DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

Memorandum

Date: May 25, 2012

From: Consumer Safety Officer
CFSAN, Office of Compliance, Division of Field Programs and Guidance
Thru: Paige Shelborne Chief, Field Programs Branch (HFS-615)

Subject: FY 2012; Request for Inspections and Environmental Sampling for *Listeria* at Soft Cheese Firms --- DFPG NO: 12-05,
ORA Concurrence #2012051802
FACTS #1412198

Priority: **High** Priority

Firms(s): See Attachment A

Schedule: See Attachment B

Reporting PAC Code: 03F834 (03F830 for planning only)

To: DIBs: All

DCBs: All

Director of Laboratory Branches: All

Info: RFDDs: All
DDs: All

PLEASE DISTRIBUTE COPIES OF THIS ASSIGNMENT TO ALL ADDRESSEES AND OTHER APPROPRIATE DISTRICT/REGIONAL PERSONNEL. IF YOUR DISTRICT IS NOT LISTED ON THE ATTACHMENT, THEN CONSIDER THIS COPY FOR INFORMATIONAL PURPOSES ONLY.

NOT FOR PUBLIC DISTRIBUTION

BACKGROUND

Listeria monocytogenes contamination and listeriosis have been associated with such foods as raw milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish. The ability of *Listeria*

monocytogenes to grow at temperatures as low as 0°C (32°F) permits its growth in refrigerated food.

Listeriosis is an atypical foodborne illness of major public health concern because of the severity of the disease (meningitis, septicemia, and spontaneous abortion), a high case-fatality rate, a long incubation and a predilection for individuals with underlying conditions. *Listeria monocytogenes* differs from most other foodborne pathogens because it is widely distributed, resistant to diverse environmental conditions, including low pH and high NaCl concentrations, and is micro aerobic and psychrophilic. The various ways it can enter food processing plants; its ability to grow and survive for long periods of time in the environment, on foods, and in food processing plants; and its ability to grow at low temperatures and to survive in or on food for prolonged periods under adverse conditions have made it a major concern for many manufacturing industries over the last decades.

Discussion of FY 2010 Soft Cheese Assignment DFPG #10-04

Due to product recalls resulting from *Listeria monocytogenes* positive environmental sampling, in April 2010, CFSAN issued the Request for Inspections and Environmental Sampling for Listeria at Soft Cheese Firms – High Priority, DFPG NO: 10-04, (FACTS #:1168701) The assignment instructed Districts to collect environmental samples from areas in facilities that are not generally sampled. The purpose of these inspections was to determine whether or not *Listeria* is present in the food processing environment in firms producing soft cheese. The original assignment is found at: http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/FieldPrograms/UCM210217.pdf
This assignment was extended on September 9, 2010 and can be found http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm015774.htm See Table 1 for discussion of results.

The previous assignment found 30 firms with positive *Listeria* results. There was a 24% occurrence of *Listeria* in all the firms inspected under this assignment (30/124) as well as a 20% finding of *Listeria* of all artisanal cheese firms inspected (8/41). Out of the 184 samples collected, 41 were found positive for *Listeria* for a 22% occurrence. Soft cheese firms and artisanal cheese firms continue to have a high risk of contamination and this assignment will focus on identifying the firms that pose this risk to the public.

OBJECTIVES

- To conduct a routine surveillance CGMP inspection at each establishment identified on Attachment A;

- To document measures the firm has taken to ensure the safety of their products (e.g., internal testing, kill step);
- To collect environmental samples at each location following the guidance in DDFI Field Bulletin #30
- To provide laboratory analyses and supporting documentation necessary for ORA and the Center to consider regulatory action against an establishment and affected product.

Note: These objectives do not preclude the initiation of a comprehensive inspection if clear mechanisms of routes of contamination or other evidence of product adulteration are encountered. If such action is taken, the investigator should advise his/her supervisor immediately so district management can consider expansion of the inspectional team to address these violations and this directed assignment simultaneously.

Note: *Listeria* contamination of the food processing environment for the types of processing plants covered in this assignment is not necessarily related to the sanitary conditions in these facilities. In other words, it is possible to have a plant that appears to have an excellent implementation of CGMPs and that seems to maintain a high standard of housekeeping and still have significant environmental contamination of the plant's environment with *Listeria*. Similarly, a processing plant with apparently poor implementation of CGMPs and housekeeping may not have any detectable *Listeria* in the plant's environment.

Implementation

Note: Investigators are encouraged to read the section of this assignment entitled District Response to Laboratory Findings from Environmental Samples. This section describes how the results of the investigation and the documentation collected will be utilized for developing a strategy to address positive findings.

Firm Selection

The firms listed on Attachment A were identified as artisanal cheese firms on the basis of intelligence gathering. Internet searches combined with reviews of written references and industry-based literature searches were used by the Center in developing Attachment A.

This list includes only firms which are manufacturing unpasteurized cheese for inspection under this assignment.

Note on Wash-outs: The number of firms each District is asked to inspect is an estimate based on the best inventory/product information available at the time. Districts will not be penalized for not inspecting a firm that does not meet the criteria of the assignment. Visits to firms that do not meet the criteria for inspection under this assignment should be converted to a Washout (Operations 13 – Domestic Investigation) in FACTS. This would not preclude a general GMP inspection being conducted and reported under the appropriate program PAC.

Scheduling Inspections

Attachment A was used to establish the inspection schedule and analytical lab scheme in Attachment B.

Attachment A is an Excel spreadsheet containing 3 tabs described as follows:

Tab 1: FSMA High Risk lists FSMA high risk firms identified for inspection in FY 2012. One firm, Smith's Country Cheese was already inspected in June 2011 and should not be re-inspected for this assignment.

Tab 2: FSMA High Risk Non-Assigned FY lists FSMA high risk firms identified for inspection in FY 2013.

Tab 3: NON-FSMA lists non-FSMA firms that are highly recommended for inspection because they are small, specialty cheese manufacturers that have a high potential for *Listeria* contamination.

NOTE: CFSAN excluded firms that were already inspected in FY11. Firms that the district has already inspected in FY12 need not be re-inspected under the assignment.

Collection Weeks

ORA/DDFI has worked with ORA/DFS to identify on Attachment B both the week of the assignment that each firm should be scheduled for inspection and the servicing laboratory for each inspection. Districts should first coordinate with the assigned laboratory to coordinate scheduling of the inspections and delivery of samples before sending teams to conduct inspections. Due to the number of swabs being collected and since multiple districts may be using the same service laboratory, the laboratory needs to ensure it can process them the day they are received.

Should your District be unable to perform the assigned inspection as scheduled, contact Chyla Hunter, DDFI, 301-796-5473 to reschedule and also notify the assigned laboratory in advance that samples will not be collected as scheduled.

Attachment C is the Tracking Sheet for reporting inspectional data. This should be sent by Thursday, COB, of each week an inspection is conducted or assigned to ORA HQ DFI DOM FOODS mailbox.

Inspection

Since many of these inspections may be the initial inspection of the firm, investigators should collect information on the firm as outlined in IOM Subchapter 5.4 (Food Establishment Inspections).

In addition, investigators must refer to the procedures outlined in DDFI Field Bulletin #34 on the newly implemented Reportable Food Registry.

Districts are requested to conduct a GMP surveillance inspection and collect environmental samples following the directives found in DDFI Field Bulletin #30. Develop a floor plan of the establishment and document the product and traffic flow during the manufacturing process.

Diagram of Floor Plan and Sample Collection Report.

- Create or obtain a floor plan of the establishment and document the product and traffic flow during the manufacturing process.
- Identify the areas of product processing (see Selection of Areas to Collect Environmental Samples in DDFI Bulletin #30).
- Record in the Remarks section of the Collection Report where samples were collected and explain their relationship to product and product flow using a numbering scheme. (Zones 1-4: High Risk → Low Risk). **If more space is needed use the Collection Report Continuation Sheet, however, note that the continuation sheet is not available in FACTS and must be attached to the collection report when forwarded to CFSAN.**
- Record in the Remarks section of the Collection Report the product/lot code(s) being produced in the firm at the time environmental samples were collected on the line(s) where sampled or in close proximity to the lines that are in operation.
- Pictures of the sampling areas may be used to show potential routes of cross contamination with finished product.
- The Collection Report should be flagged that dealer is holding sample, as appropriate, and for how long it is being voluntarily held. The firm should be alerted promptly after finalized analytical results are available.

Additional information to be included as part of the be covered and documented

- The firm's cleaning/sanitation procedures

- Types and concentrations of cleaning agents and sanitizers
- How often the firm wet cleans equipment and the facility
- The firm's product and environmental sampling and Quality Control (QC) procedures
- If the firm samples finished or in-line product, manufacturing equipment and manufacturing environment for *Listeria*. If so, per DDFI Field Bulletin #32, ask to review pertinent records with results of internal or outside lab testing. Determine whether there are potential sources of contamination, whether the firm took appropriate corrective actions when positive samples were reported, and/or whether controls and checks are in place to provide a greater assurance of product safety

- If the firm employs a kill step in the manufacturing process for products, e.g., for the filling component, and, if so, how the firm has validated that the process is effective in killing *Listeria.* Provide a detailed description of the kill step
- Identify processing steps or product handling which may cause contamination after the *Listeria* kill step, if any
- If the firm contracts out any portion of their operations. If yes, the degree of control the firm maintains over those contracted operations
- If the firm has implemented supplier controls for ingredients that may be contaminated with *Listeria*, e.g., do they require such suppliers to have a *Listeria* control program
- **Samples should be double bagged as per DDFI Field Bulletin #30. Samples that are not double bagged leak and may not be able to be tested**
- **Products manufactured by the firm and documentation of interstate commerce**

These inspections should be conducted by a team, including an investigator and a microbiologist, if possible.

INSPECTIONAL AND SAMPLING EQUIPMENT REFERENCE

IOM 4.3.6Aseptic Sampling;
http://www.fda.gov/ICECI/Inspections/IOM/ucm122525.htm#4.3.6
IOM 4.3.7.7.2 Environmental Sampling
http://www.fda.gov/ICECI/Inspections/IOM/ucm122525.htm#4.3.7.7.2
IOM 5.4 Food http://www.fda.gov/ICECI/Inspections/IOM/ucm122532.htm#SUB5.4

Guide to Inspection of Dairy Product Manufacturers:
http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074974.htm

DDFI Field Bulletin #30 and Attachment 1 Final 3/22/09**–Instructions for Environmental Sampling Equipment; Identification of Equipment Sources;**

and Sample Collection Technique for Large and Small Area Environmental Surface Sampling.
DDFI Field Bulletin #32**--Internal Testing Programs and Environmental Sampling. Dated 2/10/2009**
DDFI Bulletin #34—**Outreach and Regulatory Procedures to Implement the Reportable Food Registry; Dated 09/08/2009**

Sample Collection

Districts should coordinate with their respective servicing labs prior to sample collection.

- Only collect environmental samples.
- Do not collect in-line or finished product samples.
- Aseptically, collect between 100-300 environmental samples in each firm, depending upon the size of the facility and the opportunities for good samples given the criteria outlined.
- **When environmental swabs are collected over more than one day, create a new sample number/CR each day**.
- If product, personnel, or equipment used to process the products are moving from one area to another, environmental sampling in multiple areas will be necessary.
- **Identify the subs which are environmental swabs using numerals, i.e. 1, 2, 3 etc. and which are controls using letters, i.e. a, b, c, etc. on the collection report.**
- Closed controls are required for each distinct lot of sterile equipment, including gloves, swabs, D/E broth and Whirlpaks® or other sample containers per IOM 4.3.6.5.
- Open controls are not to be submitted for environmental samples.
- Review DDFI Bulletin #30 and your district's policy regarding glove use and according to your district's policy, if applicable. Please note that gloves are to be changed between subs when collecting environmental swabs in Zone 1 and when moving to another zone and according to your district's policy, if applicable.

Areas of Emphasis for *Listeria Swabbing*

DDFI Field Bulletin #30 provides guidance on the most important areas for swabbing when conducting Listeria environmental sampling. DDFI Field Bulletin #30 has been revised. Sampling locations for *Listeria monocytogenes* have changed: **Do not collect any environmental samples in Zone 4; sampling should be concentrated in Zones 1 and 2.**

Sample Shipment

Note: Investigators must use the Remarks Section of the Collection Report to identify the zone from which the subsamples were collected, i.e., subs 1-30 zone 1; subs 31-60, zone 2, etc. This will assist the laboratory in prioritizing PFGE analysis for positive samples.

It may take more than one day to complete sample collection i.e. sample # xxxxxx Subs 1-150 on day 1 and sample #yyyyyy Subs 151-300 on day 2.

Districts should notify laboratories of pending sample shipments. Samples should be shipped by UPS Next Day Air Early A.M. shipping for earliest arrival to servicing laboratories. The NSD will not be utilized for this assignment. Servicing laboratories are shown for each firm identified on Attachment B. Ship samples in an insulated transport container with frozen gel packs to keep the samples cold, but not frozen to microbiology field laboratory for analysis within 24 hours. If samples cannot be processed immediately, refrigerate at 4±2°C (39±2°F). Start sample analysis within 48 ±2h of collection. Samples will be considered invalid past the 2 hour window.

REPORTING OF INSPECTION AND SAMPLE COLLECTION DATA TO HEADQUARTERS

ORA/DDFI and ORA/DFS will be responsible for tracking the inspections and sample analyses under this assignment. Attachment B provides the inspection schedule and assigned laboratories for the assignment. Chyla Hunter, ORA/DDFI, 301-796-5473 and Peggy Carter, ORA/DFS, 301-796-6239 are the contacts for this purpose.

Attachment C is the Tracking Sheet for reporting inspection completion data. This should be sent by Thursday, COB, of each week an inspection is conducted or assigned to ORA HQ DDFI DOM FOODS mailbox.

IMPORTANT NOTE: The following information must be received and available to CFSAN during discussion of appropriate follow-up to positive results. The information should be express mailed to the CFSAN assignment contact listed below in advance of final district decision and loading of the inspection report into Turbo EIR. **Timely access to this information is relevant for all firms in which environmental sampling is conducted regardless of sample outcomes.**

Floor plan diagram
Description of product flow
Collection Reports including the continuation sheet for each sample
Photographs if any were taken

Other exhibits that provide information relevant to the product flow, swabbing locations, and sampling zones

Send to:

Melinda Chen
Soft Cheese Environmental Sampling Assignment Contact
CFSAN/OC/DFPG/Field Programs Branch
5100 Paint Branch Parkway, HFS-615
College Park, MD 20740

Material may also be scanned and e-mailed to Melinda.Chen@fda.hhs.gov.

RESOURCES AND FACTS REPORTING

Report all inspections (op 12) and investigations (op 13) against **reporting** PAC 03F843.

Estimated accomplishment hours: 100 hours

Note: The special reporting PAC of 03F843 will continue through the 1st half of FY 13 so that inspections planned and conducted in FY 13 can be reported under the same PAC.

Accurate reporting of the actual time expended under the special reporting PAC identified below will assist in future planning for environmental sampling assignments.

Inspections and Investigations:

03F843 – FY12 SOFT CHEESE INSPECTION / ENVIRONMENTAL SAMPLING ASSIGNMENT
Product Code Industry Code 12 – Cheese. Please use Product Code Builder to select the appropriate Product Code.

> **NOTE (1):** Please remember to report all related sample numbers from related collection reports on Page 2 of the FACTS Maintain Inspection Results Section.
> **NOTE (2):** If any Firms inspected as a part of this assignment were identified by CFSAN as a FSMA High Risk or FSMA Non-High Risk Firm to be inspected in FY12 and have been flagged F2 or A2 respectively, then they will receive credit towards these frequencies so long as the visit conducted per this assignment is the first visit to the firm in FY11 or FY12.

Note that the FY12 PG is the same as the FSMA High Risk Frequency. For more information regarding "What Counts" towards the FSMA Frequencies and the FY12 Performance Goal, please refer to the following link on the DPEM Web Page: http://inside.fda.gov:9003/ProgramsInitiatives/FieldOperations/ORAContractPerformanceGoals/ucm278915.htm

Sample Collections/Analyses:

03F843 – FY12 SOFT CHEESE INSPECTION/ENVIRONMENTAL SAMPLING ASSIGNMENT
PAF: MIC
Sample Basis on CR: 'Environ-Survl'
Product Code: 52YYY99

NOTE: When environmental samples are collected over more than one day, create a new sample number/CR each day.

Although these are not 704(d) samples, include the name and address for firm contact to receive results of analysis.

- Positive and negative results will be reported by the Compliance Branch as indicated below under REPORTING OF ANALYTICAL RESULTS.

Analytical Approach

Field servicing labs will only test for *Listeria*.

The following instructions should be used:

Safety Precautions:

Media preparation for *L. monocytogenes* directs the use of cycloheximide, which is an **extremely toxic** chemical. Likewise, the *L. monocytogenes* method requires the use of acriflavine HCl that is a powerful mutagen (**use caution**).

Since the *L. monocytogenes* method gives the option of using α - naphthol, **DO NOT** use α - Naphthylamine. All analysts should take **extreme safety precautions** when handling this chemical; i.e., weigh in a containment hood free of drafts; wear gloves and face mask. Those laboratories with pesticide capabilities should take additional precautions against possible contamination, as cycloheximide is a fungicide.

Isolation and Identification

Use BAM On-Line 2001, at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm, Chapter 10, *Listeria monocytogenes*, and Chapter 11, Serodiagnosis of *Listeria monocytogenes*.

PFGE

If samples are found to be positive for *L.monocytogenes,* perform PFGE according to the current version of the ORA SOP for Routing Sub typing (Document # ORA-LAB 2).

Pulse-field gel electrophoresis (PFGE) must be performed on *L. monocytogenes* isolates by each laboratory and the results submitted to PulseNet (the national sub-typing network for foodborne disease surveillance coordinated by CDC).

When large numbers of positives are detected, use the following criteria to prioritize the PFGE analysis:

A. If resources are not sufficient to perform PFGE analysis immediately for all environmental isolates, isolates from Zone 1 should be given priority and be analyzed by PFGE upon isolation.

B. Environmental isolates from other areas should be prioritized for PFGE analysis in consultation with DFS/DDFI and should be based on environmental isolates collected from locations most likely to serve as a source of contamination of food contact surfaces and food due to proximity or because of operational activities that could result in cross contamination (potential to be transmitted by a food handler from the site, potential to be aerosolized, etc.)

   The remainder should be stored (frozen) until further instruction.

C. Primary and secondary enzyme—Perform PFGE analysis with both primary and secondary enzymes simultaneously.

RAPID SCREENING METHODS FOR LISTERIA

Environmental Samples

AOAC RI (No. 981202) VIDAS Listeria (LIS) for the detection of Listeria in environmental specimens.

Listeria AOAC Official Method 999.06 *Listeria* in Foods, Enzyme-Linked Immunofluorescent Assay (ELFA) VIDAS LIS Assay Screening Method. Official Methods of Analysis of AOAC International, current edition.

CONFIRMATORY METHOD FOR *LISTERIA*

Use BAM On-Line 2001, at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm Chapter 10, *Listeria monocytogenes*, and Chapter 11, Serodiagnosis of *Listeria monocytogenes.* No enumerations will be performed on environmental swab/sponge samples. Questions regarding *Listeria* analysis may be directed to Yi.Chen@fda.hhs.gov

Listeria Isolate Shipment

All *Listeria* isolate shipments will occur after sample disposition. The sample disposition is completed following receipt of the disposition authorizations in FACTS or by memorandum in a timely manner. Date of disposal is documented in FACTS. Isolates should be shipped overnight on a brain heart infusion agar slant at room temperature to CFSAN as follows:

Atin R. Datta, Ph.D.
Chief, Virulence Mechanisms Branch
FDA/DVA/OARSA/CFSAN
8301 Muirkirk Road
College Park, MD 20708
301-210-6084; Atin.Datta@fda.hhs.gov

Also, send isolate details to Yi.Chen@fda.hhs.gov

District Response to Laboratory Findings from Environmental Samples

When positive or negative environmental samples are reported to the district by the servicing laboratory, the firm is to be notified within 48 hours, and advised of the findings as per DDFI Bulletin #30). It is important to report negative findings as well, as some firms may hold product pending results.

These procedures are a decision-making framework to guide District and Headquarters staff to implement a consistent national approach to respond to environmental sample results in an effort to streamline corrective actions and public health protection. It is important to note that while this broad approach should be applied across all cases, the specific regulatory response taken will be based on a case-by-case review by Headquarters and District staff considering the firm's history, the inspectional findings, the location of the sample, the potential for a route of contamination of final product, the public health risk, and the firm's response to the findings. For this reason, it is essential that the possible link between the environmental sample and contamination of the food product be documented and clearly presented. See IOM 4.3.7.7.1.

Next steps will be determined by the assessment of the environmental sample locations:

1. ***For Listeria in Zone 1***, a conference call including the District, DDFI, CFSAN/OC, CFSAN/OFS/DPDFS, CFSAN science advisors, and ORA OE should be scheduled by the District to determine next steps, including whether the firm should be asked to recall the product (DDFI can assist in this if needed). See below for conference call details.
2. Following the above discussions, the District Office will contact the firm with the findings and discuss the firm's next steps and elicit the firm's response. For this reason, **the conference call must be scheduled within 48 hours so that the firm can be contacted within that timeframe as well**

3. **Note: If the district is unable to coordinate the above conference call within 48 hours, the District's state counterparts and the firm should be contacted and notified of the positive finding. Let the firm know that additional discussions will be taking place within the agency and we will get back to them as soon as possible.**

4. The timing of follow-up targeted inspection will be based on the firm's response to the positive findings and the corrective action plan the firm intends to take. If the district is certain that the contamination issue has been adequately addressed and any potentially adulterated product is promptly being pulled from commerce, the district may delay conducting a targeted inspection. A re-inspection is to be conducted within 6 months to verify the firm's effectiveness of their cleaning procedures. Once the district determines that a targeted inspection is appropriate, the inspection should include an investigation of the routes of cross contamination and collection of finished product lots processed at the time of the initial inspection or at the time of the follow-up visit. The District should invite the state to participate in the follow-up inspection and in the conference call (FDA Commissioned Officials only). For contract inspections conducted by the State, please see response by the State below for procedures.

5. **For Listeria in Zone 2**, the district must review the environmental sample locations to determine if there is a route of possible contamination to finished product. If there is a route of possible contamination or if the district is unsure of the route of possible contamination, the district may schedule the conference call as discussed above. A re-inspection is to be conducted within 6 months to verify the firm's effectiveness of their cleaning procedures

6. **For *Listeria* in Zone 2 (with no route of contamination identified) or Zones 3 or 4**, the District should discuss with the firm what acceptable remedial steps would be expected. A re-inspection, which includes collection of environmental samples, should be scheduled within one year to verify the effectiveness of the firm's clean-up procedures. A strategy call as described in

1. is not needed, but DDFI should be advised of the outcome including a brief description of the findings and the firm's response.

Finished product samples should be collected for all re-inspections due to environmental positives of Listeria.

* Conference Call invitation should be set up with an invitation via e-mail sent to the following groups:

Organization	Outlook Address or List
District Staff	As determined by the District
DE	ORA HQ OE Management
ORO Immediate Office	ORA HQ ORO Management
DDFI	ORA HQ DDFI DOM FOODS
DFS	ORA HQ DFS Management
CFSAN	Priya.Rathnam@fda.hhs.gov
	Mickey.Parish@fda.hhs.gov
	Melinda.Chen@fda.hhs.gov
	Monica.Metz@fda.hhs.gov
	Obianuju.Nsofor@fda.hhs.gov

Call in information to be used for these conference calls is (866)453-3628, passcode: 758522 leader code: 430957. The District should use the leader code.

Possible Regulatory Actions Resulting From Positive Environmental Samples

Refer to the Regulatory Procedures Manual and Part V of the appropriate Compliance Program.
http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm013763.htm
.
In some cases, based on the significance of the findings, voluntary correction may be the most appropriate action by the firm. When voluntary correction is not forthcoming, the Agency should pursue the routine regulatory procedures listed in DDFI Field Bulletin #30 to obtain compliance (refer to FMD-86 for classification):

Enforcement Action

When the firm's response is inadequate to protect the public health, all available administrative and legal tools should be considered.

- FDA-Requested Recall or Mandatory Recall Order

Although not usual in the absence of demonstrating specific product contamination, an FDA-requested recall could be considered in sufficiently urgent situations, normally involving a Class 1 health hazard evaluation. Refer to RPM

Chapter 7. If a determination is made that there is reasonable probability that an article of food is adulterated under section 402 and will cause a serious adverse health consequences or death to humans or animals (SAHCODHA), mandatory recall authority under section 423 may be warranted.

- Administrative Detention

If a determination is made that there is reason to believe that an article of food is adulterated (or misbranded), administrative detention under section 304 may be considered to prevent the movement of such food.

- Seizure/ Injunction

- Suspension of Food Facility Registration

If a facility registered under section 415(a) manufactures, processes, packs, receives, or holds food that has a reasonable probability of causing SAHCODHA; and that facility created, caused or was otherwise responsible for that reasonable probability of SAHCODHA; or knew of, or had reason to know of, the reasonable probability of SAHCODHA, and packed, received, or held such food, suspension of food facility registration may be considered.

If warranted, the state should be engaged to determine if state enforcement actions such as embargo or permit revocation can be utilized to stop the movement of product or production while FDA is considering enforcement actions. The District should consult with OE, OCC, and the appropriate Center, to determine an appropriate enforcement strategy for each scenario on a case-by-case basis.

Re-inspection

A re-inspection of the firm should be conducted within 6 months of initial regulatory action (regulatory meeting or Warning Letter) or much sooner if there is reason to believe there are serious ongoing deficiencies. This re-inspection should again include collection of environmental swab samples and verification of corrective action taken by the firm to eliminate harborage of the pathogen and any violative practices whereby the finished food product could become contaminated. Finished product samples should be collected for all re-inspections due to environmental positives of Listeria.

The district should submit any resulting recommendation for enforcement follow-up via electronic copy (e.g., doc, pdf files, etc) via the Compliance Management Services link (“MARCS – CMS”) located on Inside FDA’s IT Applications Page under ORA Applications http://intranet.cfsan.fda.gov/vts/

Specimen charge (conditions):

The article of food is adulterated under section 402(a)(4) of the Act (21 U.S.C. 342(a)(4) in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

Note: The above charge applies to the food produced by the firm that can be associated with the positive environmental swab.

CONTACTS

General Assignment Contact:
Melinda Chen OC/DFP&G/FPB, HFS-615, phone 240-402-1471,
Melinda.Chen@fda.hhs.gov; or

Regulatory Contact:
Priya Rathnam, OC/DE/FAAB, HFS-607, phone 240-402-2078,
Priya.Rathnam@fda.hhs.gov

CFSAN Scientific Contact:
Donald Zink, CFSAN, Office of Food Safety, HFS-302, phone 240-402-1693,
Donald.Zink@fda.hhs.gov

Yi Chen, CFSAN, Office of Regulatory Science, HFS0710, phone 240-402-2783,
Yi.Chen@fda.hhs.gov (*Listeria* SME)

CFSAN Program Office Contact:
Monica Metz, CFSAN, Office of Food Safety, HFS-316, phone 240-402-2041
Monica.Metz@fda.hhs.gov

ORA/DFS Scientific Contact
Peggy Carter, ORA/DFS, phone 301-796-6239
Peggy.carter@fda.hhs.gov

ORA/DDFI Contacts:
Chyla Hunter, ORA/ORO/DDFI/DOB, phone 301-796-5473,
Chyla.Hunter@fda.hhs.gov

TIMEFRAME

The assignment has the concurrence of ORA (ORA Concurrence #2012051802) and has been designated as a ***High Priority***.

Inspections and sample collections should begin upon receipt of this assignment and will continue through the first half of FY 2013 (March 29, 2013). Samples should be completed and worksheets forwarded to the appropriate collecting district within two weeks of receipt of the sample.

Melinda E. Chen, JD, PhD

Cc:

HFC-100 (Romano, L. Chasey)
HFC-130 (Clausen, Hunter, Fogg, Caphart)
HFC-141 (Dreisch, Salem, Carter)
HFS-300 (Beru)
HFS-302 (Metz)
HFS-315 (Sheehan)
HFS-302 (Zink)
HFS-600 (Roosevelt)
HFS-605 (Thomas)
HFS-607 (Correll, Rathnam)
HFS-615 (Chen, Aloi, Barringer, Shelborne)