

CONSIDERATIONS FOR

CIDER SALES

BY FARM RETAILERS
IN TENNESSEE

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FOREWORD

The information contained in this document is intended for educational purposes and does not constitute legal advice or regulatory oversight. For the purposes of this document, the term cider generally encompasses apple juice, apple cider, other fruit juices and fruit ciders; it does not pertain to ciders containing alcohol. The primary purpose of the information in this publication is to assist Tennessee fruit growers who are interested in manufacturing nonpasteurized cider for retail-only sales. The information here does not address all of the requirements and regulations for cider manufactured for wholesale or pasteurized cider.

The intent of this publication is not to promote unpasteurized ciders but to

educate agricultural producers and food manufacturers about the regulations for marketing unpasteurized cider. Fruit cider is considered a potentially hazardous food. Unpasteurized cider has been associated with several food recalls over the years. Cryptosporidiosis (a parasite), *Escherichia coli* 0157:H7 (commonly referred to as *E. coli*), and salmonella (pathogenic bacteria) are just some of the organisms that have been involved with these recalls. Consumers most susceptible to potential hazards of consuming unpasteurized cider are young children, the elderly, pregnant women and immunocompromised populations. The health, safety and well-being of these populations should be considered when unpasteurized cider is being marketed.





BACKGROUND

In recent years, there has been a considerable amount of confusion regarding processing, labeling and regulatory requirements for farmers selling cider. Some of the confusion has come from inconsistent answers to questions including the following:

1. Does cider have to be prepared for sale in an inspected food processing facility?
2. Is pasteurization required for cider that is sold at farmers markets?
3. Is a warning label required on cider sold directly from fruit farms?
4. Can the required warning statement be displayed at the point of sale rather than on each package?



Cider is considered a potentially hazardous food and can result in serious foodborne illness if not properly manufactured, packaged and handled. Farmers in Tennessee who want to add value to fruit by manufacturing unpasteurized cider and selling directly to consumers (retail sales) must adhere to federal and state food manufacturing requirements in order to reduce risk to consumers. This publication outlines regulations administered by the U.S. Food and Drug Administration and the Tennessee Department of Agriculture (TDA) for the manufacture and retail sale of cider in Tennessee. Those interested in processing and marketing cider should thoroughly review the federal Juice HACCP rules and the FDA Food Code and discuss their specific processing methods and marketing outlets with the proper regulatory agencies.



FEDERAL REQUIREMENTS

As a result of several foodborne illnesses traced to the consumption of unprocessed juices during the mid-1990s, the FDA developed new regulations in 1998 for manufacturers of commercial juices to reduce the risk of foodborne illness and to better inform consumers of the hazards posed by unprocessed juice products. Ciders fall within this realm as they are the result of pressing fruits, most commonly apples. A fruit cider manufacturer is anyone preparing fruit cider for sale.

The FDA regulation for fruit juices and ciders has often been referred to as Juice HACCP and is found in Title 21 Code of Federal Regulations Part 120. The federal regulations require that fruit juices and ciders prepared for wholesale be manufactured in an inspected facility and that manufacturers have a written HACCP (Hazard Analysis and Critical Control Point) plan that guides their juice/cider-making process. Further, the rules require that the HACCP plan include control measures that achieve a 5-log reduction of any pertinent foodborne pathogen, which is discussed in more detail later in the publication.

Several exemptions appear in the federal Juice HACCP rules. The rules provide stipulations for three procedure exemptions:

1. Shelf-stable juices using a single thermal processing step.
2. Low-acid canned juice and juices subject to the acidified foods regulations.
3. Retail food establishments that make and sell juice directly to consumers.

A retail establishment is an operation that provides juice only directly to consumers. In this case, the term “provides” includes storing, preparing, packaging, serving and vending. A retail establishment does not include an establishment that sells or distributes juice to another business, even if the business also provides juice directly to consumers. The FDA Food Code provides guidance to retail juice producers on making safe products.

WHAT IS JUICE/CIDER?

The federal Juice HACCP rules apply to juice sold as a beverage or as an ingredient. Juice is the aqueous liquid expressed or extracted from one or more fruits or vegetables.

FOOD CODE

U.S. Public Health Service

FDA Food Code is a standard for protecting consumer health and ensuring the food supply is unadulterated and safe for consumption.

It is important to understand that when the criteria for an exemption is met, it does exclude a processor from all other requirements of the HACCP rules. For example, in the case of a retail exemption, juice manufacturers who only make and sell juice directly to consumers and do not sell or distribute juice to wholesalers are exempt from the HACCP rules. However, the manufacturers still must comply with state food processing regulations (TN Code Annotated Title 53), FDA food labeling regulations (21 CFR 101), weights and measures regulations (21 CFR 101.7), and must include the specific warning statement on the packaged juice products (21 CFR 101.17).

SPECIFICS FOR RETAIL-ONLY CIDER SALES

A fruit grower in Tennessee who is considering making cider for sale at their farm or for a farmers market booth may just manufacture the cider in a retail facility that has a TDA permit. For information regarding a permit from TDA for a retail food store/manufacturing facility, contact the Food and Dairy Division of TDA Consumer and Industry Services at 615-837-5193.

If the cider will be sold only to retail customers, a HACCP plan is not required; however, adherence to the FDA Food Code is still required. Cider is considered a potentially hazardous food product. Therefore, it cannot be made for sale in home kitchens. Cider that is sold at retail-only sites must be packaged in approved, unused and properly labeled containers. The label should include an accurate statement of the product's net weight, ingredient list, retailer name and address, product name and percent of juice.

Packages of nonpasteurized cider that are prepared by retail-only establishments must contain a specifically worded warning statement. The details of the warning statement are as follows:

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.





The FDA does not require warning labels for juice or cider that is sold by the cup/glass and intended to be consumed immediately; for example, at fruit orchards, farmers markets, roadside stands, juice bars and some restaurants.

The warning label must appear prominently and conspicuously on the information panel or on the principal display panel of the container's label. The word WARNING shall be capitalized and shall appear in bold type. The warning statement shall be set off in a box by the use of hairlines. A date marking (i.e., use by date) must be used to indicate the shelf life of the prepared food. This date must not exceed seven days, with the day of preparation starting the count and assigned as day one.

Refrigeration shall be applied to the prepared product and should not exceed 5 C (41 F). An exception to the use of refrigeration can be made through a variance request to the regulatory body doing the inspection. This process of requesting a variance would be initiated for prepared foods that were intended to be shelf stable using a reduced-oxygen packaging method or another form of preservation.

It is important to understand that when cider is manufactured for retail-only sales, 100 percent of the sales of the cider must be to retail customers. The cider in this scenario cannot be sold to wholesale customers. In addition, cider that will be sold at retail cannot be made in a domestic kitchen nor in an uninspected kitchen.

WHAT IS CONSIDERED RETAIL, RETAIL- ONLY AND RETAIL MANUFACTURING?

In the food industry, a retail sale occurs when a food item is sold to the final consumer. The final consumer is often called the end user or a household consumer. A retail-only food manufacturer is a business that prepares food items for sale only to retail customers. Retail manufacturers are those who provide juice directly to consumers, which includes storing, preparing, packaging and serving.

WHAT ARE THE MINIMUM FOOD LABELING REQUIREMENTS?

The following information must be on all food items packaged for sale:

- ☐ Name, street address, city, state and ZIP code of the manufacturer, packer or distributor.
- ☐ Accurate statement of the net weight of the food in the package expressed in English and metric units (ounces and grams).
- ☐ Use by date (date marking).
- ☐ Common or usual name of the food.
- ☐ The ingredients in the food in order of predominance by weight.
- ☐ Nutritional labeling (unless you are taking the small business exemption).
- ☐ Percentage of juice.

Definition: Small Business Nutritional Labeling Exemption. A food business would qualify for this exemption if the following criteria are met:

- ▶ Total gross sales for all products, food and non-food, do not exceed \$500,000.
- ▶ An employer has fewer than 100 full-time employees and produces fewer than 100,000 units (a unit is based on the primary packaging or, if unpackaged, the form in which the product is offered for sale (i.e., 1 jar = 1 unit, 1 apple = 1 unit, etc.) that are sold in the United States in a 12-month period.
- ▶ A nutritional content claim is not being made (i.e., “sugar free,” health claim, etc.).

CONSIDERATIONS FOR WHOLESALE CIDER SALES

Fresh cider is considered a potentially hazardous food. Therefore, cider manufacturing and packaging is subject to all food regulations applicable to potentially hazardous foods. The facility in which commercial cider will be manufactured in Tennessee must be permitted (issued a permit) by the TDA. Part of TDA's permitting process includes an inspection of the facility, equipment and processing procedures. These procedures are outlined in Rules of the Tennessee Department of Agriculture 0080-04-13. Wholesale cider manufacturers in Tennessee must adhere to a written HACCP plan, which includes measures to reduce pathogenic microorganisms by 5-logs and current Good Manufacturing Practices (GMPs). They must also follow written Sanitation Standard Operating Procedures (SSOPs).

The purpose of a HACCP plan is prevention rather than reaction to a problem. With its direct focus on prevention, a HACCP plan assures the production of food products are safe for consumers. The HACCP plan has seven key steps:

1. Conduct a Hazard Analysis,
2. Identify Critical Control Points (CCPs),
3. Establish Critical Limits,
4. Monitor CCPs,
5. Establish Corrective Actions,
6. Establish Verification Procedures, and
7. Recordkeeping

Adhering to these seven steps is essential in controlling biological, chemical and physical hazards. The control of biological hazards is the reason a 5-log reduction is so important for wholesale juice manufacturers.



As the seven steps of a HACCP plan are studied, it becomes apparent that the supporting material for the plan comes from GMPs and SSOPs. These procedures help to ensure the safety of the product as well as create a standard for employees to follow. The regulations for these procedures can be found in the Code of Federal Regulations under 21 CFR 117 part b. The following sections should be considered:

- | | |
|------------------------------------|--|
| 1. Personnel | 6. Processes and Controls |
| 2. Plant and Grounds | 7. Warehousing and Distribution |
| 3. Sanitary Operations | 8. Food Byproducts for Animal Feed Use |
| 4. Sanitary Facilities and Control | 9. Defect Action Levels |
| 5. Equipment and Utensils | |

Each one of these sections will provide a HACCP plan with a good foundation, which is needed to push food manufacturing procedures to be more proactive in identifying hazards.

Sanitation Standard Operating Procedures (SSOPs) can be found in 21 CFR 120.6. These operating procedures consist of control measures that help to prevent any unsanitary condition. Monitoring and recordkeeping shall take place to provide documentation that procedures are being followed and sanitary conditions are being maintained. SSOPs can be addressed in the HACCP plan, if they are not already being addressed in accordance with 21 CFR 120.6.

WHAT IS A 5-LOG REDUCTION?

With each log reduction, you will see microbial numbers drop by 10-fold. If we consider a 1-log reduction thermal process, this would mean we decreased the microbial population by 90 percent. Given we had 100 microorganisms at the start of our process and we go through a 1-log reduction thermal process, we would be left with 10 microorganisms after the process is complete. A 5-log reduction would be calculated the same way and give us a 100,000-fold (99.999 percent) microbial population reduction ($10 \times 10 \times 10 \times 10 \times 10 = 100,000$). A thermal process called pasteurization aids in our 5-log reduction achievement.

PASTEURIZATION

Pasteurization is the process of using heat to inactivate pathogenic microorganisms. This process not only inactivates pathogenic microorganisms, but also some spoilage microorganisms as well. The FDA recommends the following time/temperature pasteurization process for cider having a pH value of 4.0 or less. This process would achieve the 5-log reduction process.

Temperature (F)	Holding Time (seconds)
160	6.0
165	2.8
170	1.3
175	0.6
180	0.3



SUMMARY

Tennessee farmers can manufacture and market unpasteurized cider when several criteria are met. The manufacturing of the product (which includes pressing fruit and packaging the juice) must be done in a facility that holds a valid retail food permit from the Tennessee Department of Agriculture, and farmers must follow the correct regulation for retail (FDA Food Code,) and manufacturing (21 CFR Chapter 1 subpart b). The cider can be sold only to retail customers (the cider cannot be sold wholesale). Containers must be properly packaged and labeled including the minimum food label requirements and weights and measures requirements. A precisely worded warning statement must also be included. Although having a HACCP plan, which includes a 5-log reduction, is not required for retail sales, it is strongly recommended for one to have this in place for the protection of the consumer and business.

FREQUENTLY ASKED QUESTIONS

The following are the answers to some of the commonly asked questions regarding cider:

Does cider have to be prepared for sale in an inspected food processing facility?

Yes. All cider and juice products (pasteurized and nonpasteurized) that are prepared for sale must be made in a permitted and inspected facility.

Is a warning label required on cider sold directly from fruit farms?

Yes, a warning label is required on unpasteurized cider sold direct to consumers. However, if the cider is sold by the glass for immediate consumption, a warning label is not required.

Is pasteurization required for cider that is sold at farmers markets?

Not if the cider is made in a retail facility permitted by TDA and only sold to retail customers.

Can the warning statement be at the point of sale rather than on each package?

No. The warning label must be on each container.

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