Date: January 20, 2011

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

Subject: Amendment to Assignment: Request for Inspections and Environmental Sampling for Listeria at Soft Cheese Firms --- High Priority, DFPG NO: 10-04, FACTS# 1168701, ORA Concurrence #2010042801

To: DIBs: All
DCBs: All

Director of Laboratory Branches: All

Info: RFDDs: All
DDs: All

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CHANGE TO INSPECTIONS OF ARTISANAL CHEESE FIRMS

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 is to determine whether or not Listeria are 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

A summary report through December 29, 2010 compiled by ORA/DFS shows that from the 154 firms to have been inspected and sampled, 115 have been done. The assignment was extended on September 9, 2010 (see http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm015774.htm)
From the list of firms, 41 are identified as artisanal cheese firms. Results of environmental sampling in 31 of these firms inspected thus far reveals a high level of positive Listeria findings (9 out of 31 firms inspected have yielded positive environmental samples for a positive findings rate of 29%). 9 firms have found to have positive samples, 22 firms had negative samples and 10 firms have yet to be inspected.

Because of the potential of a high positive rate for the environmental sampling, changes are being made to this assignment are for these artisanal cheese firms only. Note: Any remaining non-artisanal cheese firms are to be inspected and No Finished Product Sampling is to be done in these firms.

Attachment C contains two tabs: 1) 41 ARTISANAL CHEESE FIRMS. Blanks under the Inspection Status column identify the firms that have not been inspected yet and are highlighted in yellow; and 2) FIRMS TO BE INSPECTED. These are the 10 remaining artisanal cheese firms to be inspected.

Sample Collection: Artisanal Cheese Firms Finished Product

For each firm on Attachment C that has not yet been inspected under this assignment, the district should collect finished product samples in addition to the environmental samples. Based on the investigator’s observations, priority of collection should be as follows:

1. Raw Milk Cheese
2. Pasteurized Cheese

Note: Collect up to three (3) unique finished products.

Sample Size

Follow the instructions in the Domestic and Import Cheese Compliance Program (7303.037) for sample size and shipment instructions. http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm181909.htm Questions regarding sample collection can be directed to Monica Metz, 301-436-2041

Indicate on the collection report analyses for E.coli and Listeria only.

Ship samples to the servicing laboratory for analysis of the environmental samples as well as the finished product.
RAPID SCREENING METHODS FOR LISTERIA

Environmental Samples

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


Finished Cheese Samples


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 Chapter 10 requires that all Listeria monocytogenes positive samples be enumerated using reserve sample (Section J). Questions regarding Listeria analysis may be directed to Anthony.Hitchins@fda.hhs.gov

E. COLI ANALYSIS FOR FINISHED CHEESE SAMPLES

For E.coli, follow the updated procedure below which will be included in the next version of the cheese program. Refer to the December 2010 Compliance Policy Guide Sec. 527.300 found at http://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM238465.pdf for the latest policy on E.coli.

E.coli/Enterotoxigenic E. coli (ETEC)

- Examine each subsample individually.
• **Isolation, identification, and enumeration**: BAM On-Line, at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm Chapter 4. Alternatively, the ColiComplete assay (BioControl) may also be used for the analysis of *E. coli* in cheese as stated in the DFS Notification No. 2009-09-29. In the event that generic *E. coli* levels exceed the action limit, be sure to perform the *E. coli* confirmation procedure specified in the above Notification. Furthermore, as specified in DFS Notification No. 2009-11-13, analysis whether using BAM or ColiComplete may be stopped if the levels of *E. coli* will not exceed the action limit.

• **Analysis for ETEC in Cheese Samples using Multiplex PCR (LIB# 4227)**

Cheese subsamples that contain generic *E. coli* at levels > 10,000 MPN/g need to be tested for the presence of enterotoxigenic *E. coli* (ETEC) using PCR primers specific to the heat-labile (LT) and heat-stable (ST) toxin genes. The PCR method to be used is: “Use of multiplex PCR for Identification of ETEC” described in the Retail Cheese Assignment DFP #06-10, LIB #4227, Oct. 2000. To use this multiplex PCR method for ETEC analysis in cheese, follow the protocol outlined in: DFS Notification No. 2009-09-29.

**Enterohemorrhagic *E. coli* (EHEC)(0157:H7)**

• Examine each subsample individually.
• Use the method "Isolation Methods for Enterohemorrhagic *E. coli* (EHEC)"*, BAM On-Line, at [http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm](http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm)

Chapter 4a, Section K. Screening Method for *E. coli* serotype O157:H7 from foods.

• ***E. coli* O157:H7 PFGE**

If samples are found to be positive for *E. coli* O157:H7, then submit two (2) positive isolates recovered from each subsample. Submit the culture on Trypticase Soy agar slants in screw cap tubes (13x100mmx125mm) with caps secured tightly. Label each tube with the sample number and sub sample number. Submit copies of the collection report and analytical worksheets. Place cultures in a culture container with an official FDA seal. Place accompanying records inside the shipping carton but not within the
officially sealed culture container. Prepare cultures for shipment according to the requirements for shipment of etiological agents.

Send the container by the most rapid mail service available. Maintain duplicate cultures of those submitted for all cases, which are under consideration for regulatory action.

Submit E. coli O157.H7 isolates for PFGE analysis to the ORA laboratories designated in the ORA SOP for Routine Subtyping (Document# ORA-LAB2) dated August 6, 2001.

REGULATORY/ADMINISTRATIVE FOLLOW-UP

The Center is prepared to consider regulatory action against establishments found to be manufacturing products in conditions favorable to the presence and growth of Listeria monocytogenes, and/or found to manufacture products that are contaminated with L. monocytogenes or pathogenic E. coli.

Listeria monocytogenes

When CRO is reported positive for environmental samples

In the event that the positive environmental sample was taken from a Zone 1 location (food contact surface), the district must immediately initiate a targeted inspection at the firm to include an investigation of the routes of cross-contamination and collection of finished product. If the positive sample was taken from Zone 2, the district should initiate a conference call with, OE, DDFI, DFS, and the appropriate Center to discuss the criteria described above and to determine what regulatory actions should be pursued. If the environmental sample was not taken from either of these Zones, a conference call is not necessary and the district should independently assess the significance of the positive sample, informs the firm, and solicit their response. The district would subsequently be charged with communicating the firm’s response and any proposed regulatory action and/or follow-up to ORAHQ and the center. The district should take into account any finished product samples (along with the positive environmental sample) when making the decision to convene a conference call.

Specimen charge: Regulatory action under section 402(a)(4) would have to be based on sufficient evidence (such as routes of cross-contamination) to show that the food was prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Pathogenic *E. coli* or *L. monocytogenes*

When CRO is reported positive for finished product samples

Positive findings in cheese product must be reported to the CFSAN/DE assignment contact (Priya.Rathnam@fda.hhs.gov) and the collecting district as soon as possible.

Specimen charge:
The article of food is adulterated under section 402(a)(1) of the Act (21 U.S.C. 342(a)(1) in that it bears or contains a poisonous or deleterious substance, namely [identify pathogen; for example, E. coli 0157:H7 or *L. monocytogenes*], a human pathogen.

The districts should notify their state counterparts of any confirmed positive results, and contact the firm to assess the potential adverse impact on the public health. If product has already been distributed, districts should encourage the firms to take appropriate steps, including voluntary recall.

If the firm doesn’t perform a voluntary recall, or if the firm doesn’t agree to take action to ensure the product doesn’t enter the marketplace, Districts should request a strategy call with CFSAN/Division of Enforcement, OE, and OGC to discuss enforcement options, such as FDA requested recall, seizure, or injunction.
CONTACTS

General Assignment Contact:
Melinda Chen OC/DFP&G/FPB, HFS-615, phone 301-436-1471, Melinda.Chen@fda.hhs.gov; or

Brenda Aloi OC/DFP&G/FPB, HFS-615, phone 301-436-2065, Brenda.Aloi@fda.hhs.gov

Regulatory Contact:
Priya Rathnam, OC/DE/MSAB, HFS-607, phone 301-436-2078, Priya.Rathnam@fda.hhs.gov

CFSAN Scientific Contact:
Donald Zink, CFSAN, Office of Food Safety, HFS-302, phone 301-436-1693, Donald.Zink@fda.hhs.gov

CFSAN Program Office Contact:
Monica Metz, CFSAN, Office of Food Safety, HFS-316, phone 301-436-2041, Monica.Metz@fda.hhs.gov

ORA/DFS Scientific Contact
Ann Westerman, ORA/DFS, HFC-141, phone 301-827-1482, Ann.Westerman@fda.hhs.gov

ORA/DDFI Contacts:
Chyla Hunter, ORO/DDFI/DB, HFC-130, phone 301-827-4310, Chyla.Hunter@fda.hhs.gov

TIMEFRAME

The assignment has the concurrence of ORA (ORA Concurrence #2010042801) and has been designated as a High Priority.

Inspections and sample collections should begin upon receipt of this assignment and should be completed within 60 days. Samples should be completed and worksheets forwarded to the appropriate collecting district within two weeks of receipt of the sample.

Melinda E. Chen
Attachment C: 41 Artisanal Cheese Firms

Cc:
HFC-100 (Elder)
HFC-101 (Rogers)
HFC-10 (Roosevelt)
HFC-132 (Caphart)
HFC-132 (Hunter, Fogg)
HFC-141 (Dreisch, Westerman)
HFS-300 (Beru)
HFS-302 (Metz)
HFS-315 (Sheehan)
HFS-302 (Zink)
HFS-600 (Wagner)
HFS-605 (Thomas)
HFS-607 (Correll, Rathnam)
HFS-615 (Chen, Aloi, Barringer, Bass, Honeyblue)