CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT:	**IMPLEMENTATION DATE**
Juice HACCP Inspection Program (Processor and Importer Inspections)	UPON RECEIPT
	COMPLETION DATE Continuing

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES	
INDUSTRY CODES: 20-22, 24,25 USE APPROPRIATE PRODUCT CODES		<u>REPORT TIME FOR HACCP INSPECTIONS UNDER THE FOLLOWING PACS:</u>
	03847H	Processor HACCP Component of Inspection
	03847	Processor Filth/Sanitation Component of Inspection
	03847H	Importer HACCP Inspection *(use Establishment Type A)*
	03S004	State Contract Inspections
		<u>REPORT VERIFICATION SAMPLES UNDER THE FOLLOWING PACS:</u>
	03847H	HACCP Microbiological/Physical Hazards
	04847H	HACCP Toxic Elements (Lead)
	07847H	HACCP Mycotoxins (Patulin)
	09847H	HACCP Color and Food Additives
	21847H	Labeling
		<u>REPORT FOR CAUSE SAMPLES UNDER THE FOLLOWING PACS:</u>
	03847	For Cause Microbiological, Filth or Physical Hazards
	04847	For Cause Toxic Elements (Lead), Pesticides, Contaminants
	07847	For Cause Mycotoxins (Patulin)
	09847	For Cause Color and Food Additives

Note: The performance of non HACCP inspection work may be guided by instructions in the current Domestic Food Safety Program, CP 7303.803 but <u>reported under</u> 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.

Districts are no longer required to complete or submit a Juice HACCP Questionnaire.

FIELD REPORTS TO HEADQUARTERS

Domestic and Importer enforcement action recommendations (including copies of Warning and Untitled Letters) should be submitted directly to CFSAN/Division of Enforcement via the "MARCS-CMS" link located on Inside FDA's Information Technology page under ORA Applications.

LABORATORY REPORTING

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

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

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 ("Juice HACCP Final Rules : HACCP Procedures for the Safe and Sanitary Processing and Importing of Juice : Final Rule"). 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 compliance program covers domestic processors and importers of fruit and vegetable juices and provides instructions to ensure that they are being operated in accordance with 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 with 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

Domestic and Foreign 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 control 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 juice safety is a system inspection to determine whether the processor is controlling food safety hazards that are reasonably likely to occur. It should be performed by investigators who are trained to conduct juice HACCP inspections. Investigators should inspect HACCP records and HACCP controls as they relate to food safety hazards.

2. Inspectional coverage of non-HACCP areas (i.e., GMPs) for those parameters such as filth, sanitation, personal hygiene, etc., for 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 takes place at the importer's place of business and is essentially a record review 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 written procedures including product specifications and 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 (inspect high risk firms annually unless otherwise instructed)

1. Processors: Priority of inspections of firms should be given in the following order:
   - Juice processors that have been linked to recent outbreaks (high risk)
   - Unpasteurized juice processors (high risk)
   - 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 (high risk)
   - Importers with previous Juice HACCP violations (after initial inspection)
   - Importers with the highest number of entry lines for juice products (the greater number of juice entries, the higher the priority for 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 extracts juice from the apples themselves), try to obtain evidence regarding the type of apples used to produce the specific lot of juice sampled and whether those apples had been stored before processing 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 analysis 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 sampled 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 - Import and Domestic, 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. NLEA, Nutrient Sample Analysis, and General Food Labeling Requirements – Domestic and Import, CP 7321.005

Refer to the current version of CP 7321.005 for instructions on labeling coverage. Coverage of labeling 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: CO, CT, NJ, NY, OH, and WI.

All Juice HACCP inspections conducted under state contract must be HACCP based and consistent with this compliance program, the contract Statement of Work (SOW), and with the methods included in the "Juice HACCP and Conducting Juice Inspections" Training Course. Districts must ensure that current or future state contractor's staffs that will conduct HACCP inspections have completed the "Juice HACCP and Conducting Juice Inspections" 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, whether or not 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
- Juice HACCP Hazards and Controls Guidance First Edition
- 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 6137) 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
- Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices

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

- Attendance at FDA's (4.5 days) "Juice HACCP and Conducting Juice Inspections" 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 a Juice HACCP Regulatory training component.

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 are 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 likelihood of occurring. Such evidence may include firm records 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 and Conducting Juice Inspections" Training Course. The investigator should:

- Conduct an initial interview to present credentials and determine which product to cover during the inspection.
  - 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 inspection should concentrate on those, or similar products before moving on to other products.
- Determine the firms manufacturing operations and sanitation procedures by doing a "walk through", writing a description at each step of the process for the product being evaluated. This "flow chart" for the product(s) should be incorporated into the EIR narrative or as an attachment;
- Independently identify the appropriate significant hazards and Critical Control Points i.e., conduct their own hazard analysis and afterwards, evaluate the processor's hazard analysis.
- Evaluate the processor's HACCP plan by determining the adequacy of the critical limits, monitoring and verification procedures and records.
- Determine if the HACCP plan is being implemented by asking employees to "show what they do" at each critical control point.
- Determine if sanitation monitoring is being implemented by accompanying the person performing the monitoring to "show what they do".
- Conduct their own sanitation inspection.
- Review records, including monitoring, verification, corrective action and sanitation correction records.
- Document deficiencies listing them on a FDA-483 or State report in a manner consistent with the "Juice HACCP and Conducting Juice Inspections" Training Course. Citations for Juice HACCP are available in Turbo EIR and should be used for 483s and EIRS.
  - If GMP deficiencies directly related to the firm's SSOPs are observed, the investigator should list them on the Form FDA 483 using the appropriate 21 CFR 120.6 citation. For other GMP deficiencies 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.
- 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.

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 and Conducting Juice Inspections" Training Course and as outlined above. While the investigator 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.

NOTE: Firms subject to the Juice HACCP regulation can no longer use the Juice Warning Statement (21 CFR 101.17(g)) in lieu of developing a HACCP plan and having controls in place for hazards that are reasonably likely to occur. 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.

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. 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." Use the NSD locator in FACTS to determine the 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. The investigator should use separate sample collection numbers, one for the micro sample and one for the chemical sample collection.

"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 use 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 do 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 and Conducting Juice Inspections" Training Course.

The investigator should:

- Conduct an initial interview to present credentials and an FDA-482 and select products for inspection.
- Determine the foreign sources of the selected imported juice product(s).
- If the source country has an MOU with FDA applicable to juice HACCP, the country will be listed on CFSAN's home page and other available resources. If the juice is imported from a country with an FDA MOU applicable to juice HACCP, document that information and select a non-MOU juice for inspection.
- For non-MOU juices, review the importer's written procedures to determine whether the importer has met the obligations listed in 21 CFR 120.14 for specifications and affirmative steps.
- Review the importer's written product safety specifications to determine if they address the biological, physical, and chemical hazards associated with the products that are imported.
- Review the importer's affirmative steps to determine whether they provide the requisite assurance that the product has been processed in accordance with the requirements of Part 120.
- Review the importer's verification records.
- Document objectionable conditions as outlined in the "Juice HACCP and Conducting Juice Inspections" training course.
- Cite failures to comply with 21 CFR 120.14 on the 483 using TURBO citations.

- Collect necessary records and document your findings in the inspection report.

Refer deviations in the foreign processor's HACCP plan to district compliance officers for review and referral as outlined in part V of this program.

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://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/MacroanalyticalProceduresManualMPM/default.htm

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 K, "Screening method for *E. coli* O157:H7 from Foods".

Each subsample should be analyzed on an individual basis. Take 200 ml 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 mBPWp for incubation by the standard procedure. Refer to Section N of eBam Chapter 4a.

a. After enrichment, Refer to section O of Chapter 4a for performing the real-time PCR screening.
b. Continue with the isolation methodology as outlined in eBAM, Chapter 4a, Section P.

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. Do not test juices with a pH less than or equal to 4.4, see Draft guidance on *Listeria monocytogenes* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm136694.htm. CPG 555.320

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 subsamples. Composite an equal volume or weight portion of each subsample. Thoroughly homogenize the composite (analytical sample) before taking analytical portion.

Analyze the analytical portion for lead using FDA Elemental Analysis Manual (EAM) Method 4.3 [Version 1, June 2008], microwave digestion and graphite furnace atomic absorption spectrometry, available in FDA eRooms at http://eroom.fda.gov/ [Elemental Analysis > Elemental Analysis Manual > EAM Section 4 > EAM Section 4.3 > EAM-Sect-4-3(Web).doc]. Please contact the CFSAN Scientific Contact for questions related to the method or accessing the Elemental Analysis eRoom. Report results in FACTS using Method Code 703 and enter the following in the Method Remarks field of the Method Applied screen: EAM 4.3v1.

D. 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 (21 CFR 101.30(h)).

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 label reviews against PAC 21005. Do not report inspections under NLEA. See current NLEA Compliance Program for reporting instructions.

  Contact:

  Monali Yajnik — CFSAN, Office of Compliance, Division of Field Programs & Guidance, Field Programs Branch, HFS-615, (301) 436-1616, Monali.Yajnik@fda.hhs.gov

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, 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/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm

Enforcement action recommendations should be submitted directly to CFSAN/Division of Enforcement via the "MARCS-CMS" link located on Inside FDA's Information Technology page under ORA Applications.

PROCESSOR STRATEGY

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 (High Risk) 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 no later than 60 days 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 exists.

However, if the State and Local Authorities do not have jurisdiction, the district should consult with CFSAN/OC/Division of Enforcement contact to discuss other options.

B. State Inspections under Contracts

These inspections should document deficiencies from the HACCP regulations as well as any other FDA regulation, on form FDA 483. Regulatory follow-up based on State inspections should be discussed with CFSAN/OC/Division of Enforcement's Regulatory Contact.

C. Sample Follow-up

Districts should notify CFSAN/OC/Division of Enforcement 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 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. The district should discuss how the firm intends to correct the problem and prevent the product from being introduced into interstate commerce. If the firm decides to recall, the district should 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 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 0.05 mg/kg 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 Contact to report all lead levels detected above 0.05 mg/kg. 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.

DOMESTIC IMPORTER STRATEGY

Cite domestic importers for inadequate affirmative steps. A HACCP plan from a foreign processor is an inadequate affirmative step under 21 CFR 120.14(a)(2) if the plan fails to list a hazard that is reasonably likely to occur. Refer to the Foreign Processor Strategy (below) for guidance regarding foreign processor deviations.

A. Unpasteurized Juice Importers (High Risk)

If the district determines that one or more deficiencies exist, consult with the CFSAN/OC/Division of Enforcement to discuss options.

B. Pasteurized Juice Importers

When the district has documented one or more significant 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 no later than 60 days 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 about pursuing other options.

FOREIGN PROCCESSOR STRATEGY (Importer Inspection)

Submit a warning letter recommendation to CFSAN for foreign firms with inadequate HACCP plans.

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 First Edition

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

Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices

DFI Miscellaneous Inspection Guide, Section 10 and 11

PROGRAM CONTACTS

Program Contact:

Edette J. Newby	CFSAN, Office of Compliance, Division of Field Programs and Guidance, Field Programs Branch, HFS-615, (240)402-2068, Edette.Newby@fda.hhs.gov

General Investigational Contact:

Norman Fogg	ORA, ORO, DDFI, HFC-130, (301) 796-5448, Norman.Fogg@fda.hhs.gov

General Juice HACCP Questions:

Martin Stutsman	CFSAN, Office of Food Safety, Division of Plant and Dairy Food Safety, Plant Products Branch, HFS-317, (240)402-1642, Martin.Stutsman@fda.hhs.gov

General Analytical Questions: ORA, Division of Field Science, HFC-141, (301) 827-7605

Microbiological Yuelian Shen	ORA/ORO/Division of Field Science, HFC-141, (301) 796-6235, Yuelian.Shen@fda.hhs.gov
Filth Blake Hamann	ORA/ORO/Division of Field Science, HFC-140, (301) 796-6258, Blake.Hamann@fda.hhs.gov
Natural Toxins Changya (Jake) Chae	ORA/ORO/Division of Field Science, HFC-140, (301) 796-8159, Changya.Chae@fda.hhs.gov
Toxic Elements Blake Hamann	ORA/ORO/Division of Field Science, HFC-140, (301) 796-6258, Blake.Hamann@fda.hhs.gov

Center Filth and Natural Toxins Analysis Contact:

George Ziobro	CFSAN, Office of Food Safety, Division of Plant and Diary Food Safety, HFS-316, (240)402-1965, George.Ziobro@fda.hhs.gov

Center Microbial Analysis Contact:

E. coli O157:H7: Peter Feng	CFSAN, Office of Regulatory Science, Division of Microbiology, HFS-711, (301) 436-1650, Peter.Feng@fda.hhs.gov
Listeria: Anthony Hitchins	CFSAN, Office of Regulatory Science, Division of Microbiology, HFS-710, (301) 436-1649, Yi.Chen@fda.hhs.gov
Salmonella: Thomas Hammack	CFSAN, Office of Regulatory, Division of Microbiology, HFS-711, (240)402-2010, Thomas.Hammack@fda.hhs.gov

Center Toxic Elements Contact:

Lead: John Cheng	CFSAN, Office of Regulatory Science, Division of Bioanalytical Chemistry, HFS-716, (301) 436-2251, John.Cheng@fda.hhs.gov

CFSAN Recall Coordinator:

Kerri Harris (Team Leader)	CFSAN, Office of Compliance, Division of Enforcement, Recall and Product Reconditioning Team, HFS-605, (240)402-1742, Kerri.Harris@fda.hhs.gov

Compliance Matters:

Millie Benjamin	CFSAN, Office of Compliance, Division of Enforcement, Food Adulteration and Assesment Branch, HFS-607, (240)402-1424,

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Denise Beuttenmuller	CFSAN, Office of Compliance, Division of Enforcement, Food Adulteration Assesment Branch, HFS-607, (240)402-2439, Denise.Beuttenmuller@fda.hhs.gov

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 CFSAN's Program Evaluations Model.

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