

October 3, 2018

Todd Cato
Acting Director, Office of Enforcement and Import Operations
Food & Drug Administration

Armando Zamora
Deputy Director, Office of Enforcement and Import Operations
Food & Drug Administration

Dr. Paul Norris
Director, Office of Regulatory Science
Food & Drug Administration

Mr. John Verbeten
Director, Division of Import Operations
Food & Drug Administration

Transmitted by Electronic Mail

RE: Recent FDA Rejections of DWPE Report Packages due to sampling procedure

Dear Enclosed Recipients:

We write on behalf of the undersigned organizations to bring to your attention an issue involving the practices of FDA Compliance Officers that is having a disruptive and burdensome effect on commerce. Specifically, there have been at least three recent incidents where FDA Compliance Officers have rejected Detention Without Physical Examination (DWPE) Laboratory Report Packages based on the accredited laboratories sampling procedure in public refrigerated and frozen warehouses. In these cases, FDA Compliance Officers have stipulated that the samples collected were not representative or random with respect to the product on import alert. This new policy raises a number of issues for our members and we are asking FDA to reconsider or provide consistent guidance and enforcement, so that commerce is not unnecessarily disrupted. The entries in question are: EF1-0052388-7 (Boston), 082-0387638-1 (Los Angeles) and 9EX-1807388-5 (Chicago). This letter is meant to describe our view of the situation and ask for FDA to clarify and implement a consistent policy moving forward.

As a matter of background, the FDA has historically accepted a copy of a current public warehouse inventory record as verification of the quantity of detained product present in the warehouse at the time of sampling. A public warehouse inventory record is a legal document, and FDA relies on similar legal documents in verifying the quantity of goods in a lot; i.e., bills of lading, packing lists, and commercial invoices that serve as Customs Entry Documents. The quantity of food packages shipped in ocean containers is usually stated on the Ocean Bill of Lading as "Shipper's Load and Count," and is not verified at the time of loading on the ship. Instead, the first party to count and verify the actual quantity of packages in a shipment is the warehouse where the container is unloaded, and where the warehouse accounts for the quantity remaining in storage on a daily basis. In addition, the public warehouse records notations on the condition of the shipment, for which it is liable when it receives the product for storage.

When containers arrive and are unloaded for placement in the warehouse, pallets that comprise a shipment are not always placed together in a warehouse. Whenever possible, samplers conduct a visual inspection of all of the pallets in a lot, at the time of sampling, but in the case of product that is in freezer storage that is often practically impossible. Freezer space is usually restricted to warehouse personnel only, and there is very limited space for staging pallets for inspection. It is increasingly the case that freezer and general storage warehouses are fully automated with robotic forklifts. It is standard operating procedure that absolutely no persons are allowed in automated warehouse spaces. In a typical freezer warehouse, pallets are scattered in random pallet-rack positions, some up to 20 feet above the floor or higher, rather than in one central location. Throughout the day, these warehouses are actively receiving and delivering product, and the constant activity of the forklifts limits the area where it is safe to conduct inspections and sampling operations. In addition, there is usually insufficient room for entire lots to be staged for inspection or sampling on a daily basis, and certainly not multiple lots. Given this situation, it is our view that by definition samples taken from the available pallets from the lot are by definition random.

In the case of the first entry in Boston, FDA Compliance Officer, Jay Patria, required that the sampler visually inspect every pallet of detained lots in freezer storage even though the inventory record is updated daily, and after every movement of pallets in or out of the building. Compliance Officer Patria stated in an email message that he reached out to multiple reviewers throughout FDA. He also contacted the ORA Office of Regulatory Science, and that office concluded,

“The (report) package was unacceptable as the sample collector cannot visually examine the entire lot. Therefore, it is impossible to effectively determine number of lots or lot sizes. In addition, it is impossible for the sample collector to visually determine the condition of the entire shipment (lot or lots). The Center has determined per the ORA Lab Manual, Chapter 7, that the sample collector must be able to visually examine the entire shipment.”

In addition, Compliance Officer Patria contacted the FDA Division of Import Operations. This practice has spread to the other two entries we reference where FDA Compliance Officers are now stating that warehouse inventory records are unacceptable and that the sampler must inspect and sample an unknown number of pallets in the lot in order to be representative in the eyes of the Compliance Officer.

We sincerely appreciate Compliance Officer Patria’s and his fellow Compliance Officer’s diligence and effort to make sure that the samples taken ensure the welfare of the public. However, we believe that the ORA and DIOP were not aware of the situation samplers are confronted with at freezer warehouses and the legitimacy of warehouse inventory documents as legal records. In addition, we do not agree that Chapter 7 of the ORA Field Science Laboratory Manual supports FDA’s rejection of the sampling process. There are two sentences that are usually cited by FDA from the Laboratory Manual:

“If, in the judgment of the reviewing district office, the method of collection does not result in a representative sample, the analytical package would be rejected.”

“Verify the location and identity of the lot to be sampled”

Regarding the first quote, this has always been a great concern to private labs because it has given FDA reviewers freedom to refuse report packages for arbitrary reasons that cannot be supported by written FDA procedures and guidance. In the second quote, the sampler has identified the lot by lot number and labeling, and has noted the lot location on the sample collection report. It is not necessary to observe every pallet in the freezer, to verify that the pallets were in the freezer, when the randomly selected sample pallets are brought out from the freezer and staged for sampling. The random pallets are in essence a sample of the pallets in the lot, and package labels are used for lot verification.

Therefore, it is not clear as to what exactly the ORA is referring to in the Laboratory Manual. In the absence of specific FDA guidance or instruction, we believe it is inappropriate to reject a report package based on sampling procedures that have historically always been accepted by compliance officers, including Mr. Patria. We would note that it is very difficult without notice and an explanation to comply with this new standard and we are requesting that FDA please review these entries and change in practice.

Ultimately, we believe this whole issue arises from a misunderstanding about the practical reality of sampling lots in freezer warehouses and a lack of familiarity with the sampling procedures that are stipulated in the import alert. As a result, we request that FDA establish a sampling plan for selecting pallets of product in a lot. The plan would be based on the square root of the total number of pallets in the lot, and from which subsamples of product will be randomly and proportionally collected for laboratory analyses.

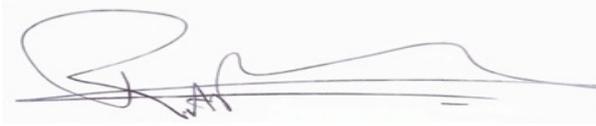
If FDA continues this practice it will add significant cost to the product, create costly delays, and directly interfere with the ability of seafood importers, warehouses, transportation companies and the private laboratories to operate. If FDA chooses to continue to enforce these practices, a public warehouse might only be able to accommodate a sampler once or twice a week and stage one or two lots at most. Prior to this practice taking effect, a sampler might be able to sample 25 lots of seafood per week. Utilizing this standard could extend the time it takes to sample the same number of lots to 12 weeks. Without any notice the cost of this requirement and burden on importers and samplers will significantly impact commerce.

Furthermore, our organizations would appreciate FDA's feedback on the following concerns:

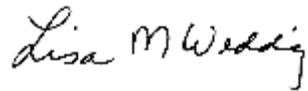
- 1) Now that Mr. Patria's comments are in the Private Lab Analysis Tracking System (PLATS), other Compliance Officers may begin following his precedent.
- 2) We would also like to address why we believe it is impractical and unsafe to sample and inspect seafood in a public freezer warehouse in the manner that Mr. Patria requested.
- 3) We would like to clarify that FDA recognizes that a public warehouse inventory record is an independent legal record.

Thank you for your consideration and we would be happy to provide any further information that would be helpful in investigating this matter.

Best regards,



Richard Bright
Chief Operating Officer
American Council Independent Laboratories



Lisa M Weddig
Vice President, Regulatory and Technical Affairs
National Fisheries Institute



Lowell Randel
Vice President, Government and Legal Affairs
Global Cold Chain Alliance

cc:

Ms. Jessica L. Zeller
ORA Ombudsman
U.S. Food and Drug Administration