Testing Method Recommendations for Filth in Cocoa Beans on IA 34-01

Date: 8-14-2024

**Please note, this recommendation is intended to provide supplemental general information to private laboratories on methods of analysis and test portion sizes of cocoa beans. 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

Analytical Protocol:

Samples should consist of 10 subsamples, each with a minimum of 1 pound, for official analysis.

Sample Methods:

FDA Macroanalytical Procedures Manual (MPM) V-4. Chocolate, Sugars, and Related Products, Part A. Method For Cocoa Beans.

Perform both procedures:
(4) Procedure: Determination of Insect-Damaged and Moldy Cocoa Beans
(5) Procedure: Determination of Extraneous Material in Cocoa Beans

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 21 CFR 1.1107.