Testing Method Recommendations for
Filth in Dried Shark Fins, Dried Fish Maws and
Dried Shark Cartilage Powder on IA 16-02

Date: 9-25-2024

**Please note, this recommendation is intended to provide supplemental general information to private laboratories on methods of analysis and test portion sizes of dried shark fins, dried fish maws and dried shark cartilage powder from shark fins. This document does not outline all the analytical method or worksheet requirements for packages being submitted for FDA review. **

Please refer to the current FDA Laboratory Manual, Volume III, Section 7 for comprehensive information on private laboratory package requirements and the review process: https://www.fda.gov/media/73540/download

Sample collection:

Collect subsamples as outlined in IA 16-02.

Analytical Protocol:

To analyze for **filth in capsules of ground shark fins**, we recommend using either one of these two methods. The analytical portion should be 100 g, regardless of method used.

- AOAC Official Method 972.38 Light Filth in Fish (Canned) and Fish Products.
- LIB 3242 Light Filth Analysis of Canned Fish & Fish Products. Note that with this method there is a chance of heavy residue on the sieve. In that case it would need to go through a trap flask step, such as AOAC Official Method 970.66 B(b) with mineral oil / heptane (85/15) as the flotation liquid. Liquid in the trap flask would need to be room temperature. If it is too warm, the heptane could evaporate too quickly.

To analyze for **filth in dried shark fins or dried fish maws**, we recommend using this method. The analytical portion should be one pound, or entire contents of consumer size package.

- LIB 2957 Examination of Dried Fish for Microscopic Filth

Count all filth elements and report findings according to AOAC 970.66. Note that other extraneous materials (e.g., fibers, paint chips, etc.) need to be described and reported by type and appropriate quantitative figure.

Quality Assurance:
Laboratory must follow the methodology specified in the private laboratory package submission. Any method modifications or deviations to the cited method must be explained and validation must be documented.

FDA does not endorse any private laboratory firms, nor requires specific methods to be used for Private Laboratory Analytical Packages (PLAPs). Information herein is provided as a courtesy, but private laboratories are not required to use them. The requirements state the method should be locally validated and should adequately identify and or quantitate the violative analyte(s). The information herein may also provide supplementary sampling, method information and/or sample preparation information to assist private laboratories who are analyzing products being held under Detention Without Physical Examination (DWPE) as part of an Import Alert to assist private laboratories with submitting scientifically sounds PLAPS as testimony pursuant to FD&C Act section 801 and 21 CFR 1.94 or FD&C Act section 422(b) and 21CFR 1.1107.