industry & government experts.

Although the GMPs address cider production, they are applicable for other minimally processed juice products that are non-shelf stable (products which require refrigeration after production). Cider operators should consider the role GMPs play as one component in an overall food safety system that also includes standard sanitation operating procedures (SSOPs) and a hazard analysis critical control points (HACCP) plan.

**Scope of GMPs:** These standards apply to the production of treated and untreated cider and juice that is not shelf stable.

## Definitions:

**CFR:** The Code of Federal Regulations, Title 21 Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. These federal requirements are adopted by the Michigan Food Law, PA 92 of 2000, as amended.

**Dropped Apples:** Apples that have contacted the ground in any manner in the orchard, storage cooler, pressing room, or any other area. Where prudent precautions have not been taken to maintain separation of tree-picked and dropped apples, all apples shall be considered to be dropped apples.

**FFC:** Food Code, 1999 recommendations of the United States Public Health Service, Food and Drug Administration. This model retail code is adopted by the Michigan Food Law, PA 92 of 2000, as amended.

**Fresh, Raw, Unpasteurized, or Untreated:** Apple cider or juice which is produced by methods which do not include processing steps which have been shown to result in a 5-log (99.999%) reduction of disease causing microorganisms.

**HACCP:** Hazard Analysis Critical Control Points - A systematic approach to the identification, evaluation, and control of food safety hazards.

**Pasteurized:** Apple cider or juice, which has been sufficiently heat-treated to result in a 5-log (99.999%) reduction of disease causing microorganisms.

**Patulin:** A carcinogenic chemical substance that is produced as a metabolite of molds that occur naturally in the environment. These molds can grow on fruits such as apples, peaches and pears but they are most often associated with brown rot on apples. The action level for cider containing patulin is 50 µg/kg (50 parts per billion).

**Tree-Picked Apples:** Apples, which have been picked directly from the tree and segregated under sanitary conditions from dropped apples.

**UV Treated:** Treating a product with ultraviolet light to attain a 5-log (99.999%) reduction of disease causing microorganisms.

*Note:* use of the word "*should*" indicates that the item is a recommendation. Where "*shall*" or "*must*" is used, the item is tied to a requirement under existing law.

## Facility Requirements

1. Cider processing and other food-processing operations must be conducted in a separate, enclosed room or building. The food-processing room must have impervious walls and ceilings, the floors must be made of continuous sealed concrete or other equally impervious and cleanable materials provided with adequate floor drains. [21 CFR 110.20(B), FFC 6-101.11]
2. The processing and food sales areas must be adequately screened (16 mesh to 1 inch) to eliminate insect and rodent entry. Outer openings must be protected by closed, tight-fitting windows; solid tight-fitting doors or properly designed and installed air curtains or other effective means to prevent pest entry. Cold storage door plastic curtains are effective where entrance is by forklift. During the cider-processing season, overhead garage door openings can be framed in with temporary screened panels and a walk-in access door. Temporary screens should be tight fitting and constructed in a manner that allows the garage doors to be closed whenever desired. [21 CFR 110.20 (B) (7), FFC 6-202.15(A) (3), FFC 6-202.15 (D)]
3. Completely enclosed toilet facilities must be provided and should be conveniently located near the work area. A sign or poster, in the language(s) used by the current food employees, should be posted at all hand washing facilities to remind employees to wash hands. Conveniently located hand washing facilities must be provided and must have hot and cold running water and soap available. Also, there should be disposable towels and covered trash containers. [21 CFR 110.37 (D) (1-4), 21 CFR 110.37 (E) (1-6), FFC 5-

203.12, FFC 6-202.15, FFC 6-301.11, FFC 6-301.12, FFC 6-301.14, FFC 6-301.20, FFC 6-302.11, FFC 6-402.11]

4. Walls and ceilings should be light colored for easier cleaning and to provide better lighting on all work surfaces. Adequate lighting must be provided. All interior lights must be shielded to prevent pieces of glass getting into food in the event of bulb or tube breakage. [21CFR 110.20 (B) (4-5), FFC 6-202.11, FFC 6-303.11]
5. Grounds and buildings surrounding the cider operation must be free of conditions that may result in contamination of the product. This includes improperly stored equipment or spray materials, litter, waste, uncut weeds & grass, and other rodent or pest harborage. Grounds must be properly drained. [21 CFR 110.20 (A) (1-3), FFC 6-102.11, FFC 6-501.114]
6. All wash and wastewater must be disposed into an approved septic system, a municipal sewer system, or discharged in accordance with the Michigan Department of Environmental Quality regulations. [21 CFR 110.20 (A) (4), FFC 5-402.13, FFC 5-403.11]-
7. Storage of Equipment, utensils, chemicals, and supplies not used in food processing must be in an area clearly separated from storage of food processing items. [21 CFR 120.6 (A)(3), FFC 4-401.11, FFC 6-501.113]
8. All food contact surfaces must be constructed of food-grade materials that are safe, durable, corrosion-resistant, non-absorbent, and can be easily cleaned and sanitized. [21 CFR 110.40 (A), FFC 4-101.11, FFC 4-201.11, FFC 4-202.11]
9. Utensils and equipment made of copper and copper alloys must not be used to process or store apple cider or juice products. [21 CFR 110.40 (A), FFC

4-101.14]

10. All food contact equipment and supplies (examples: racks, cloths, tubing) must be stored off the floor at least 15 cm (6 inches) in a well-ventilated location that minimizes the potential for contamination from splash, dust or other contaminants. These items cannot be stored in toilet or mechanical rooms. [21 CFR 110.35 (E), FFC 4-903.11, FFC 4-902.12]
11. Hot and cold potable water must be available in all processing areas. Sufficient volume and water pressure must be available to dislodge particles of fruit and film from all surfaces. A high-pressure washer is highly recommended. Plumbing systems must be installed and maintained according to law. [CFR 110.37 (A), 21 CFR 110.37 (B) (1-5), FFC 5-101.11, FFC 5-202.13, FFC 5-201.11, FFC 5-103.11, FFC 5-103.12, FFC 205.15]
12. Potable water must come from an approved source, either through a municipal supply or private well. The water supply must be constructed, maintained and tested in accordance with MDEQ regulations. Approved wells must be tested at least once per year, preferably within 2 months prior to the processing of cider. [21CFR 110.37 (A), FFC 5-102.11, FFC 5-101.11]
13. All tubing carrying cider must be approved for food use. Plastic tubing should be transparent for ease of inspection and cleaning. Tubing must be protected from abrasion or breakage and should be easy to replace. Tubing must be as continuous as possible with couplings kept to a minimum and should be positioned so that no pockets of liquid remain when the tubing is rinsed (self-draining). [FFC 4-101.11]
14. Disassembling, cleaning, and sanitizing of tubing, clamps, couplings, and connections must be performed at least

after each day's run and prior to use following extended interruption. [21CFR 110.35 (D), FFC 4-602.11 (A) (5)]

15. The use of insecticide and rodenticide is permitted only in accordance with manufacturer labeled use and as permitted by state law. Precautions must be taken to prevent the contamination of food or packaging material with illegal residues. Poisonous or toxic materials must be stored separately by means of a partition or spacing away from food, equipment, and utensils. If used within the processing area, precautions must be taken to protect all raw ingredients and packaging materials. After spraying and before commencement of any food-processing operation, all food contact surfaces must be thoroughly cleaned and sanitized. [21 CFR 110.35(C), FFC 7-201.11, FFC 7-202.12]
16. Since pesticide regulations are constantly changing, be sure to know the current status of regulations regarding any pesticide used in and around your operation. For further information about insecticide and rodenticide, contact the Michigan Department of Agriculture, Pesticide and Plant Pest Management Division at (517) 373-1087.

## Employees

17. A person in charge must be assigned the responsibility to supervise the overall sanitation of the facility. The person in charge must ensure that employees working in the food operations are trained in and follow the GMPs. [21 CFR 110.10, FFC 2-101.11, FFC 2-102.11, FFC 2-103.11]
18. To prevent contamination of food products, all persons working in the processing and filling areas must wear clean outer garments, maintain a high degree of personal cleanliness and conform to hygienic practices while on

duty. Hands must be washed thoroughly before starting work, after each absence from the working area, between operations, and any other time when they have become soiled. All jewelry, except wedding bands, should be removed. Hair restraints (hairnets, headbands, caps, etc.) must be worn. If gloves are used, they must be designed for food handling operations. Whenever personnel change from non-food contact or cleaning operation to food contact operation, the individual must replace gloves or wash hands thoroughly before resuming food-contact operations. [21 CFR 110.10 (B), FFC 2-3, FFC 2-4]

19. Tobacco in any form must not be used in rooms where food or food ingredients are processed, handled or stored. [21 CFR 110.10 (B) (8) (9), FFC 2-401.11]
20. A person who has diarrhea or is a carrier of a communicable disease that can be transmitted by is prohibited from working with cider, apples, or other food. That person must be excluded from working in receiving, inspection, washing, or other processing areas. [21 CFR 110.10 (A), FFC 2-201]

## Harvesting

21. Steps can be taken in the orchard to minimize microbial contamination of apples. Harvest dropped apples as frequently as possible and keep separate from tree-picked apples. Care should be taken during collection to prevent the contact of rotten apples with wholesome fruit. [FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables]
22. Dropped apples must not be used for the production of fresh cider; but may be used where processing includes steps shown to effectively reduce the pathogenic microbial population in the resulting

product by at least 5 logarithms (99.999% destruction). Processors who use methods that effectively reduce the pathogenic microbial population by at least 5-log may use dropped apples. However, the use of dropped apples is strongly discouraged. Many factors should be considered when using dropped apples:

- Dropped apples have been shown to contain a higher bacterial load than tree picked fruit
- Contact with the orchard floor increases the likelihood for the presence of pathogens
- A very high level of fruit inspection, culling, and cleaning is required for using dropped apples.
- Patulin levels can be higher in bruised or lower quality fruit such as dropped apples.
- Cider makers cannot be assured of the safety of purchased dropped apples

23. Good hygienic practices should be used by those collecting apples and toilet and hand washing facilities should be readily accessible to field workers. [FDA Guide To Minimize Microbial Food Safety Hazards For Fresh Fruits And Vegetables]

24. Know the quality of the apples from which you will be making your cider. Only clean, wholesome apples must be used. The use of written contract specifications is highly recommended for cider producers who purchase cider apples. [21 CFR 110.80(A)(2)]

25. Visibly clean containers must be used to harvest and transport apples. Containers should be maintained and inspected continually. [21 CFR 110.80]

26. Unpasteurized apple cider must not be made from apples of orchards fertilized with human or animal wastes unless those wastes have been appropriately treated to eliminate pathogens. [FDA Guide To

## Receiving

27. If cider apples are purchased, adequate records should be kept of incoming lots, which identify the date of purchase and source of apples used to produce each lot of cider. Accurate records can limit product recalls and producer liability in the event of an outbreak.

28. Apples for processing should be kept in an enclosed area or otherwise protected from insects, rodents, and other pests. [FFC 3-305.11 (A), 21 CFR 110.80]

29. Animals (cats, birds, dogs, wild animals, etc.) are prohibited from processing and storage areas of the building. [21 CFR 110.37 (C), FFC 6-501.115]

30. Apple containers must be inspected upon receipt and before apples are used to assure the containers are free of visible filth that may contaminate the apples. [FFC 2-103.11 (E), 21 CFR 110.80]

## Inspection

31. Effective fruit inspection immediately prior to processing is a critically important step in assuring safe cider. All apples must be inspected so operators should assign enough trained employees to this task and make physical adjustments to equipment for adequate inspection (line speed, use of rollers, depth of line, ample spacing, etc.). All visible extraneous organic material must be removed by effective means prior to crushing/milling. Only intact, wholesome, tree picked fruit shall be used in the production of fresh apple cider. Wormy, decayed, or rotten fruit must be discarded before entering the washing step. [21 CFR 110.80]

32. If used, flume water must contain an adequate level of a sanitizer to prevent the spread of contamination from organic material via wash water. Flume water should be changed or reprocessed frequently to maintain adequate quality. [21 CFR 110.80]

33. Apples are susceptible to contamination by certain molds. Key strategies that may be used for the control of hazards associated with these molds are:

- Require supplier guarantees that no dropped apples are used
- Use apples that have been treated with an approved fungicide
- Review research on the interaction of varieties and storage conditions that limit growth
- Initiate effective culling and trimming processes
- Monitor for core rot throughout storage periods
- If apples are stored at 40°F or warmer for an extended period of time, treat apples with an approved post-harvest fungicide
- Remove decayed apples prior to washing
- Prevent mold growth on equipment by conducting effective daily cleaning and sanitizing

[21 CFR 110.80 (a)(3); FDA Juice HACCP Hazards and Controls Guidance]

## Washing and Brushing

34. Apples must be effectively washed and thoroughly cleaned (free of visible filth and debris) by an effective means prior to crushing. This can be accomplished as part of the grading operation. [21 CFR 110.80]

35. A food grade detergent and sanitizer used

in accordance with the manufacturer's specifications is recommended to further reduce biological contamination. [21 CFR 110.80, FFC 7-204.11]

## Crushing and Pressing

36. Crushing and pressing equipment must be cleaned and sanitized prior to start-up and at the end of each day of operation at a minimum. [21 CFR 110.35 D 2, FFC 4-702.11]

37. Equipment must be dismantled or disassembled as needed to insure adequate cleaning and sanitizing. [21 CFR 110.35 (D) (2), FFC 4-602.11 A 5]

38. Press cloths must be specifically designed for cider production, made of durable materials, and replaced when necessary. During processing, the cloths must be handled in a sanitary manner, which includes hanging the cloths on a line or placing them in a clean container off the floor between runs. At the end of each day's operation, all press cloths must be washed, rinsed, sanitized, and dried. The cloths may be dried by spreading them on a clean line in a well-ventilated and screened area away from flies and vermin. If a washing machine or dryer is used, it must be dedicated solely for the cloths and not for personal and work clothing. Use only approved detergents for washing press cloths. [21 CFR 110.40 (A), FFC 4-501.11, FFC 4-803.13]

39. Press racks must be made of food-grade plastic or hardwood, which has been maintained free of excessive breaks, open seams, cracks, chips, inclusions, pits and similar imperfections. Poorly maintained equipment can be impossible to clean and sanitize adequately. Keep press racks off the floor at all times. At the end of each day, all used press racks should be cleaned, sanitized, and allowed to dry. [21 CFR 110.40 (A), FFC 4-202.11]

## Antimicrobial Interventions

40. When pasteurization is used as a means of pathogen control, the time/temperature parameters found in current accepted studies should be met. Here are some combinations for cider at pH values of 4.0 or less using the target organism *Cryptosporidium parvum*:
- 161° F for 15 seconds (as used for milk)
  - 160° F for 6 seconds
  - 165° F for 2.8 seconds
  - 170° F for 1.3 seconds
  - 175° F for 0.6 seconds
  - 180° F for 0.3 seconds
  - Other scientifically validated parameters may be identified.

[21 CFR 110.80(b)(4); FDA Juice HACCP Hazards and Controls Guidance]

41. If UV treatment is used, lethality must be effective and should be validated. [21 CFR 110.80(b)(4)]

## Additives

42. If additives like sodium benzoate and potassium sorbate are used, care must be taken to assure they are weighed properly and added at safe & effective levels. [FFC 3-302.14, 21 CFR 110.80]

## Bottling

43. Cider must be bottled using new containers and caps, which have been properly stored to be free of dust, debris, and insects. Inspect containers carefully before filling. Refilling used, consumer containers risks contamination of filling equipment and cider and can take place only in a manner approved by the

44. Use microbiological testing procedures on production batches to identify sanitation failures or product contamination. While end product testing may not be a complete assurance that the cider is free of pathogens, indicator organisms such as coliforms or generic *E. coli* may help determine if adequate and consistent sanitation is being practiced. Testing may also play a role in HACCP plan verification and establishes a quality history. [21 CFR 120]

## Labeling

45. Retail containers must be properly labeled with the following information:
- Product identity (Apple Cider).
  - Ingredients (if additives are used, the function must be indicated. For example, “potassium sorbate (a preservative)” or “preserved with sodium benzoate”).
  - Sell-by Date.
  - Name, address, city, state, and zip code of manufacturer, packer, or distributor.
  - Net quantity.
  - A "Keep Refrigerated" statement should appear on the label.

Containers should be marked with a lot code. The Sell-by Date may be used for the lot code. Positive lot identification can limit the extent of a product recall should that occur. [21 CFR 101]

46. The method of treatment used on the cider (pasteurization or UV treatment), is not required to appear on the label but may be useful information to consumers. It is not permissible to use the term “pasteurized” for UV treatment. [21 CFR 101]

47. It is permissible to use terms like “tree-picked” or “made with hand-picked apples” if no dropped apples are used.
48. Containers of untreated cider must be labeled with the following statement:

**“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.”**

[21 CFR 120, 21 CFR 101.17 (g)]

## **Waste**

49. Pressed pomace must be disposed of properly and in a timely manner. Waste products must be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents. [FFC 5-502.11, 21 CFR 110.80]

## **Off-season**

50. During the off-season, press racks and cloths should be stored so that birds, animals, insects, etc. are unable to come in contact with them. Thoroughly clean, sanitize, and dry racks and cloths before storage. [21 CFR 110.80]

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