Laboratory Methods (Food)

Listed below are resources containing some of the analytical laboratory methods used by FDA to help ensure food safety. These methods may be utilized by the food industry as well. The information is divided into three sections, a chemical methods resource section, a microbiological and biological methods resource section, and a macroanalytical methods resources section. Within each section there may be multiple manuals/collections of methods and some methods may appear in more than one manual/collection. Links to methods that FDA utilizes, but that have not yet been incorporated into an official FDA manual/collection are also provided.

Also found on this page are links to additional resources, including: the FDA Foods Program Compendium of Analytical Laboratory Methods; the FDA Foods Program Method Validation Guidelines; and laboratory quality management manuals that outline principles and practices for FDA foods researchers to implement throughout their labs.

Chemical Methods Resources

FDA Foods Program Compendium of Analytical Laboratory Methods: Chemical Analytical Manual (CAM)

The Chemical Analytical Manual (CAM) (https://www.fda.gov/food/laboratory-methods-food/foods-program-compendium-analytical-laboratory-methods#CAM) contains chemical methods that have been validated using the FDA Foods Program Guidelines for the Validation of Chemical Methods (https://www.fda.gov/media/81810/download) and are currently in use by FDA. Some of the methods in the CAM can be found in other FDA methods collections.

Chemistry Methods Collections for Specific FDA Program Areas

The following are additional methods collections generated for specific FDA analytical laboratory program areas. They may contain methods found in the CAM, as well as older methods that FDA no longer uses or that lack the validation to be included of the CAM.

Elemental Analysis Manual (EAM) (/food/laboratory-methods-food/elemental-analysis-manual-eam-food-and-related-products)
FDA's mission to ensure a safe U.S. food supply is met in part by monitoring food and related products for both toxic and nutritional elements. FDA laboratories perform these sample analyses using sound analytical practices and methodology which are documented in the Elemental Analysis Manual for Food and Related Products (EAM).

Pesticide Analytical Manual (PAM) (/food/laboratory-methods-food/pesticide-analytical-manual-pam)
The PAM is a repository of analytical methods used by FDA to examine food for pesticide residues. FDA is responsible for enforcing tolerances established by the Environmental Protection Agency (EPA) (https://www.epa.gov/pesticide-tolerances/indexes-part-180-tolerance-information-pesticide-chemicals-food-and-feed) for the amounts of pesticide residues that may legally remain on food and animal feed in accordance with 40 CFR 180.101 (c).

DNA-based Seafood Identification (/food/reference-databases-and-monitoring-programs-food/dna-based-seafood-identification)
FDA researchers use DNA sequencing technology to definitively determine the species of fish they are analyzing. FDA's Single Laboratory Validated Method for DNA-Barcoding for the Species Identification of Fish (/food/reference-databases-and-monitoring-programs-food/single-laboratory-validated-method-dna-barcoding-species-identification-fish) can be found on FDA's DNA-based Seafood Identification page, which also contains links to other seafood identification resources.

National Shellfish Sanitation Program (NSSP) Guide (/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp)
The NSSP is the federal/state cooperative program recognized by FDA and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. Laboratory standards and methods to support sanitary control of shellfish are identified in the NSSP Guide for the Control of Molluscan Shellfish.

Laboratory Information Bulletins (/science-research/field-science-and-laboratories/laboratory-information-bulletins)
FDA's Office of Regulatory Affairs manages FDA's regulatory analysis laboratories and posts Laboratory Information Bulletins that may be of interest to the public. The Laboratory Information Bulletin (LIB) is a tool for the rapid dissemination of laboratory methods (or

information) which appear to work. It does not report complete scientific work. The user must assure himself/herself by appropriate validation procedures that the LIB methods and techniques are reliable and accurate for the intended use. Once a method has been validated, it is added to the CAM.

Other FDA Chemical Methods of Interest

In addition to established FDA methods collections, there are **other chemical methods that may be of interest (/food/laboratory-methods-food/other-analytical-methods-interest-foods-program)**. These methods may have been recently developed and not yet fully validated, cited in the past, or used briefly for collection of data. They are not necessarily validated to current FDA or equivalent standards.

Additional FDA Chemistry Resources

FDA has additional resources related to chemical analyses (/food/laboratory-methods-food/additional-chemistry-and-microbiology-resources-used-foods-program) conducted by its Foods Program and its government partners. These resources include protocols and training videos.

Microbiological and Biological Methods Resources

FDA Foods Program Compendium of Analytical Laboratory Methods: Microbiological Methods

The FDA Foods Program Compendium of microbiological methods includes the Bacteriological Analytical Manual (BAM) and methods validated under the FDA Foods Program's Guidelines for Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds (/media/83812/download?attachment) but not yet entered into the BAM.

Bacteriological Analytical Manual (BAM) (/food/laboratory-methods-food/bacteriological-analytical-manual-bam)
FDA's BAM contains the agency's preferred laboratory procedures for microbiological analyses of foods and cosmetics. As new methods are validated for use in FDA laboratories, there is a delay before chapters are updated and the methods are added to the BAM. In these instances, the new methods will be listed individually on FDA's website until the BAM has been updated.

FDA Validated Methods for Addition to the BAM (https://www.fda.gov/food/laboratory-methods-food/foods-program-compendium-analytical-laboratory-methods#BAM)

These methods have been validated by the FDA Foods Program Method Development, Validation, and Implementation Program (MDVIP), but have not yet been published in the BAM.

Other FDA Microbiological Methods of Interest

There are other microbiological methods of importance to the FDA (https://www.fda.gov/food/laboratory-methods-food/other-analytical-methods-interest-foods-program#micro). They are either methods in use but not yet validated at the multi-laboratory level, or they have been specifically cited in rules or guidance.

Additional FDA Microbiology Resources

FDA has additional resources related to microbiological analyses (/food/laboratory-methods-food/additional-chemistry-and-microbiology-resources-used-foods-program) conducted by its Foods Program and its government partners. These resources include protocols and training videos.

Macroanalytical Methods Resources

Macroanalytical Procedures Manual (MPM) (/food/laboratory-methods-food/macroanalytical-procedures-manual-mpm)
The Macroanalytical Procedures Manual contains standardized methods of macroscopic analysis which are useful in determining defects in various types of foods.

Food Defect Action Levels Handbook (/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/food-defect-levels-handbook)
The Food Defect Action Levels Handbook lists the levels of natural or unavoidable defects in foods that present no health hazards for humans. Each listing indicates the analytical methodology (defect method) used, as well as the parameters for the defect (defect action level).

FDA Foods Program Method Validation Guidelines

All methods developed for the FDA Foods Program are validated according to established guidelines and appendices to those guidelines (/food/laboratory-methods-food/foods-program-methods-validation-processes-and-guidelines), as defined by the Method Development, Validation, and Implementation Program (MDVIP).

A description of the goals of the MDVIP, and guidelines for the validation of chemical (/media/81810/download?attachment), microbiological (/media/83812/download?attachment), and DNA-based (/media/121751/download?attachment) methods are included.

Guidance for the use of Exact Mass Data for Confirmation of Identity of Chemical Residues (/media/96499/download?attachment) is also provided.

Successfully validated methods are added to the FDA Foods Program Compendium of Analytical Methods (/food/laboratory-methods-food/foods-program-compendium-analytical-laboratory-methods).

FDA Laboratory Quality Management Manuals

CFSAN Laboratory Quality Assurance Manual (/food/laboratory-methods-food/cfsan-laboratory-quality-assurance-manual)
The CFSAN Laboratory Quality Assurance Manual (LQM), 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.

ORA Laboratory Manual (/science-research/field-science-and-laboratories/field-science-laboratory-manual)
The ORA Laboratory Manual provides FDA personnel with information on internal procedures to be used as an agency policy for testing consumer products, training of laboratory staff, report writing, safety, research, review of private laboratory reports and court testimony.