U.S. Food and Drug AdministrationCenter for Food Safety and Applied NutritionApril, 2003

Guidance for Industry

Juice HACCP Small Entity Compliance Guide

The Food and Drug Administration has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (P.L. 104-121). This guidance document restates in plain language, the legal requirements set forth in 21 CFR part 120 concerning the safe and sanitary processing of fruit and vegetable juices. The regulations at 21 CFR part 120 are binding and have the force and effect of law. However, this guidance document represents the agency's current thinking on this subject and does not, itself, create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

SUMMARY

On January 19, 2001, the FDA published a final rule in the **Federal Register** that requires processors of juice to develop and implement HACCP systems for their processing operations (66 FR 6138). For all but small and very small businesses, the Juice HACCP regulations (21 CFR part 120) became effective on January 22, 2002. For small businesses the regulations became effective on January 21, 2003, and for very small businesses, the regulations will become effective on January 20, 2004.

This guidance focuses on key aspects of the juice HACCP regulations to assist small and very small businesses in implementing the regulations. The "Draft Juice HACCP Hazards and Controls Guide" is another source of information that small and very small businesses may find helpful in meeting the requirements of the regulations.

A. Coverage

1. What types of juice and juice products are covered by the regulations?

The regulations apply to juice sold as such or used as an ingredient in beverages . Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree as defined in § 120.1(a). Juice produced by a person who operates a retail establishment as defined in § 120.3(e) is not covered by the regulations.

The regulations require that processors apply HACCP principles if they make juice or juice concentrates for subsequent beverage use. Any processor making a product that could be labeled as 100 percent juice or a concentrate of that juice for subsequent beverage use must apply HACCP principles. For beverages containing less than 100 percent juice, only the juice ingredient must be made applying HACCP principles.

2. *When do I need to comply with the juice HACCP regulations?*

FDA encourages all juice processors to begin to comply with the regulations as soon as possible. The effective date was January 22, 2002. However, if your firm meets the definition for a small business, the effective date was January 21, 2003. If your firm meets the definition of a very small business, the effective date is January 20, 2004.

3. What are the definitions of a small business and a very small business?

Small businesses employ fewer than 500 persons (§120.1(b)(1)). Very small businesses must meet one of the following three criteria: annual sales of less than $500,000, total annual sales greater than $500,000 but total food sales less than $50,000, or operations that employ fewer than an average of 100 full-time equivalent employees and sell fewer than 100,000 units of juice in the United States (§120.1(b)(2)). The size of the business is determined by the magnitude of the corporate operation, not of the business unit.

4. If my juice is sold only within my state, do I need to comply with the new regulations?

Yes. These regulations applies equally to juices produced and sold within the same state as well as juices sold in interstate commerce.

5. If I pasteurize my juice, do I need to comply with the regulations?

Yes. All juice processors (except retail processors as defined in the regulations) must comply with part 120 for each type of juice they produce.

6. I am a dairy processor who purchases pasteurized apple juice concentrate to make a 5% apple juice beverage and a 15% apple juice beverage. Am I required to comply with the juice HACCP regulations, including the 5-log reduction?

Because you are not making juice as defined by § 120.1(a), you are not required to produce your juice beverage under a HACCP system, although it is highly recommended. However, the juice ingredient

(i.e., the pasteurized apple juice concentrate) must have been made under a HACCP program (including compliance with § 120.24).

7. Do these regulations cover fruit and vegetable purees?

The regulations apply to products sold as juice or used as an ingredient in beverages, including fruit and vegetable purees that are used in juices and beverages.

8. Are non-beverage foods that contain juice as an ingredient, e.g., a fruit flavored candy, required to be produced under a HACCP system?

No. The juice HACCP regulations apply to the processing of juice that is sold either as juice or sold for use as a beverage ingredient. Thus, a fruit flavored candy that contains juice as an ingredient is not required to be produced under a HACCP system.

9. Are food ingredients, other than juice, that are derived from fruit, e.g., citrus oil, required to be produced under a HACCP system?

No, the juice HACCP regulations apply only to the aqueous extract of fruits and vegetables that is sold either as juice or for use as an ingredient in beverages and not to other fruit or vegetable by-products such as citrus oil.

10. Would pulp from a fruit or vegetable used to make a juice or diluted juice beverage be considered juice under the juice HACCP regulations?

Yes. As noted, fruit and vegetable purees used as a juice ingredient are considered "juice" under the regulations. Pulp (i.e., pressed edible fruit or vegetable matter) is often a part of the aqueous liquid stream expressed or extracted from fruits and vegetables (e.g., citrus juice) and is comparable to puree except that it may not undergo the same degree of maceration. Pulp in a juice or a diluted juice beverage is considered juice or a juice ingredient; with a diluted juice beverage, processors are only required to comply with part 120 when making the juice ingredient (e.g., the pulp).

11. Would juice concentrates intended for uses such as flavors or sweeteners in foods other than beverages be subject to the regulations?

Juice concentrates intended for use as flavors, sweeteners, or similar uses in products that are not beverages are not subject to the regulations. However, because there may be problems segregating product used in beverages from that used in other foods, prudent juice concentrate processors should consider implementing HACCP for all of their juice products, not just those products that will be made into juice or used in beverages.

B. Retail Exemption

12. If a retailer decides to pasteurize his apple cider, does he need to have a HACCP system?

Retail producers of juices are not covered by the regulations and would not be required to establish a HACCP system regardless of whether they pasteurize their products.
A retail establishment is an operation that only provides juice directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending. A retail establishment does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers.

FDA's Food Code provides guidance to retail producers for making safe products.

13. Do the regulations cover apple cider that I make from my own apples and sell over the Internet directly to consumers? What about apple cider that I make from my own apples and sell at a farmers market?

If you make cider from your own apples (or apples that you have purchased) and only sell it directly to consumers (e.g., internet sales, farmers markets), you are considered a retailer and thus, your cider does not need to be processed under a HACCP system.

14. If I hire someone to make cider from my apples and I sell this cider at my roadside stand, is this juice producer required to have a HACCP system?

Yes. Only retail establishments are exempt from the regulations. Under the regulations, a retail establishment stores, prepares, packages, serves, and vends its product exclusively and directly to consumers. If someone else processes juice for a retail establishment, that processor is required to operate under HACCP principles.

C. Relationship to CGMP's

15. Do FDA's "Current Good Manufacturing Practices" (CGMP) regulations in 21 CFR Part 110 apply to firms that are subject to the juice HACCP regulations? Does compliance by these firms with the juice HACCP regulations replace the need to comply with the CGMP regulations?

Firms covered by the juice HACCP regulations are still subject to the CGMP regulations in Part 110. In fact, CGMP's are an essential foundation for a successful HACCP system.

D. The Juice Hazard Analysis

16. What is a hazard analysis?

The hazard analysis is an evaluation of potential microbiological, chemical, and physical hazards associated with a particular product and process and is used to determine which hazards are reasonably likely to occur and, if they occur, how they can best be controlled. The regulations requires that the hazard analysis be written.

17. Who should conduct the hazard analysis?

The regulations require that a trained individual, whether an employee or consultant, conduct the written hazard analysis that juice processors (except retail processors) are required to have for their process.

18. What is a "hazard that is reasonably likely to occur?"

A food hazard that is reasonably likely to occur is defined in § 120.7(a)(2) as one for which a prudent processor would establish controls to reduce to acceptable levels, prevent, or eliminate the hazard because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed.

A potential hazard that has a severe, acute public health impact (e.g., injury caused by ingestion of glass fragments) and that presents a significant risk, even at an extremely low frequency of occurrence, should be identified as a hazard that is reasonably likely to occur. A hazard that requires long-term (chronic) exposure to cause harm would need to occur at a higher frequency to be identified as a hazard that is reasonably likely to occur. The mycotoxin, patulin, which can occur at high levels in apple juice made from damaged, moldy or rotten apples, is an example of a chronic exposure hazard that could occur at such a frequency that it may need to be controlled through a HACCP plan if drops (i.e., apples that have fallen from the tree to the ground) are used to make juice or if apples are stored inappropriately prior to use for juice production.

19. What is the best way to begin a hazard analysis?

FDA believes that carrying out the five preliminary steps as outlined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) will assist processors in conducting a hazard analysis, as well as in other HACCP functions. These are:

- Assemble a HACCP team
- Describe the food and its distribution
- Identify the intended use and consumers of the food
- Develop a flow diagram that describes the process
- Verify the flow diagram

(See *"Hazard Analysis and Critical Control Point Principles and Application Guidelines,"* Journal of Food Protection, *Vol. 61, No. 6, pp. 762-775*).

Although FDA is not specifically requiring that juice processors use the preliminary steps, these steps will aid them in focusing on their specific product and process.
Flow diagrams that identify each significant step in the process are particularly helpful in conducting a hazard analysis, by facilitating determination as to whether a hazard may be introduced or controlled at each process point.

20. How do I conduct a hazard analysis?

You must do the following in a written hazard analysis (see § 120.7(a)):

(1) List all potential physical, chemical, and biological hazards that might occur in your juice.

(2) For each of the hazards identified in step 1, assess the likelihood of occurrence and the severity of health consequences in the absence of control. Then, determine, based upon the information gathered, whether each hazard is reasonably likely to occur in your product. You do not have to include hazards in your HACCP plan that are not reasonably likely to occur.

(3) Identify the measures that you can apply to control the food hazards identified in step 2 as reasonably likely to occur.

(4) Review the current process to determine whether modifications are needed.

(5) Identify critical control points for hazards determined in step 2 to be reasonably likely to occur.

21. What is a control measure?

A control measure is any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard (§ 120.3(c)). Control measures are further discussed in the next section.

22. What is a critical control point?

A critical control point (CCP) is a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level (§ 120.3(d)).

E. Control Measures

23. When am I required to implement a HACCP control measure?

You are required to implement a HACCP control measure if you determine in your hazard analysis that a food hazard (e.g., a microbial pathogen, potentially hazardous levels of patulin, glass shards) is reasonably likely to occur in a juice product you produce.

24. What are some examples of HACCP control measures?

Examples of control measures include thermal processing of juice and culling produce to eliminate visibly moldy, rotten, or damaged fruit.

25. If a grower implements FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," also referred to as FDA's Good Agricultural Practices (GAP) guidance document, is it considered a HACCP control measure?

No. However, juice processors are encouraged to work with the growers of the produce that they use to produce juice to evaluate and modify agricultural practices consistent with FDA's GAP guidance.

26. If I sell juice in bulk to company X for final processing and packaging of a diluted juice product, who is responsible for determining whether HACCP controls for chemical and physical hazards are needed for the juice?

Both firms are responsible for ensuring that the products they make are safe. However, only juice processors must comply with the juice HACCP regulations. Therefore, you must conduct a hazard analysis and determine whether there are chemical, physical, and microbial hazards that are reasonably likely to occur. You are responsible for controlling in your HACCP plan all hazards that are reasonably likely to occur. As a processor of a diluted juice beverage, company X is not a juice processor as defined by the HACCP regulations, and thus, is not required to have a HACCP system. However, company X must ensure that the juice ingredient used in the diluted juice beverage complies with part 120.

F. The 5-log Reduction Performance Standard

27. What is the 5-log pathogen reduction performance standard?

Performance standard requirements in general are goals that processors should achieve but provide flexibility on how processors accomplish them. The 5-log pathogen reduction performance standard required by the regulations 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 (see next question). Juice processors must apply controls (e.g., heat, UV light) to achieve the 5-log reduction required by the regulations.

28. Does a 5-log reduction in the bacterial plate count (i.e., aerobic plate count or total plate count) of a juice sample meet the performance standard requirement?

No. Under the rule, the 5-log reduction must be targeted to the "pertinent pathogen." The "pertinent pathogen" is the most resistant microorganism of public health concern that may occur in the juice. The pertinent pathogen may vary with the type of juice and the type of treatment used, though typically it would be *Salmonella*, *Escherichia coli* O157:H7 or *Cryptosporidium parvum.*

29. What times and temperatures should I use to pasteurize my juice?

Precise times and temperatures depend on the type of juice you make and your process. Scientific literature is an excellent source of information.

(See the following articles:

- Mazzota, Alejandro S., "Thermal Inactivation of Stationary-Phase and Acid-Adapted *Escherichia coli* 0157:H7, *Salmonella*, and *Listeria moncytogenes* in Fruit Juices," Journal of Food Protection, 1998, Vol. 64, No. 3, 2001, pp. 315-320,

- Deng, Ming Qi, and Cliver, Dean O., "Inactivation of *Cryptosporidium parvum* Oocysts in Cider by Flash Pasteurization," Journal of Food Protection, Vol. 64, No. 4, 2001, pp.523-527,

- Harp, James A., Fayer, Ronald, Pesch, Bruce A., and Jackson, George J., "Effect of Pasteurization on Infectivity of *Cryptosporidium parvum* Oocysts in Water and Milk," Applied and Environmental Microbiology, Vol. 62, No. 8, 1996, pp. 2866-2868, and

- Mak, Peggy P., Ingham, Barbara H., and Ingham, Steven C., "Validation of Apple Cider Pasteurization Treatments against *Escherichia coli* 0157:H7, *Salmonella*, and *Listeria moncytogenes*, Journal of Food Protection, Vol. 64, No. 11, pp. 1679-1689.)

30. How can I achieve a 5-log reduction without pasteurizing the product?

You can achieve a 5-log reduction by using control measures that have been shown to be effective in reducing the number of microorganisms. You can use one control measure that has been shown to reduce the pertinent microorganism by at least 5-log (e.g., high pressure) or a combination of control measures that have a cumulative effect of a 5-log reduction. Citrus juice processors may use surface treatments of the fruit to contribute towards attaining the 5-log reduction. All other juice processors must apply the 5-log process to the juice.

31. May I do the 5-log reduction on the fruit before extracting the juice?

Producers of juice other than citrus must apply the 5-log reduction treatment on the extracted juice. Citrus processors have the option of treating the surface of the fruit because it is unlikely that pathogens will enter sound, intact citrus fruit under current industry processing practices. If citrus juice processors use surface treatments to achieve all or part of the 5-log reduction, they must conduct tests to verify that the surface treatment is effective. Process verification procedures are found in § 120.25. (Note that according to § 120.24, the 5-log reduction treatment must occur within a single processing facility.)

32. May cleaning (i.e., washing of the produce) and culling (i.e., removal of damaged produce) be included among the control measures used to meet the 5-log reduction requirement?

No. All produce used for making juice must be cleaned and culled prior to extraction or, in the case of surface treated citrus fruit, prior to control measures used to meet the 5-log reduction requirement. For surface treated citrus, culled fruit is undamaged, tree-picked fruit.

33. May juice be treated in one processing facility to achieve part of a 5-log pathogen reduction, i.e., a 2-log reduction, and then transported to another facility for treatment to achieve the remainder of the 5-log reduction?

No. The entire 5-log reduction must be accomplished within a single production facility operating under CGMP's.

34. May I use fruit that has fallen from the tree to the ground (i.e., drops) to make juice?

You may use fallen apples if the fruit is cleaned and culled (i.e., damaged fruit removed) and the 5-log treatment is applied to the extracted juice. Citrus juice manufacturers using surface treatments must use undamaged tree-picked fruit.

35. I make shelf-stable juice that receives over a 10,000-log reduction. Am I still required to have microbial control measures in a HACCP plan? What about juice concentrates that are processed with over a 100-log reduction?

If you make thermally processed juice that is shelf stable or thermally processed juice concentrate, you are not required to include control measures in the HACCP plan for achieving the 5-log pathogen reduction. However, you must include a copy of the thermal process in your hazard analysis.

36. If I use a heat treatment process on my juice, can I assume that the process meets the 5-log pathogen reduction requirement of the HACCP regulations?

No. Except for processors of thermally processed shelf stable juices and juice concentrates, juice processors must establish and meet critical limits to ensure that the heat process is effective and consistently fulfills the 5-log reduction standard. Critical limits are the maximum or minimum values to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

37. If a juice product is treated by a means other than heat to meet the 5-log pathogen reduction requirement, is FDA approval required for the treatment?

Food additive regulations are required for treatments that use irradiation (e.g., pulsed light, UV light, ionizing radiation) and may be required for the use of certain chemicals. You are responsible for ensuring that all treatments, regardless of compliance with food additive regulations, achieve the 5-log pathogen reduction for your juice and process.

38. Does each processor handling a juice have to do a 5-log reduction?
Each processor handling the juice (except retail processors) must conduct a hazard analysis to determine whether there are hazards, including microbial hazards, that are reasonably likely to occur. Each processor must have controls for microbial hazards. This may be assurances that the juice will be given the required 5-log treatment at another processing location.

39. In the past, some processors have added a small amount of untreated juice to pasteurized juice for flavor enhancement. May I do this?

No. All ingredients of the juice must have received a 5-log reduction. Pathogens may be present in untreated juice and could contaminate the treated juice.

40. Can a flavor essence recovered during a juice concentration operation be added back to a juice after the juice has received a 5-log pathogen reduction treatment without requiring an additional 5-log treatment?

If you can demonstrate that the recovery process used to capture the flavor essence achieved the 5-log reduction, you can add the essence to the treated juice and you will have complied with § 120.24. Otherwise, the flavor essence must undergo a 5-log reduction process before it is added to treated juice or the juice with the flavor essence must undergo a 5-log reduction to comply with § 120.24. If the essence is not treated along with the juice, you must ensure that the process by which the essence is added to the juice does not allow for contamination.

G. Control Measures for Chemical and Physical Hazards

41. Are there any mandatory HACCP control measures for chemical hazards such as patulin or lead?

HACCP controls for specific chemical hazards such as patulin and lead are required when a processor determines that the presence of the chemical in the juice is a hazard that is reasonably likely to occur. In conducting a hazard analysis, a juice processor must consider all potential hazards and determine whether any of these hazards are reasonably likely to occur. If a hazard is reasonably likely to occur, a processor must include controls for that hazard in its HACCP plan.

42. I am a dairy processor who also makes juice using my milk processing equipment. Should I be concerned about milk residues (allergenic proteins) being present in the juice? What are the controls to prevent possible allergen cross-contamination (cross-contact) in this situation, and should these controls be included in my HACCP Plan?

Yes, when using milk processing equipment to process juice, cross-contact of milk protein into the juice is a concern. Allergens, such as milk, soy (soy milk), or egg (egg nog) should be considered chemical hazards that need to be addressed in your hazard analysis. Controls to prevent cross contact may include a rigorous sanitation regime in between a production run of milk products and a production of juice products. In addition to sanitation, production scheduling can have a large impact on minimizing cross-contact from shared equipment. Processors should try to schedule all non-allergen containing products first, followed by allergen containing products, with a full clean-up before again running a non-allergen product. Depending on the outcome of the hazard analysis, sanitation and production scheduling may be managed through Sanitation Standard Operating Procedures (SSOPs) or as part of the HACCP plan.

See Compliance Policy Guide 555.250 for the list of common food allergens recognized by the Agency.

43. Are HACCP control measures required for any specific physical hazards such as glass?

HACCP controls for specific physical hazards, e.g., glass, are required under the juice HACCP regulations when the processor determines in its hazard analysis that the specific physical hazard is reasonably likely to occur in the juice.

H. Records

44. What types of records will I be required to maintain to document my HACCP system?

You must maintain records pertaining to:

- SSOPs monitoring and corrective actions
- The hazard analysis
- The HACCP plan
- Operational records such as records of process monitoring, corrective actions, Verification, and validation activities
- Importer verification

General requirements and documentation requirements for records are included in §§ 120.12 (b) and (c).

45. How long must I keep the required HACCP records?

A processor of perishable or refrigerated juices and an importer of such juices must retain required HACCP records at the processing facility (processors) or at the importer's place of business in the United States (importers) for at least 1 year after the date that the products were prepared. A processor of frozen, preserved, or shelf stable products and an importer of such products must retain the required records at the processing facility (processors) or at the importer's place of business in the United States (importers) for 2 years or the shelf life of the product, whichever is greater, after the date that the products were prepared.

46. *Are juice processors required to make all of their records related to juice available to FDA inspectors?*

Only those records that are specifically required under § 120.12 must be made available for review and copying by FDA at reasonable times. These records are listed in the response to question 44.

47. What records are necessary to show that consumer complaints have been reviewed?

You must make a record that documents that you have performed a review of the consumer complaints that you have received. However, you are not required to show consumer complaints to FDA.

I. Training

48. What specialized training is needed to establish a HACCP system?

Certain key aspects of HACCP require training in HACCP principles. Individuals who perform certain functions related to the development of the hazard analysis and HACCP plan, and the verification, validation, corrective action, and record review requirements of the regulations must be trained (see § 120.13(a)). Training must be equivalent to a standardized curriculum that FDA recognizes as adequate. Job experience may qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. The Juice HACCP Alliance developed a standardized curriculum with input from FDA. The guidance document and the first edition of the Juice HACCP Training Curriculum can be accessed at: www.iit.edu/~ncfs/juice/JUICEHACCP.HTML.

49. Does the person(s) doing the key aspects of the HACCP system need to be an employee(s) of the juice processing firm?

No, the trained individual need not be an employee of the processor. However, regardless of who the trained individual is, the firm processing the juice is ultimately responsible for the safety of the juice and for compliance with part 120.

J. Imports and Exports

50. Does imported juice that will only be used as an ingredient in beverages have to be produced in compliance with part 120?

Yes. All imported juice, even if the juice is for use as an ingredient in a beverage, must comply with the juice HACCP regulations.

51. What are the responsibilities of juice importers under the juice HACCP regulations?

In brief, importers of juice either must ensure that all juice they offer for entry into the U.S. has been processed in compliance with Part 120, or import such juice from a country that has an appropriate memorandum of understanding (MOU) with the U.S. In addition, importers must maintain records that document the performance and results of the affirmative steps taken to demonstrate compliance with the regulations. Requirements for importers of juice are set out in § 120.14.

52. Do the regulations apply to juices and juice concentrates produced in the U.S. and intended for export either as bulk shipment or in consumer packages?

Processors of juice intended for export must comply with the juice regulations unless the juice at issue satisfies all of the following conditions:

- Meets the specifications of the foreign purchaser;
- Conforms to the laws of the importing country;
- Is labeled on the outside of the shipping package that the product is intended for export; and

- Is not sold or offered for sale in domestic commerce.

53. Are there any established memoranda of understanding (MOUs) for juice? How does someone go about establishing an MOU?

There are currently no established MOUs for juice HACCP. Normally, the process is started by a letter to FDA from a foreign government requesting initiation of the MOU process. Letters to establish MOUs for juice should be submitted to:

> Mr. Charles W. CooperDirector, International ActivitiesHFS-585Center for Food Safety and Applied NutritionFood and Drug Administration5100 Paint Branch ParkwayCollege Park, MD 20740

Examples of FDA MOUs can be found at the Food and Drug Administration International Cooperative Agreements web page.

K. Labeling Questions

54. If I want to label my product as pasteurized, what criteria do I need to meet?

Pasteurization is a heat treatment sufficient to destroy pathogens. Therefore, to be labeled as "pasteurized," a juice must be heat treated to destroy pathogens.

55. May I use the warning label statement on my products in lieu of implementing a HACCP system?

Generally speaking, use of the juice label warning statement is not an alternative to compliance with the HACCP regulations. All juice that is not appropriately treated to achieve a 5-log reduction in the pertinent pathogen is required to comply with the warning statement regulations; in the case of HACCP, all juice processors are required to comply with the regulations according to the staggered effectiveness dates (§ 120.1(b)) except retail establishments as defined by the regulations. Juice required to be produced under a HACCP system that is not so produced will be considered adulterated.

56. How can I label my apple cider that is processed using ultraviolet (UV) light ? Can I label it as "pasteurized" or "UV treated?" Can it be called "fresh?"

As discussed above, pasteurization is a heat treatment sufficient to destroy pathogens. Therefore, use of the term "pasteurized" on products that have been treated with UV light to attain the 5-log reduction is misleading and the product would be considered to be misbranded under section 403(a) of the Food, Drug, and Cosmetic Act. Possible terms you may use that would convey to consumers that the product has been treated with UV to control pathogens are "treated with UV light to control pathogens," "treated with UV light to control harmful bacteria," or "UV treated." Juice processed using UV light cannot be labeled "fresh."