U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Elemental Analysis Manual

for Food and Related Products

The following is a section of the Elemental Analysis Manual for Food and Related Products.

For additional information and to view other sections of the manual, visit the Elemental Analysis Manual for Food and Related Products web page at https://www.fda.gov/food/laboratory-methods-food/elemental-analysis-manual-eam-food-and-related-products

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1 Elemental Analysis in FDA's Food Program

Version 1.0 (September, 2021)

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GLOSSARY and ACRONYMS

Elemental analysis of food provides data that FDA uses to make science-based decisions in support of its mission to ensure the safety of the nation's food supply. These data are necessary, whether the elements are called nutrients, metals, chemicals, ingredient, native, etc., and whether the levels are considered deficient, healthy, toxic, normal, added, etc.

FDA's Food Program addresses the interests of consumers, manufacturers, nations, states, and other agencies. It encompasses food that is consumed, produced, processed, packaged, labeled, imported and exported and its objectives vary with national needs and interests.

Table 1 shows how the current program is organized into several focus areas. Day-to-day work, however, is cross-cutting and will usually involve multiple focus areas. Elemental analysis, for example, is central to three of these: Compliance & Enforcement (focus on monitoring programs), Chemicals, Metals & Pesticides (focus on the analytes), and Science & Research (focus on laboratory operations). All, however, are inherently tied in with Food Safety. This Elemental Analysis Manual addresses the methodological needs of an elemental analysis laboratory and this first section introduces how elemental analysis supports these three focus areas.

1.1 Table 1 FDA Food Program Focus Areas

Program Area	FDA Activities
Labeling & Nutrition	Addresses food and nutrition labeling requirements
Science & Research	Invests in science-based activities (e.g., measurement & analysis, scientific methods development, original scientific research, reference database development, bioinformatics, and risk analysis)
Ingredients & Packaging	Regulates the safety of substances directly or indirectly added to food, as well as how most food is processed and packaged
Compliance & Enforcement	Monitors domestic and imported foods and the firms that produce them
Food Defense	Protects food from acts of intentional adulteration
International & Interagency Coordination	Performs strategies related to the safety of import & export foods and works with other U.S. government agencies to ensure clarity of jurisdiction and responsibilities
Dietary Supplements	Regulates dietary products and their ingredients
Chemicals, Metals & Pesticides in Food	Monitors for toxins, pesticides, and contaminants and assesses potential exposures and risk

1.1 COMPLIANCE & ENFORCEMENT

To protect public health, FDA monitors domestic firms and the foods that they produce. FDA also has multiple initiatives for monitoring imported products and foreign firms exporting to the United States. FDA protects consumers from unsafe foods through:

- Research and methods development
- Inspection, sampling, and analysis
- Voluntary destruction, recall
- Injunction, seizure, criminal prosecution

Elemental analysis in Compliance & Enforcement is integral to various compliance resources and compliance programs.

1.1.1 Compliance Resources

FDA's Manual on Compliance Policy Guides provides information on Compliance Policy Guides (CPGs). These guides explain FDA policy on issues related to FDA laws or regulations. They advise FDA's field inspection and compliance staffs, as well as the industry, as to the Agency's strategy and policies to be applied when determining industry compliance.

The Regulatory Procedures Manual (RPM)is a reference for FDA personnel. The RPM provides

information on internal procedures to be used when processing domestic and import regulatory and enforcement matters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

The Investigations Operations Manual (IOM) is the primary operational guide for FDA employees who perform field investigational activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field investigational activities. As such, it provides a resource to assure quality, consistency, and efficiency in field operations. Other FDA manuals and field guidance supplement, but do not supersede, the information in this manual.

1.1.2 Compliance Programs

Food Compliance Programs are organized along with those pertaining to other program areas in FDA's Compliance Program Guidance Manual (CPGM). Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA. Compliance Programs do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used as long as the approach satisfies the requirements of the applicable statutes and regulations.

The levels of metals and other elements are monitored in food and food contact surfaces to inform and enforce FDA rules and guidance. This occurs through monitoring programs such as the Total Diet Study and the FDA's Toxic Elements in Food and Foodware, and Radionuclides in Food compliance program; and through targeted sampling assignments.

1.2 CHEMICALS, METALS & PESTICIDES IN FOOD

FDA oversees the safety of food through assessment of potential exposure and risk.

Whether elements are classified as chemicals, metals, or simply elements, they can be beneficial or harmful and are present in food, depending on many factors, including: growing conditions; industrial, manufacturing, and agricultural processes; the DNA of the food crops; and past or current environmental contamination.

Elements such as iron and iodine are intentionally added to certain foods to enhance their dietary benefits. Others, such as arsenic, cadmium, lead and mercury, have no established health benefit and have been shown to lead to illness, impairment, and in high doses, death. People's exposure comes partially from many different foods containing these elements. Information on health risks, FDA regulations and guidance to industry, FDA monitoring and testing, and consumer resources is available via the arsenic, lead and mercury webpages.

The FDA also monitors and regulates levels of metals in animal feed and in cosmetics.

1.3 SCIENCE & RESEARCH

As a science-based agency, FDA performs measurements and analyses and conducts scientific research. Analyses need to be performed on food products, food packaging materials and sometimes on materials associated with the environments in which foods are grown, packed, or processed. Because of this, there is a strong emphasis on high-quality laboratory operations and

methods development research. Many resources such as those emphasized here are available via FDA's Laboratory Methods (Food) web page.

1.3.1 Compendium

The FDA Foods Program Compendium of Analytical Methods ("the Compendium") contains analytical methods that have a defined validation status and are currently used by FDA regulatory laboratories. There are slight differences in the historical approaches for inclusion of methods in the Compendium for the chemistry and microbiology disciplines. For the chemistry discipline (which includes elemental analysis), methods at all validation levels may be included, depending on the circumstances.

1.3.2 Method Validation

FDA scientists develop and validate elemental analysis methods to show that they can measure the presence and/or quantities of the elements of interest and, in some cases, their chemical forms. Broadly, food program method validation is discussed in the Foods Program Methods Validation Processes and Guidelines and governed by processes outlined in detail in the

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These processes cover chemical, microbiological, and DNA-based methods and were developed under the former Office of Foods and Veterinary Medicine (OFVM) and are now managed by the FDA Foods Program Regulatory Science Steering Committee (RSSC). The RSSC is made up of representatives from the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), the Office of Regulatory Affairs (ORA), the National Center for Toxicological Research (NCTR). Validation studies are conducted under the oversight of the Chemical Methods Validation Subcommittee (CMVS), which is responsible for the content and application of the guidelines, with input from the Chemistry Research Coordination Group (CRCG) and associated Technical Advisory Groups (TAGs).

The criteria used to evaluate and validate element analysis methods are detailed in the Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products. These guidelines are used in FDA laboratories as they develop and participate in the validation of analytical regulatory methods for chemical analytes in food, feed, and cosmetics in anticipation of Agency-wide Program implementation and to support regulatory analytical needs.

1.3.3 Quality Management

The Office of Regulatory Affairs (ORA) Laboratory Manual (LM) contains regulatory and scientific guidance on primary functions of field laboratories. The LM covers all ISO 17025 elements and operations such as research, court testimony, analysts on inspections, private laboratory reviews, and training. The LM also contains references to applicable ORA documents such as ORA-QMS and ORA-LAB procedures.

The CFSAN Laboratory Quality Assurance Manual (4th Edition, 2019) contains the policies and instructions related to laboratory quality assurance in CFSAN. The manual is a central resource for understanding CFSAN's quality system and provides guidance on quality concepts, principles, and practices.

1.4 HISTORY

EAM 1. Table 1. History

Version	Revisions Made	Effective Date
1.0	Section 1.0 *Program Areas* (noted to be "Under development") Section 1.2 *Regulatory Operations*	June 2008 (hard copy only)
1.1	Minor changes; Started web posting	June 2010
2.0	CPG examples deleted; phrasing modified; converted to pdf format	September 2014
3.0	Major expansion with a complete re-write to better show how element analysis supports FDA's wide-ranging food program and to align with how the program is presented on the web; added *History* section.	September 2021