

Generalized FDA Sampling Protocol

Collecting samples on FDA Detention Without Physical Examination requires careful attention to detail. This is the first stage in a legal process to ensure that the commodity meets legal pesticide residue tolerance laws, and a data package which includes the sample collection form is required by FDA to release product for distribution into the US. Deviations from the procedures or incomplete documentation may result in delays for release or rejection of the data package by FDA.

- 1) Gather sample collection materials. These should include FDA Sample Collection Form, Import Documents (including Bill of Lading, FDA Notice of Action, and Commercial Invoice), a digital camera, 10 individual sample collection containers (usually gallon size zip-lock bags will suffice), shipping container, blue ice or dry ice (Unless dehydrated or canned), as indicated, marker to label sample collection containers, rubber gloves, and a top loading scale.
- 2) Count all containers in the shipment, to verify that the number matches the notice of action. Verify that the container and item or lot codes on the invoice and bill of lading match the shipment.
- 3) Select 10 containers at random from the shipment. Ensure that each subsample is collected from a different pallet, and at a different part (Top, Middle, Bottom) of each pallet (if applicable), Open each container, and select a sub-sample of about 2 pounds from each container if fresh, or 100g if dehydrated and place that sub-sample into a zip lock bag and seal it. Label each bag with the Entry Number and Line Number, followed by the sub sample number (1 of 10, 2 of 10, etc.), date sampled, and sampler name and initials. Then label each container that was sampled with the Entry Number and Line Number, followed by the sub sample number (1 of 10, 2 of 10, etc.), date sampled, and sampler name and initials
- 4) Complete all sample collection portions of the FDA Sample Collection form, leaving the "Laboratory" section to be filled in by the laboratory. Be sure to include Entry Number and line number, Provide information on how the lot identity was verified, and a description of where each sample was pulled from. Be sure to remember to sign and date the sampling form.
- 5) Ensure that the following photos for each line being sampled are taken during the sampling: entire lot(s) being sampled, the case's product label, a photo showing containers being taken from different parts of the pallets, a pictures of all subsamples gathered for an individual entry/line, and a picture showing the samples packed into the shipping container.
- 6) Load all samples into the shipping container with the blue ice, place the FDA Sample collection form and sample collection photos into a plastic bag along with a copy of the import documents, and place it into the shipping container as well. For multiple samples being shipped in the same box, ensure that each entry/line's sampling documents are kept separate from each other.

7) Send the shipping container by overnight courier to:
Environmental Micro Analysis, Inc.
460 N East Street
Woodland, CA 95776
(530) 666-6890