

## **General Information Document**

### **FDA Artisanal Cheese Producer Inspections, Sample Collections, Analyses, Post Sampling Communications**

#### **Background**

FDA regulates food products produced and shipped in interstate commerce, including artisanal cheese. FDA's focus during inspections and sample collections is on the safety of food products and with cheese, specific emphasis is on the facility's food safety program to prevent pathogenic microbial contamination.

#### **Inspections**

When FDA conducts an inspection of a cheese producer, they will identify themselves by displaying their federally-issued credentials and issue a Notice of Inspection (FDA 482) to the most responsible individual on-site at the time of the inspection. The investigator will begin by explaining the purpose of their visit and asking general questions about your establishment, including what types of products you produce, how you produce them, from where your raw ingredients are procured and where you distribute your products.

The inspection will proceed with the investigator conducting a physical inspection of your establishment. Generally they will want to view all areas of your facility used to produce, pack, store, and ship FDA-regulated products. They may start in your receiving area and progress through the food processing and storage operations observing testing, preparation, packaging, storing, and distribution areas. Observations and questions asked will be focused on learning the processes you use to produce artisanal cheeses, the environment in which products are produced and stored, practices and procedures used for effective cleaning and sanitizing of equipment and your facility, and the controls you have in place to ensure the safety of the product you produce and distribute.

If the investigator performing the inspection is a PHS Commissioned Officer, the investigator will be wearing his/her uniform. The officer wears the uniform as a Commissioned Officer in the Public Health Service. The officer may engage in a discussion with you regarding his/her uniform, discuss what he/she is wearing (e.g., blues, khakis) and also explain why the officer wears the uniform as a Commissioned Officer in the Public Health Service.

#### **Sample Collection**

FDA collects food samples for various different reasons. For instance, samples may be collected for general surveillance programs, collected "for cause" based upon observations made by an

investigator while conducting an inspection, as a follow-up to a complaint, or report of foodborne illness. You can expect the sample size to be as below.

If your product is:

- Less than one pound retail units: 10 subsamples with each subsample consisting of enough units to make up a one pound subsample
- One pound to five pound retail units: 10 subsamples consisting of one intact unit each
- Wheels, loaves and bricks weighing greater than five pounds: 2 subsamples consisting of one intact unit each

FDA may also collect environmental samples within your facility during an inspection, particularly in follow-up investigation to product contamination events or foodborne illness reports. Those samples will generally consist of 100 – 300 swabs collected in your production and storage environment. The purpose of these environmental samples is to assess the environment for pathogenic microorganism of public health significance that may have established niche residency.

### **Sample Payment**

When an investigator collects samples from you, you may provide those samples at no cost to the government or request payment. The investigator will provide you with a Receipt for Samples (FDA 484) whether or not payment is desired. When payment is requested, there are two business processes to accomplish payment. Payment may be made by the investigator at the time of collection using a cash advance of government funds that the investigator acquires prior to collecting samples. Another process is that you may submit a request for payment to FDA for the samples collected. FDA pays the fair, wholesale cost for products sampled when reimbursement is sought. The investigator will provide you with the address of their district office where billing for the samples will be processed. You will submit your invoice and a copy of the receipt the investigator provides you to seek reimbursement for samples collected. You may also wish to prepare an invoice for the products sampled by the investigator and provide it to the investigator at the time s/he provides you with a receipt for samples. The investigator should be communicating with you as to whether you wish to provide the samples to the government at no charge or seek payment and the amount the samples will cost.

### **Sample Analysis**

Samples collected may be analyzed for microbial contamination, filth contamination and/or phosphatase. Microbial analysis may examine for *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* (*E. coli*) and Enterotoxigenic *E. Coli* (ETEC), Enterohemorrhagic *E. coli* (O157:H7),

and *Staphylococcus aureus* (if indicated). Samples will be analyzed in accordance with the Bacteriological Analytical Manual (BAM). Results of analysis: preliminary Cannot Rule Out (CRO) results may be available in as little as three days and full analytical results are usually completed within 14 days.

### **Communications Post-Sampling and Analysis**

If your cheese was sampled during an inspection of your facility (a Notice of Inspection was issued to the most responsible individual on-site during the inspection), section 704(d) of the Food, Drug and Cosmetic Act requires FDA to provide you with results of analysis for samples collected for filth and microbiological analyses. A report of the analytical results will be sent to the most responsible person at your establishment. If the samples were not collected during an inspection, you may request results of analysis through the Freedom of Information Act (<http://www.fda.gov/regulatoryinformation/foi/default.htm>). If you are voluntarily holding your product pending analysis or the investigator collected environmental samples, FDA will provide the results of analysis when they are available. You should tell the investigator that you intend to voluntarily hold the product pending hearing the results.

If analytical results are negative for contaminants, you may resume shipping your products if you were holding them. If analytical results are positive for contaminants, the local FDA district office Compliance or Investigations Branch management will be contacting you to discuss the results and what steps are appropriate due to these results. Follow-up activities may include an inspection of your facility, discussion of corrective actions that may be taken and recall of products remaining in the market place. FDA also works closely with its State partners and will share results of analysis with our Integrated Food Safety System partners, and the State regulatory authority may participate in follow-up activities.