

Elemental Analysis Manual

for Food and Related Products

Archive Notes

This is an archived file provided for historical reference purposes only. Links to sites external to this file are not maintained and have therefore been removed. For the most recent information, readers are directed to the current [EAM](#).

1.2 Regulatory Operations

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GLOSSARY

1.2.1 REGULATORY PROCEDURES MANUAL

The Regulatory Procedures Manual is a reference manual that provides FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters.

1.2.2 COMPLIANCE POLICY GUIDES MANUAL

The purpose of the Compliance Policy Guides (CPG) Manual is to provide a convenient and organized system for statements of FDA compliance policy, including those statements that

contain regulatory action guidance information. The statements made in the CPG are not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended for internal guidance.

Example of CPGs related to elements:

- §540.600 Fish, Shellfish, Crustaceans and Other Aquatic Animals - Fresh, Frozen or Processed - Methyl Mercury (CPG 7108.07)
- §545.400 Pottery (Ceramics); Imported and Domestic - Cadmium Contamination (CPG 7117.06)
- §545.450 Pottery (Ceramics); Imported and Domestic - Lead Contamination (CPG 7117.07)
- §545.500 Silver-Plated Hollowware - Lead Contamination (CPG 7117.05)

1.2.3 COMPLIANCE PROGRAM GUIDANCE MANUAL

Compliance programs and program circulars (program plans and instructions) directed to field personnel for project implementation. See “Food and Cosmetics” through the following link for Current Food Compliance Programs (*link removed*).

1.2.4 ORA LABORATORY MANUAL

The Office of Regulatory Affairs (ORA) Laboratory Manual (LM) contains definitive regulatory and science guidance on primary functions of field laboratories. The LM contents cover all ISO 17025 elements and operations such as research, court testimony, analysts on inspections, private laboratory reviews, and training. The LM also contains Intranet links to the ORA Quality Manual, the Division of Field Science master list of procedures and work instructions, and the master lists of each ORA laboratory.