

CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

<b>SUBJECT:</b>		<b>IMPLEMENTATION DATE</b>
<p align="center"><b>Juice HACCP Inspection Program (FY 07/08/09)</b> (Processor and Importer Inspections)</p> <p>This Program has completed a Good Guidance Practice clearance by CFSAN's OC/DFP&amp;G/FPB in May 2007 per CFSAN's ORP instructions</p>		UPON RECEIPT
		<b>COMPLETION DATE</b>
		09/30/09 or until revised
<b>DATA REPORTING</b>		
<b>PRODUCT CODES</b>	<b>PRODUCT/ASSIGNMENT CODES</b>	
<p>INDUSTRY CODES: 20-22, 24,25</p> <p>USE APPROPRIATE PRODUCT CODES</p>	<p align="center"><u>REPORT TIME FOR HACCP INSPECTIONS UNDER THE FOLLOWING PACS:</u></p> <p>03847H Processor HACCP Component of Inspection</p> <p>03847 Processor Filth/Sanitation Component of Inspection</p> <p>03847H Importer HACCP Inspection (<i>use Establishment Type A</i>)</p> <p>03S004 State Contract Inspections</p> <p align="center"><u>REPORT VERIFICATION SAMPLES UNDER THE FOLLOWING PACS:</u></p> <p>03847H HACCP Microbiological/Physical Hazards</p> <p>04847H HACCP Toxic Elements (Lead)</p> <p>07847H HACCP Mycotoxins (Patulin)</p> <p>09847H HACCP Color and Food Additives</p> <p>21847H Labeling</p> <p align="center"><u>REPORT FOR CAUSE SAMPLES UNDER THE FOLLOWING PACS:</u></p> <p>03847 For Cause Microbiological, Filth or Physical Hazards</p> <p>04847 For Cause Toxic Elements (Lead), Pesticides, Contaminants</p> <p>07847 For Cause Mycotoxins (Patulin)</p> <p>09847 For Cause Color and Food Additives</p>	

**Note:** Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted, (&) denotes one or more paragraphs were deleted, and (%) denotes an entire attachment was deleted.

**Note:** The performance of non HACCP inspection work may be guided by instructions in the current Domestic Food Safety Program, CP 7303.803 but reported under 03847, 04847, 07848, 09847 and not 03803. Exceptions are possible, (i.e., performing major functions outside the juice HACCP program in a dairy plant, e.g., bottled water, ice manufacturing, etc.) during a juice HACCP inspection. But normally, PAC 03803 should not be used for reporting time in performing juice HACCP and non-HACCP inspections.

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Districts are no longer required to complete or submit a Juice HACCP Questionnaire (Attachment A in the FY03 Juice HACCP Inspection Program).

**FIELD REPORTS TO HEADQUARTERS**

Domestic and Importer enforcement action recommendations (including copies of Warning and Untitled Letters) should be submitted directly to Division of Enforcement #.

**LABORATORY REPORTING**

Report the following analytical results into the FACTS Data System using the identified Problem Area Flags (PAF):

- |   |                                |
|---|--------------------------------|
| A. Microbiology: PAF = "MIC"            | F. Food Additives: PAF= "FAD"  |
| B. Filth: PAF = "FIL"                   | G. Color Additives: PAF= "COL" |
| C. Mycotoxins: PAF = "MYC"              | H. Labeling: PAF= "FDF" then   |
| D. Toxic Elements in Foods: PAF = "ELE" | "FDL"                          |
| E. Pesticides: PAF = "PES"              |                                |

PART I - BACKGROUND

On January 19, 2001, the Food and Drug Administration (FDA) published a final rule requiring the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of fruit and vegetable juices (66 FR 6137 "Hazard Analysis and Critical Control Point (HACCP): Procedures for Safe and Sanitary Processing and Importing of Juice"). FDA took this action because there have been a number of food hazards associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products are safe.

The regulation (21 CFR 120) took a phased-in approach for compliance to permit the regulated industry time to accomplish the training of personnel and adjust its activities to include necessary HACCP components. This approach resulted in the regulation becoming effective 1 year after the date of publication of the final rule, with special provisions that extended the phase-in to up to 3 years after publication of the final rule. In addition, FDA elected to make the first juice HACCP inspection educational, rather than regulatory, as long as there was sufficient progress to implement HACCP and there were no adulteration issues unrelated to the HACCP plan. FDA chose this approach because the first inspection would provide the first direct feedback from the agency on the status of the firm's HACCP system.

As of January 20, 2004, all processors and importers of juice and juice products have been subject to the juice HACCP regulation and the phased-in approach for compliance has ended. Furthermore, the educational inspections have been phased-out.

The compliance program covers domestic processors and importers of fruit and vegetable juices and provides instructions to ensure that they are being operated in accordance to the existing juice HACCP regulation.

**PART II - IMPLEMENTATION****OBJECTIVE**

The program objective is to ensure the safe and sanitary processing of fruit and vegetable juices. This will be accomplished by conducting inspections of domestic processors and importers in accordance to the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act, and the regulations promulgated under the authority of these acts.

**APPROACH****Processor Inspection:**

Note: A HACCP inspection is not a stand-alone part of the Juice HACCP Inspection Program but is one part of a larger system of controls procedures. For HACCP to function effectively, non HACCP areas of production should be working properly and therefore, non-HACCP elements of production should be reviewed.

The processor inspection component of the Juice HACCP Inspection Program consists of two parts:

1. A HACCP inspection for food safety by investigators trained to conduct juice HACCP inspections, at which investigators should inspect HACCP records and HACCP controls as they relate to safety hazards and
2. Inspectional coverage of non-HACCP areas (i.e., cGMPs, SSOPs) for those areas such as filth, sanitation, personal hygiene, etc., at which investigators will perform traditional inspections for the non-HACCP areas for all firms.

**Importer Inspection:**

The Importer inspection component of the Juice HACCP Inspection Program includes an inspection of the importer's place of business to determine compliance with the importer requirements found in 21 CFR 120.14 by investigators trained to conduct juice HACCP inspections. When the importer does not obtain the juice from a country that has an active MOU or similar agreement that covers the product, investigators should review the importer's records that document product specifications, the performance and results of the affirmative steps taken by that importer to determine the adequacy of those records for ensuring that the products being offered for entry by that importer were processed in accordance with 21 CFR Part 120.

**PROGRAM MANAGEMENT INSTRUCTIONS****A. Program Resources**

1. Domestic resources in the ORA Field Workplan have been provided to cover inspections and anticipated "For Cause" samples and juice HACCP verification samples. Districts should collect sufficient Juice HACCP verification samples, so that when added to their "For Cause" collections, meets their full domestic sample collection workplan obligation.
2. Import resources in the ORA Field Workplan are to be used to carry out inspections of importers for verification of HACCP. No samples are to be collected.

**B. Inspectional Priority #**

Note: At the discretion of the district, attempt to determine the inspectional priority as resources permit

1. Processors: Priority of inspections of firms should be given in the following order:
  - Juice processors that have been linked to recent outbreaks #
  - Unpasteurized juice processors #
  - Processors whose previous inspections were OAI
  - Processors that have not been inspected (all sizes)
  - Processors whose previous inspections were NAI/VAI
2. Importers: Priority of inspections of importers should be given in the following order:
  - Importers importing unpasteurized juice products #
  - Importers with the highest number of entry lines for juice products (the greater number of juice entries, the higher the priority for inspection).
  - Importers with previous Juice HACCP violations (after initial inspection)
  - Importers whose previous inspections were NAI/VAI

**C. Sample Collection - Domestic Processor Inspections Only**

Refer to Part III, Section A, Number 4 "Sampling" for complete sampling instructions.

"Verification" samples are "Official Samples" which are analyzed for one or more of the safety hazards identified in the firm's juice HACCP plan. They are used as a means of judging the overall effectiveness of the HACCP system. The results of these samples enable the Agency to make determinations about the likelihood of the occurrence of particular safety defects in products that are produced under HACCP preventive controls. Samples must be of the product/process combination covered during the HACCP inspection. When collecting "Verification" samples, one sample per inspection should be collected, unless the product's HACCP plan includes Patulin as a chemical hazard, then collect a split sample and ship one portion of the sample to the assigned chemical lab and the other portion to the assigned microbiological lab. When collecting apple juice at an initial processor (a processor who expresses juice from the apples themselves), try to obtain evidence regarding the type of apples used to produce the specific lot of juice sampled and document this evidence in the collection report, inspection report, and affidavit.

**D. Interaction with Other Programs****1. [Mycotoxins in Domestic Foods, CP7307.001](#)**

Juice samples collected only "For Cause" or HACCP "Verification" for the hazard, patulin, should be reported against this Juice HACCP Inspection Program CP7303.847 (PACs 07847 and 07847H, respectively). Generally, surveillance samples of apple juice for patulin analyses for the Domestic Mycotoxin Compliance Program (CP 7307.001) should not be collected at processors when conducting a Juice HACCP inspection, unless the firm produces different juices and apple juice was not the product covered during the HACCP

inspection. However because of limited resources and travel funds, the field may consider collecting surveillance samples at the same time as the EI so long as the lot samples is not the same as the production lot during the EI. "For Cause" and HACCP "Verification" samples are the only samples appropriate for the juice product covered during the inspection.

2. Toxic Elements in Food and Foodware and Radionuclides in Food, CP7304.019

Juice samples collected only "For Cause" or HACCP "Verification" for the hazard, lead, should be reported against this Juice HACCP Inspection Program CP 7303.847 (PACs 04847 and 04847H, respectively). No surveillance samples are to be collected for lead or other toxic element analyses per the Toxic Elements in Food and Foodware and Radionuclides in Food, CP 7304.019.

3. Domestic Acidified and Low Acid Canned Foods, CP7303.803A

Resources expended for inspections of firms under the Low-Acid Canned Foods Regulation (21 CFR 113) or the Acidified Foods Regulation (21 CFR 114) must be reported under CP 7303.803A.

4. Domestic and Import NLEA, Nutrient Sample Analysis and General Food Labeling Program, CP 7321.005

Refer to the current version of CP 7321.005 for instructions on the Nutrition Labeling and Education Act (NLEA). Coverage of the NLEA is to be accomplished during Juice HACCP inspections. Firms that are covered under the Juice HACCP regulation cannot use the Juice Warning Statement (21 CFR 101.17(g)"Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens") as a means of reducing the incidence of foodborne illness and death caused by the consumption of juice and juice products. These firms must now ensure the safety of the juice and juice products that they produce by complying with the Juice HACCP regulation.

5. Import Programs:

Sampling of imported juice and juice products should continue to be conducted and reported as directed under import alerts and bulletins, and appropriate import compliance programs (i.e.: Import Foods - General; Pesticides and Industrial Chemicals in Imported and Domestic Foods; Toxic Elements in Foods and Foodware, and Radionuclides in Food; Mycotoxins in Import Foods; and Domestic and Import NLEA, Nutrient Sample Analysis, and General Food Labeling Requirements Program). There are no import juice sample collections planned under the Juice HACCP Inspection Program at this time.

**E. Federal/State Contracts**

The current states where contracts have been established to perform Juice HACCP inspections are the following: #.

All Juice HACCP inspections conducted under state contract must be HACCP based and consistent this compliance program, the contract Statement of Work (SOW), and with the methods included in the Juice HACCP Regulator Training Manual. Districts must ensure that current or future state

contractor's staffs that will conduct HACCP inspections have completed the FDA Juice HACCP Regulator Training Course. This will be verified through contract oversight (FMD-76) or the annual District/State contract workplanning meeting.

**F. Interstate Milk Shippers (IMS) Listed Firms**

Juice-producing firms which are also on the IMS list are to be inspected under this compliance program. It is the responsibility of the investigator to make this determination and contact the Regional Milk Specialist (RMS)/or its equivalent and confirm whether or not a check rating will be conducted within that particular fiscal year and if so, the RMS is trained in Juice HACCP. If a check rating will not be completed during the fiscal year, districts should conduct an inspection covering ONLY the juice product to complete its responsibility of covering high risk firms. Districts and RMSs/or its equivalent should work together to coordinate these inspections.

If RMSs/or its equivalent are conducting check ratings of IMS firms and have completed the required Juice HACCP training, they are to conduct Juice HACCP inspections per this compliance program. All inspections are to be reported under the appropriate Juice HACCP PACS.

**PART III - INSPECTIONAL**

For inspectional instructions and procedures, investigators are advised to refer to the following references (websites are active):

- Juice HACCP Regulator Training Manual - HACCP inspection procedures/activities
- Juice HACCP Hazards and Controls Guidance - Potential hazards and recommended controls for juice processing
- Juice HACCP Questions and Answers (August 31, 2001)
- Juice HACCP Questions and Answers (September 4, 2003)
- FDA Investigations Operations Manual (IOM)
- Federal Register: January 19, 2001 (66 FR 6138) Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule
- Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices
- Recommendations to Processors of Apple Juice or Cider on the Use of Ozone for Pathogen Reduction Purposes

Previous minimum training requirement for conducting Juice HACCP inspections:

- Completion of the FDA Juice HACCP Regulator Training Course

The current training requirements for investigators performing domestic processor and importer Juice HACCP inspections:

- Attendance at the FDA three day Juice HACCP Alliance Training Course, the 3 day Juice HACCP Alliance Training course, or any other acceptable training course using the standardized curriculum or an equivalent alternative curricula covering the application of HACCP principles to the processing of juice, and:
- The Juice HACCP for Regulators videotaped training (10/30/02).

Note: all of the training materials are posted on ORA's website.

Districts are reminded to ensure that state investigators doing HACCP inspections under contract (if one exists) have been trained to conduct HACCP inspections, as described above.

The investigator's role includes evaluating the adequacy of a processor's HACCP plan and its implementation and an importer's verification procedures and their implementation. In situations where instructions provided to the field is not definitive with regard to a particular hazard being reasonably likely to occur (such as with Patulin and Metal/Glass Fragments), the investigator should obtain additional evidence to show that the hazard has a reasonable possibility to occur. Such evidence may include firm record showing that a hazard has occurred, analysis of the finished product, or direct observations by the investigator that the hazard did occur. If a question arises about the adequacy of a processor's plan or its implementation or an importer's verification procedures and their implementation, the investigator is encouraged to seek instructions from the district, region, National Expert, DFI, or CFSAN.

**A. Processor Inspection Component**

## 1. HACCP Inspection

The HACCP component of a processor inspection should be performed in a manner consistent with the Juice HACCP Regulator Training Manual. When an investigator encounters a facility with no HACCP plan or an inadequate HACCP plan, a full HACCP inspection must still be performed following the instructions established in the [Juice HACCP Regulator Training Manual](#). The investigator should, among other things: [1] construct a flow chart for the product(s) being evaluated (to be incorporated into EIR narrative or as attachment); [2] independently identify the appropriate significant hazards and Critical Control Points (CCPs); and [3] document if the CCPs are being adequately monitored. On the Form FDA 483, document all deficiencies from the juice HACCP regulation and other regulations, as they always have been. While the inspector must do a full HACCP inspection, this should not be interpreted to mean that either the flow chart or the HACCP plan will be prepared for the firm by the investigator.

The type of juice product chosen for an inspection should be one that is actively being processed at the time of the inspection and ideally the one that has the most significant potential hazard. Where past inspections of a firm detected significant problems with HACCP programs for a particular product, the follow-up inspections should concentrate on those, or similar products before moving on to other products.

Document deficiencies of the HACCP regulation on the Form FDA 483 in a manner consistent with the Juice HACCP Regulator training manual. Narrative EIRs should be completed as directed by existing instructions. Consistent with such instructions, these narrative reports should describe the firm's HACCP control program and sanitation monitoring program deficiencies noted during the inspection. Citations for Juice HACCP are available in Turbo EIR and should be used for 483s and EIRs.

Firms subject to the Juice HACCP regulation can not use the Juice Warning Statement (21 CFR 101.17(g)) in their HACCP plan as a means of reducing the incidence of foodborne illness and death caused by the consumption of juice and juice products. These firms must ensure the safety of the juice and juice products that they produce by complying with the Juice HACCP regulation. Please refer to CP 7321.005 for instructions on labeling for firms that are not subject to the Juice HACCP regulation.

If GMP deficiencies are observed during an inspection, the investigator should, if appropriate, list them on the Form FDA 483 using a GMP citation, and thoroughly describe in the EIR the significance of the GMP deficiencies by including observations that indicate there is a reasonable likelihood of a potential problem occurring.

## 2. Intrastate Firm Inspections

The Juice HACCP regulation, in conjunction with the PHS Act, gives FDA the authority to regulate intrastate juice processing firms. When performing inspections of intrastate firms, investigators should follow the same inspectional instructions as for interstate firms. If imminent public health conditions exist, contact

CFSAN/OC/ Division of Enforcement contact, for assistance (See Part VI, Program Contacts).

### 3. Non-HACCP Inspection Component

It is important to remember that the primary component of a juice inspection is HACCP, but also includes sanitation monitoring. Investigators should apply existing skills to look for issues outside of the HACCP portion of the inspection; for example, misbranding associated with labeling violations and conditions that may be indicative of economic fraud. In addition, investigators are responsible for conducting a thorough GMP inspection, including issues that do not fall under HACCP, for example, the use of hairnets or issues with safety lighting. If problems with sanitation are observed during the inspection, focus on the firm's sanitation practices and monitoring records. As in the past, citations are available in Turbo EIR and deficiencies should be noted on Form FDA 483.

#### Filth

Care should be taken during the inspection to fully identify sources of and possible routes of contamination of the product. For example, report the number and type of flies and times when they were on the product, open doors or damaged screens providing the flies a route to a toilet or to the outside, and the specific distances to animal feces, garbage or decaying animals.

For instructions, refer to:

- IOM, Current Edition, 5.4.7.2: Microbiological Concerns
- IOM, Current Edition, 8.3.4.6: Possible Contamination Source
- CPG, Section 555.425: Foods - Adulteration Involving Hard or Sharp Foreign Objects

Refer to the appropriate sections of the Domestic Food Safety Program, CP 7303.803, for inspectional instructions regarding the following non-HACCP issues:

- In-plant Pesticides and Contaminants
- Non-HACCP Color and Food Additives

### 4. Sampling - Finished Products

For specific instructions on sample/subsample sizes, refer to Sampling Schedule for Juice HACCP Inspection Program (Attachment A) and the instructions outlined below which distinguishes between "Verification" and "For Cause" samples.

#### HACCP Verification Samples

HACCP "Verification" samples are "Official Samples" of finished products and are to be collected at juice processing firms. Each district should collect a representative number of "Verification" samples correlating with the number of NAI/VAI inspections. The special verification PACs (those ending in "847H") are only to be used for these physical samples (refer to Compliance Program cover sheet). "Verification" samples are to be collected only when the investigator expects the inspection to be either NAI or VAI.

All "Verification" samples should be analyzed for all relevant safety hazards listed in the firm's HACCP plan. The investigator who collects the sample is responsible for listing the hazards (as listed in the HACCP plan) needed to be analyzed on the FACTS Collection Report in the box labeled "Reason for Collection." Refer to the current ORA Workplan for assigned servicing laboratories.

**NOTE: If a "Verification" sample requires both patulin and micro analyses and the assigned chemical and microbiological laboratories differ, collect a split sample and send a portion to the appropriate chemical and microbiological labs.**

#### **"For Cause" Safety Sample Collection**

Physical HACCP (e.g. safety issue) samples are not to be routinely collected "For Cause" but are to be collected ONLY when it is necessary to determine the extent of a safety problem and to facilitate an appropriate follow-up. Collect "For Cause" samples of finished product to determine if an imminent public health hazard exists. Only us PACs: 03847, 04847, 07847, 09847 when collecting "For Cause" samples (refer to Compliance Program cover sheet for additional details).

**NOTE: Most deficiencies of the Juice HACCP regulation should not require a physical sample to confirm or document them.**

Some examples of situations when "For Cause" samples may be taken include:

- If the investigator observes moldy apples being mixed into batch (for Patulin).
- If investigator observes broken bottles on the processing line (for Glass).

Surveillance samples of apple juice for patulin analyses for the Domestic Mycotoxin Compliance Program (CP 7307.001) should follow the instruction listed in Part II, Page 3.

#### **Non-HACCP Sample Collection**

Samples for Non-HACCP defects are to be collected if inspectional conditions warrant (i.e. "For Cause"). Refer to Attachment A for non-HACCP food and color additive samples. Refer to the DFI Miscellaneous Inspection Guide, Section 10 and 11, for economic adulteration samples. Please collect in duplicate to provide for the 702(b) portion.

#### **Documentary Samples**

All documentary samples (e.g., to support interstate commerce) are to be reported only under PAC 03847. Documentary samples are not to use the PACs (those ending in 847H) reserved for "Verification" samples nor are they to count towards district workplan obligations.

#### **B. Importer Inspection Component**

An importer inspection should be performed in a manner consistent with the [Juice HACCP Regulator Training Manual](#), Chapter 13, Importer

Inspections and Imports. Refer to Part II, Section B, for inspectional priorities of importers.

The inspection must be performed following the instructions established in the [Juice HACCP Regulator Training Manual](#). The investigator should, among other things, [1] Determine the foreign sources of the selected imported juice product(s), [2] Review importer's product safety specifications, [3] Review importer's verification plans, and [4] Review importer's verification records. On the Form FDA 483, document all deficiencies for imported products from the requirements in the juice HACCP regulation.

Narrative EIRs should be completed as directed by the most current instructions with documentation of the firm's HACCP deficiencies noted during the inspection. Citations for Juice HACCP are available in Turbo EIR and should be used for 483's and EIRs.

**Report time for Importer HACCP Inspections under PAC 03847H and use the Establishment Type "A" for Importer/Broker.**

**PART IV - ANALYTICAL**

Use the most current compendial method that exists for particular project areas where applicable.

Note: Reserve samples should be held under refrigeration until such time as the analyses are completed. After analysis, all reserve samples from opened containers and all non shelf stable products (including 702(b) samples) should be frozen until destruction is authorized.

When HACCP "Verification" and "For Cause" samples are warranted, use the methods referenced in the appropriate section of the Part as follows:

- A Project 03: Filth, Mold and Foreign Objects: Microscopic/Macroscopic**
- B Project 03: Microbiological**
- C Project 04: Toxic Elements**
- D Project 07: Natural Toxins (Patulin)**
- E Project 09: Food and Color Additives**
- F Project 21: Food Composition, Standards, Labeling and Economics**

Please refer to the current ORA Field Workplan for servicing laboratories.

**A. Project 03: Filth, Mold and Foreign Objects: Microscopic/Macroscopic**

Methodology:

Each subsample should be examined individually (not composited).

**Filth** - Microscopic (non-HACCP sample)

1. AOAC (current edition) Chapter 16, Extraneous Materials: Isolation
2. JAOAC (Interim Official First Action Methods)
3. Microanalytical Procedures Manual (MPM)

**Hard/Sharp Objects** - Macroscopic (HACCP Physical Hazard)

1. Please reference MPM website:  
<http://vm.cfsan.fda.gov/~dms/mpm-toc.html>
2. In the interim or if inspectional evidence is found, call CFSAN Contact for special instructions.

**B. Project 03: Microbiological**

General Information for All Pathogen Isolates:

All cultures should be shipped by FedEx overnight and should conform to the rules and regulations regarding shipment of infectious agents.

Record all analytical results in FACTS using PAF = MIC, and sub PAFs = SAL, ABR, as appropriate.

Ensure that the appropriate servicing laboratory is selected and identified in FACTS - MIC screen.

**Special Method Instructions:**

1. **E. coli O157:H7**

Please refer to eBAM Chapter 4a, Section M, "Media Preparation: In preparing, EEB, in lieu of using 0.05 mg/L cefixime, use 0.0125 mg/L."

Each subsample should be analyzed on an individual basis. Take 200ml of each subsample and centrifuge the juice at 10,000 X g for 10 minutes. After decanting the supernate, the pelleted material can then be transferred to 225 ml of 1X EEB for incubation by the standard procedure. After addition of the pellet, the pH of the enrichment broth should be checked with pHDrion paper and adjusted to pH 7.0 with 1N NaOH if necessary.

- a. After 24 hrs of enrichment, spread plating 0.1 ml of 1:10<sup>2</sup> through 1:10<sup>4</sup> dilutions of the enriched sample will help assure that individual colonies will be observed without competitor overgrowth on the TCSMAC plates. The appropriate dilutions to be used may vary. Refer to the reagent section of 4a for specific diluents.
- b. Continue with methodology as outlined in eBAM, Chapter 4a, Section O, "Isolation."

For positive *E. coli* O157:H7 isolates:

One (1) isolate from each *E. coli* O157:H7 positive subsample is to be sent to the appropriate servicing laboratory as outlined under "ORA/DFS - Standard Operating Procedure: Routine Subtyping of *Salmonella* sp., *Listeria monocytogenes*, or *E. coli* O157:H7 isolated from Food and Environment" for PFGE analysis.

2. ***Listeria monocytogenes***

Samples should be analyzed on a composite basis (i.e. 2 analyses per sample). Each composite for *L. monocytogenes* will consist of 250 ml. Prepare each composite by removing 50 ml from each of five (5) subsamples for a composite size of 250 ml. Remove 25 ml from the composite and add 225 ml enrichment broth (EB).

Check the pH of juice samples. If a juice is quite acidic (pH 2.2-4.2), it may be necessary to adjust pH to 7.3 ( $\pm 0.1$ ) by the aseptic addition of an appropriate amount of sterile aqueous NaOH solution (M or 5M strength as necessary). The pH and amount of NaOH solution to add should be determined in advance on a separate portion of the sample. Alternatively, the pH of a juice and enrichment broth mixture can be checked and adjusted aseptically to pH 7.3 ( $\pm 0.1$ ) if necessary.

Refer to the following methods of analysis:

- BAM, Chpt. 10, *Listeria monocytogenes*
- Bad Bug Book, Food pH Table

For Positive Isolates of *Listeria*:

One (1) isolate from each *L. monocytogenes* positive composite is to be sent to the appropriate servicing laboratory as outlined under ORA/DFS - Standard Operating Procedure: Routine Subtyping of *Salmonella* sp., *Listeria monocytogenes*, or *E. coli* O157:H7 isolated from Food and Environment for PFGE and ribotyping analyses.

3. **Salmonella**

Samples should be analyzed on a composite basis (i.e., 2 composites per sample). Each composite for *Salmonella* analysis will consist of 375 ml. Prepare each composite by removing 75 ml from each of five (5) subsamples and place into a sterile 6 L flask. Add 3,375 ml Universal broth.

Please refer to the BAM Method, Chpt. 5 Salmonella

For positive *Salmonella* isolates:

One (1) isolate from each *Salmonella* positive composite is to be sent simultaneously to each of the specified laboratories as outlined under "ORA/DFS - Standard Operating Procedure: Routine Subtyping of *Salmonella* sp., *Listeria monocytogenes*, or *E. coli* O157:H7 isolated from Food and Environment" for PFGE and serotyping (speciation).

Following serotyping, one slant from each serotyped isolate will be sent for antibiotic resistance testing. All laboratories are to send *Salmonella* isolates for serotyping and PFGE analyses within 24 hours after completion of the analytical portion of the sample analysis. The serotyping laboratory should ship isolates of *Salmonella* within 24 hours of completion of the analysis to the identified laboratory for antibiotic resistance testing. For *Salmonella* serotyping, all bacterial cultures should be prepared and submitted according to BAM On-Line, Chapter 5, *Salmonella*, E. Identification of *Salmonella*, #11 Submission of cultures for serotyping.

**C. Project 04: Toxic Elements (Lead)**

Methodology:

Do not analyze individual sub samples. Composite an equal volume or weight portion of each subsample. Thoroughly homogenize the composite (analytical sample) before taking analytical portion.

For lead analysis, please refer to the following method, which is available from the Center Toxic Elements Contact for Lead:

Draft EAM Method 4.3 - Graphite Furnace Atomic Absorption Spectrometric Determination of Cadmium and Lead in Food Using Microwave Assisted Decomposition.

**C. Project 07: Natural Toxins (Patulin)**

This analysis is for apple juice, apple juice concentrate and apple juice products only. Split samples (with the same sample number) need

to be collected for verification samples requiring patulin analysis in addition to other microbiological analyses.

Methodology:

General: Samples of frozen concentrate should be diluted either as per recommendation for dilution or to a Brix value of 11.5 (single strength) before analysis (Federal Register 56 No. 127, pp. 30452-30466, 1991).

Follow the procedures and methods in the most current edition of the Official Methods of Analysis of AOAC International (2000), Section 49.7.02 AOAC Method 995.10 - Patulin in apple juice, liquid chromatographic method, AOAC-IUPAC-IFJU Method.

AOAC Method 2000.02 Patulin in clear and cloudy apple juices and apple puree (McDonald, S., Long, M., and Gilbert, J., "Liquid chromatographic method for determination of patulin in clear and cloudy apple juices and apple puree: collaborative study," J. AOAC Intl. 83: 1387-1394).

Confirmation of Identity of Patulin:

For regulatory samples, identity of patulin is confirmed by mass spectroscopy. The recommended procedures are:

- Rupp, H.S., Turnipseed, S.B., "Confirmation of patulin and 5-hydroxymethylfurfural in apple juice by gas chromatography/mass spectrometry," J. AOAC Intl. 83: 612-626, (2000).
- Roach, J.A.G., White, K.D., Trucksess, M.W., and Thomas, F.S., "Capillary gas chromatography/mass spectrometry with chemical ionization and negative ion detection for confirmation of identity of patulin in apple juice," J. AOAC Intl., 104-112, (2000).

LC/MS/MS full scan can also be used for confirmation of identity of patulin provided significant fragmentation is observed in the MS/MS spectrum of patulin:

- Sewram, V., Nair, J.J., Nieuwoudt, T.W., Leggott, N.L., and Shephard, G.S., "Determination of patulin in apple juice by high-performance liquid chromatography-atmospheric pressure chemical ionization mass spectrometry," J. Chromatography A, 897, 365-374, (2000).

**E. Project 09: Food and Color Additives**

Please refer to the Domestic Food Safety Program (CP7303.803), Attachment A - Project 09 - Food Additives and Color Additives for analytical instructions.

**F. Project 21: Food Composition, Standards, Labeling and Economics**

- Domestic and Import NLEA, Nutrient Sample Analysis and General Food Labeling Program, CP 7321.005.
- Report resources utilized for NLEA against PAC 21005. Do not report inspections under NLEA. See current NLEA Compliance Program for reporting instructions.

## Contact:

Glenn Bass

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**PART V - REGULATORY/ADMINISTRATIVE STRATEGY**

This program addresses both juice HACCP and non-HACCP deficiencies. In instances where a district believes that a juice product poses an imminent public health hazard (e.g., juice processor that has been linked to a recent "active" outbreak), the district should contact CFSAN/OC/ Division of Enforcement to discuss an appropriate response.

The Agency established "Procedures for Clearing FDA Warning Letters and Untitled Letters", updated March 2005 which is now Exhibit 4-1 in the RPM and can be located at the following website:

[http://www.fda.gov/ora/compliance\\_ref/rpm/pdf/ch4.pdf](http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch4.pdf)

Domestic and Importer enforcement action recommendations (including copies of Warning and Untitled Letters) should be submitted directly to Division of Enforcement #

**All model Warning Letters and Untitled Letters including appropriate Regulatory Citations (both for domestic and importers) referenced below will eventually be located on ORA's Office of Enforcement Warning Letters and Untitled Letters Main Page # after being cleared by CFSAN's OC/Division of Enforcement and Office of General Counsel.**

**PROCESSOR STRATEGY**

This part contains information in:

**Section A:** To address deficiencies of the Juice HACCP regulations, 21 CFR Part 120.

**Section B:** To address deficiencies of the Federal Food, Drug and Cosmetic Act and related Acts and regulations, such as sanitation, labeling, etc.

**A. Juice HACCP Deficiencies**

FDA adopted final regulations on HACCP requirements for the processing of juice and juice products commercially distributed in the United States to ensure food safety to the maximum extent practical. The HACCP requirements became mandatory for all juice firms on January 20, 2004.

The following information may assist in responding to Juice HACCP deficiencies:

1. Juice Processors that have been linked to recent Outbreaks and Unpasteurized Juice Processors # that have deficiencies associated with Critical Control Points

If deficiencies are not corrected appropriately and immediately, contact CFSAN/OC/Division of Enforcement contact about pursuing other options.

2. Pasteurized Juice Processors that have deficiencies associated with Critical Control Points

If deficiencies are not corrected appropriately and immediately, the district may schedule a re-inspection of the firm as resources permit. If the firm's response is inadequate, the district should attempt to resolve issues through additional correspondence, meetings, etc with the firm. However, if the firm does not respond or appears unwilling to

correct the deficiencies, the district should re-inspect the firm # from the last correspondence date. If after re-inspection, the district determines that one or more of the original deficiencies are still present, contact CFSAN/OC/Division of Enforcement contact to discuss other options.

3. Intrastate Only Juice Processors that have deficiencies associated with Critical Control Points

The district should consider leveraging follow-up action with State or Local Authorities, when the district determines that one or more of the documented deficiencies in an intrastate only juice firm. However, if the State and Local Authorities do not have the jurisdiction, the district should consult with CFSAN/OC/Division of Enforcement contact to discuss other options.

**B. Non - Juice HACCP Deficiencies**

Non-HACCP juice products will continue to be addressed per the Federal Food, Drug and Cosmetic Act (the Act) and the regulations promulgated under the Act that relate to food sanitation, wholesomeness, and labeling, including nutritional content labeling. If deficiencies that are not related to the HACCP regulations are encountered at a firm, the district may contact CFSAN/OC/Division of Enforcement contact to discuss an appropriate response.

**C. State Inspections under Contracts**

These inspections should document deficiencies from the HACCP regulations on form FDA 483, and if needed consult with CFSAN/OC/Division of Enforcement contact to discuss other options.

**D. District Discretion**

Districts should notify CFSAN/OC/Division of Enforcement contact of any juice products sampled "For Cause" and/or "Verifications" samples that are found to be non-compliant. Situations where there could be a significant health issue will be handled on a "case-by-case" basis by CFSAN. Please refer to the following instructions for each individual problem area:

- Filth, mold, and foreign objects: Microscopic/Macroscopic  
Filth and mold: Please consult with CFSAN Regulatory Contacts.  
Foreign Objects: Refer to FDA/ORA CPG, SECTION 555.425 -Foods - Adulteration Involving Hard or Sharp Foreign Objects.
- Microbiological Pathogens (E. coli O157:H7, Salmonella, and Listeria)

If one positive sample or subsample is found from one lot of juice, then, the district should determine whether the lot in question involves interstate commerce. If interstate commerce can be documented, the district should consider voluntary recall and contact the CFSAN recall team. If the owner refuses to voluntarily remove the product from the domestic marketplace and the product is still available, the district should contact CFSAN/OC/Division of Enforcement contact about pursuing other options. If there is no interstate commerce, notify state officials of FDA laboratory

findings so that the state's officials can follow-up.

- Toxic Elements (Lead)

The Codex Alimentarius Commission adopted a standard of 50 ppb lead in fruit juices for international trade. The FDA supports this level to protect the consumer, especially infants and young children who consume high amounts of fruit juices and who are the most sensitive to the adverse health effects of lead. Analyzing laboratories should first call CFSAN Juice HACCP Inspection Program Monitor to report all lead levels detected above 50 ppb. CFSAN will review on a case-by-case basis to determine the appropriate follow-up. Information about the initial sample such as the product type, detected lead levels, where and when collected, and the consignee for the lot would be needed for follow-up.

- Natural Toxins (Patulin)

For apple juice, apple juice concentrate, and apple juice product samples only (refer to [CPG Section 510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin](#)).

- Food and Color Additives

Please Refer to the Domestic Food Safety Program (CP7303.803).

- Food Composition, Standards, Labeling and Economics.

Please refer to the Domestic and Import NLEA, Nutrient Sample, Analysis, and General Food Labeling Program (CP7321.005) for general labeling instructions.

### **IMPORTER STRATEGY**

If importers use "Maintaining on file a copy, in English, of the foreign processor's HACCP plan and a written guarantee from the foreign processor" as an Affirmative Step to comply with the Juice HACCP Regulation, the district should determine whether or not the plan is adequate. Importers should only be cited for an inadequate affirmative step, in this situation, if the HACCP plan fails to list a hazard that is associated with the product and is reasonably likely to occur. In addition, if the Foreign Processor's HACCP plan is not adequate for any reason, the district should refer to the Foreign Processor Strategy (below).

#### **A. District Discretion:**

Importer Juice HACCP deficiencies, if left uncorrected, jeopardize the operational, or performance aspects of the HACCP system. In addition there may be other deficiencies that involve paper-type problems. Districts should notify CFSAN/OC/Division of Enforcement contact to discuss options (e.g., DWPE).

#### **B. Unpasteurized Juice Importers #**

If the district determines that one or more deficiencies exist, consult with the CFSAN/OC/Division of Enforcement contact, to discuss options (e.g., DWPE).

#### **C. Pasteurized Juice Importers**

When the district has documented one or more deficiencies and if the firm's response is inadequate, the district should attempt to resolve issues through additional correspondence, meetings, etc. However, if the firm does not respond or appears unwilling to correct the deficiencies, the district should re-inspect the firm # from the last correspondence date as resources permit. If after re-inspection, the district documented that one or more of the deficiencies are still present, the district should contact CFSAN/OC/Division of Enforcement contact about pursuing other options (e.g., DWPE of the products being offered for entry by the Importer).

**FOREIGN PROCESSOR STRATEGY (Importer Inspection)**

If there are deficiencies in the foreign processor's HACCP plan that has been obtained by the district during an importer inspection, and that importer also has a written guarantee from the foreign processor, which indicates that the imported food is processed in accordance with the requirements of Part 120, consult with the OC/Division of Enforcement, about pursuing other options (e.g., DWPE of the implicated products from the foreign processor).

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**PART VI - ATTACHMENT, REFERENCES, AND PROGRAM CONTACTS****ATTACHMENT**

Attachment A: Sampling Size and Preparation for Juice HACCP Inspection Program

**REFERENCES**

Juice HACCP Regulator Training Manual - HACCP inspection procedures/activities

Juice HACCP Hazards and Controls Guidance - Potential hazards and recommended controls for juice processing

Juice HACCP Questions and Answers (August 31, 2001)

Juice HACCP Questions and Answers (September 4, 2003)

FDA Investigations Operations Manual (IOM)

Federal Register: January 19, 2001 (66 FR 6138) Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule

Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices

Recommendations to Processors of Apple Juice or Cider on the Use of Ozone for Pathogen Reduction Purposes

DFI Miscellaneous Inspection Guide, Section 10 and 11

**PROGRAM CONTACTS**

Program Contact:

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General Investigational Contact:

Barbara Marcelletti  
ORA, ORO, DFI, Investigations Branch, HFC-132, (301) 827-5635,  
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General Juice HACCP Questions:

Martin Stutsman  
CFSAN, Office of Food Safety, Division of Plant and Dairy Food Safety Plant Products Branch, HFS-317, (301) 436-1642,  
[martin.stutsman@fda.hhs.gov](mailto:martin.stutsman@fda.hhs.gov)

General Analytical Questions: ORA, Division of Field Science, HFC-141,

(301) 827-7605

<i>Microbiological</i> Marsha Hayden	ORA/ORO/Division of Field Science, HFC-141, (301) 827-1039, <a href="mailto:marsha.hayden@fda.hhs.gov">marsha.hayden@fda.hhs.gov</a>
<i>Filth</i> Larry D'Hoostelaere	ORA/ORO/Division of Field Science, HFC-141, (301) 827-1032, <a href="mailto:lawrence.dhoostelaere@fda.hhs.gov">lawrence.dhoostelaere@fda.hhs.gov</a>
<i>Natural Toxins</i> George Salem	ORA/ORO/Division of Field Science, HFC-141, (301) 827-1031, <a href="mailto:george.salem@fda.hhs.gov">george.salem@fda.hhs.gov</a>
<i>Toxic Elements</i> Steve Robbs	ORA/ORO/Division of Field Science, HFC-141, (301) 827-9555, <a href="mailto:steven.robbs@fda.hhs.gov">steven.robbs@fda.hhs.gov</a>

Center Filth and Natural Toxins Analysis Contact:

George Ziobro	CFSAN, Office of Food Safety, Division of Plant and Dairy Food Safety, HFS-316, (301) 436-1965, <a href="mailto:george.ziobro@fda.hhs.gov">george.ziobro@fda.hhs.gov</a>
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Center Microbial Analysis Contact:

<u><i>E. coli</i> O157:H7:</u> Peter Feng	CFSAN, Office of Regulatory Science, Division of Microbiological Studies, HFS-711, (301) 436-1650, <a href="mailto:peter.feng@fda.hhs.gov">peter.feng@fda.hhs.gov</a>
<u><i>Listeria:</i></u> Anthony Hitchins	CFSAN, Office of Regulatory Science, Division of Microbiological Studies, HFS-711, (301) 436-1649, <a href="mailto:anthony.hitchins@fda.hhs.gov">anthony.hitchins@fda.hhs.gov</a>
<u><i>Salmonella:</i></u> Wallace Andrews	CFSAN, Office of Regulatory, Division of Microbiological Studies, HFS-711, (301) 436- 2008, <a href="mailto:wallace.andrews@fda.hhs.gov">wallace.andrews@fda.hhs.gov</a>

Center Toxic Elements Contact:

<u>Lead:</u> Stephen Capar	CFSAN, Office of Regulatory Science, Division of Bioanalytical Chemistry, HFS-716, (301) 436-2003, <a href="mailto:stephen.capar@fda.hhs.gov">stephen.capar@fda.hhs.gov</a>
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Compliance Matters:

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PART VII - CENTER RESPONSIBILITIES

Program Evaluation

During the course of this program the Office of Food Safety (OFS), will identify any deficiencies in program operations or program quality. OFS will prepare an annual evaluation of this program in accordance with #.

## Sample Size and Preparation for Juice HACCP Inspection Program

Samples do not reflect 702(b) portion (except Food and Color Additives).  
Please collect in duplicate to provide for 702(b) portion.

Analysis	Specific Instructions
Microbiological	<p>General Micro:</p> <p>Collect ten (10) subsamples (Retail Containers) with a minimum sub-sample size of 32 fl oz. (i.e. 946 ml).</p> <p>NOTE: If finished product juice retail container is greater than ½ gallon (i.e. 1893 ml), then notify Program Monitor for further instructions</p> <p>This amount is enough to cover all <i>E. coli</i> O157:H7, <i>Listeria monocytogenes</i>, and <i>Salmonella</i> analyses.</p> <p><b>Please refer to each analytical section for specific subsample and compositing instructions.</b></p>
Toxic Elements (Lead)	<p>1 sample = 12 randomly selected subs with each sub minimum of 4 oz.</p> <p>If consumer size containers, collect 12 random containers. If bulk size containers, collect 12 subs minimum 4 oz. each.</p>
Patulin	<p>For Apple Juice and Apple Cider Only</p> <p>Frozen Concentrate: Collect six subsamples with a minimum volume of 400 ml (approx. 12 fl oz.) per sub.</p> <p>Single Strength: Collect six subsamples with a minimum volume of 500 ml (approx. 16 fl oz.) per sub.</p>
Filth, Macro/ Microscopic	<p>Non-HACCP Filth samples: 1 sample = 6 subsamples</p> <p>HACCP Hard/Sharp Object samples: 1 sample = 12 subsamples</p> <p>Subsample Size = Consumer Retail Container</p> <p>Analyze each subsample individually (no compositing).</p>
Food and Color Additives	<p><b>These sample sizes include the 702(b) portion:</b></p> <p>1 sample = 6 subsamples</p> <p>Color Additives: Subsample = Two retail packages (minimum 8 oz.)</p> <p>Food Additives: In most cases the size of sample collected for filth will be sufficient for the food additive analysis as well. However, it may be necessary to consult with the analyzing laboratory on the amount of sample required for specific food additives.</p>