

**4.3.6 - ASEPTIC SAMPLE** Aseptic sampling is a technique used to prevent contamination by your sampling method. Aseptic sampling involves the use of sterile sampling implements and containers. Your sampling technique is where the lot or sample is contacted only by the sampling implements or the container. Samples collected using aseptic technique, will permit testimony that the bacteriological findings accurately reflect the condition of the lot at the time of sampling and, ideally, at the time of the original shipment. Whenever possible collect intact, unopened containers. Aseptic sampling is often used in the collection of in-line samples, environmental samples, product samples from bulk containers and collection of unpack-aged product that is being collected for microbial analysis. Note: Products in 55 gallon drums, or similar large containers, either aseptically filled or heat processed, should not be sampled while the shipment is en route unless the owner accepts responsibility for the portion remaining after sampling. Try to arrange sampling of these products at the consignee (user) so the opened containers can be immediately used or stored under refrigerated conditions. Use ASEPTIC TECHNIQUE when sampling these products. For more guidance on aseptic technique, you may consult the course Food Microbiological Control 10: Aseptic Sampling, which is available to FDA employees through the ORA U intranet site.

**4.3.6.1 - General Procedures** If it is necessary to open containers, draw the sample and submit it under conditions, which will prevent multiplication or undue reduction of the bacterial population. Follow the basic principles of aseptic sampling technique. Take steps to minimize exposure of product, sampling equipment, and the interior of sampling containers to the environment.

**4.3.6.1.1 - Sterilized Equipment** Use only sterilized equipment and containers. These should be obtained from the servicing laboratory or in an emergency, at local cooperating health agencies. Presterilized plastic or metal tools should be used. However, if unavailable, the metal tools can be sterilized immediately before use with a propane torch. Permit the tool to cool in the air or inside a sterile container before using. Soaking with 70% alcohol and flaming off is an acceptable method of field sterilization, and may be used as a last resort. If it is necessary to drill, saw, or cut the item being sampled (such as large frozen fish, cheese wheels, frozen fruit, etc.), if at all possible, use stainless steel bits, blades, knives, etc. Wooden handled sampling instruments are particularly susceptible to bacterial contamination, are difficult to sterilize, and should be avoided.

**4.3.6.1.2 - CAUTIONS** Be extremely careful when using a propane torch or other flame when sterilizing tools and equipment. Evaluate the conditions pertaining to explosive vapors, dusty air, flame restricted areas, firm's policy or management's wishes. The use of supportive devices should be considered when torch is not being hand held. Also be sure all flammable liquids, such as alcohol, in your filth kit are in metal safety cans and not in breakable containers. If it is necessary to handle the items being sampled, use sterile disposable type gloves (rubber, vinyl, plastic, etc. - surgeon's gloves are good). Use a fresh glove for each sub and submit an unopened pair of gloves as a control. See IOM 4.3.6.5. 4

**4.3.6.1.3 - Opening Sterile Sampling Containers** When opening sterile sampling containers, work rapidly. Open sterile sampling containers only to admit the sample and close it immediately. Do not touch the inside of the sterile container, lip, or lid. (See IOM 4.3.5)

**4.3.6.1.4 - Dusty Areas** Do not collect samples in areas where dust or atmospheric conditions may cause contamination of the sample, unless such contamination may be considered a part of the sample.

**4.3.6.2 - Sampling Dried Powders** Cautions - The proper aseptic sampling of dried milk powder, dried eggs, dried yeast, and similar types of products is difficult because they are generally packed in multilayer poly-lined paper bags. These may be stitched across the entire top, may have filler spouts, or the top of the poly-liner may be closed or sealed with some type of "twists". The practice of cutting an "X" or "V" or slitting the bag and folding the cut part back to expose the contents for sampling should not be used because it creates a resealing problem; the opening cannot be properly repaired. The following procedures have been approved by the scientific units in Headquarters and should be used when sampling this type product. 4

**4.3.6.2.1 - Bag And Poly-Liner Stitched Together Across Top Seam**

1. Remove as much dust as possible from the seam end by brushing and then wiping with a cloth dampened with alcohol. Note: This does not sterilize the bag as porous paper cannot be sterilized.
2. Remove the seam stitching carefully (and dust cover, if any) and spread the walls of the bag and the poly-liner open enough to permit sampling being careful that no extraneous material such as dust, bits of twine, paper, etc., drops into the product.
3. Carefully scrape off the surface of the product with a sterile device and aseptically draw the sample from the material below.
4. Carefully reclose the bag and re-stitch by hand, or by machine if firm or FDA portable sewing machine is available.

**4.3.6.2.2 - Bag Stitched Across Top And Poly-Liner Twist-Closed And Sealed With "Twist" Device - Wire, Plastic, Etc.**

1. Brush, alcohol wipe, and remove stitching as described.
2. Remove "twist" seal and carefully open poly-liner using caution that no extraneous material drops into the product.
3. Draw aseptic sample in same manner as in step 3 above.
4. Carefully close the poly-liner with a twisting motion and reseal with "twist" seal arranging it so it will not puncture the poly-liner, and re-sew bag as in step 4 above.

**CHAPTER 4 INVESTIGATIONS OPERATIONS MANUAL 2016 128 4.3.6.2.3 - Bags With Filling Spouts** The filling spout will be located at one side of the top stitching and will either pull out to form a top or side spout.

1. Brush and alcohol wipe the area around the spout and carefully pull it out to reveal the opening. It is better to have the bag on its side while pulling the spout so any dust in the opening falls outside the bag.

2. Carefully spread the sides of the spout apart and aseptically draw the sample. A trier or long handled device is usually better for this type opening because of the limited opening.

3. Carefully close the spout with a firm twisting motion and be sure the opening is closed prior to pushing back into the bag.

**4.3.6.4 - Sample Handling** For frozen samples, pre-chill sterile containers before use and keep frozen with dry ice. Use ordinary ice or ice packs for holding and transporting unfrozen samples that require refrigeration. See IOM 4.5.3.5, 4.5.3.6 and 8.3.3.3. Under normal circumstances dried products may be shipped unrefrigerated except in cases where they would be exposed to high temperatures, i.e., above 37.8o C (100o F). Submit samples subject to rapid spoilage (specimens of foods involved in poisoning cases, etc.) by immediate personal delivery to the bacteriologist where feasible.

