

Foods Program Compendium of Analytical Laboratory Methods

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. The validation status of a method may have been established through the FDA Foods Program Method Development, Validation, and Implementation Program (MDVIP) (</media/90217/download?attachment>) using the Foods Program Method Validation Guidelines (</food/laboratory-methods-food/foods-program-methods-validation-processes-and-guidelines>). In cases where methods were not evaluated under the MDVIP, internal FDA Foods Program committees have established the equivalency of the method validation level to the FDA guidelines. 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, methods at all validation levels may be included in the Compendium. The Bacteriological Analytical Manual, which primarily contains multi-laboratory validated methods, is the main component of the microbiology portion of Compendium. MDVIP multi-laboratory validated methods pending inclusion in the BAM are also listed.

More details on the respective areas of the Compendium are given below.

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

The Chemical Analytical Manual (CAM) lists validated methods that FDA regulatory laboratories currently use to determine food and feed safety. Methods that have been multi-laboratory validated using the FDA Foods Program Guidelines for the Validation of Chemical Methods (</media/81810/download?attachment>) are listed in the CAM indefinitely. Methods whose validation status was established before the 2014 institution of the FDA Foods Program Guidelines for the Validation of Chemical Methods are posted for a fixed and limited duration (subject to renewal) after their validation status has been judged to be equivalent to that outlined in the Foods Program Method Validation Guidelines. Methods developed due to an emergency need, with limited validation, are posted for one year. Methods with single-laboratory validation status are posted for up to two years, and older methods judged to have validation status equivalent to multi-laboratory validation are posted for three years. The cover page for each method provides general information about the scope and application of the

Top ()

method, and includes any recent extensions to new analytes, matrices, or platforms. The CAM does not list all methods currently in use by FDA, but it is updated continuously and will eventually include all chemical methods used in FDA labs.

CAM Methods

Program Area	Principal Analytes	Method #	Method Title
Aquaculture drugs	Chloramphenicol and nitrofurans metabolites	C-011.01	Determination of Chloramphenicol and Nitrofurans Metabolites in Cobia, Croaker, and Shrimp Using Microwave-Assisted Derivatization, Automated SPE, and LC-MS/MS (/media/131509/download?attachment)
Chemical contaminants	Pentobarbital	C-005.03	Determination of pentobarbital in ingredients of animal origin and in finished pet foods using liquid chromatography tandem mass spectrometry (/media/120102/download?attachment)
Chemical contaminants	30 perfluoroalkyl and polyfluoroalkyl (PFAS) compounds	C-010.03	Determination of 30 Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) in Food using Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) (/media/131510/download?attachment)
Drug Residues in Animal Feed	Erythromycin A, penicillin G, and virginiamycin M1 and virginiamycin S1	C-012.01	An LC-MS/MS Method for the Determination of Antibiotic Residues in Distillers Grains (/media/142158/download?attachment)
Food additives	Sulfite (free sulfite and some bound sulfites)	C-004.04	Determination of Sulfites in Food using Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) (/media/114411/download?attachment)
Mycotoxins	Aflatoxin B1, B2, G1, G2; deoxynivalenol; fumonisin B1, B2, B3; HT-2 toxin, ochratoxin A, T-2 toxin, zearalenone	C-003.02	Determination of Mycotoxins in Corn, Peanut Butter, and Wheat Flour Using Stable Isotope Dilution Assay (SIDA) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) (/media/114240/download?attachment)
Pesticides	Glyphosate, Glufosinate, N-acetyl-glyphosate	C-013.01	Glyphosate and Related Residues in Food – Harmonized Method for Detection and Quantitation (/media/150922/download?attachment)

Program Area	Principal Analytes	Method #	Method Title
Seafood	Polycyclic aromatic hydrocarbons (PAHs)	C-002.01	Screening and Determination of Polycyclic Aromatic Hydrocarbons in Seafood Using QuEChERS-Based Extraction and High-Performance Liquid Chromatography with Fluorescence Detection (https://www.fda.gov/media/114401/download).
Toxic and nutrient elements	Arsenic species in fruit juice	C-006.01	EAM 4.10 High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination of Four Arsenic Species in Fruit Juice (/media/131511/download?attachment).
Toxic and nutrient elements	Arsenic species in rice and rice products	C-007.01	EAM 4.11 Arsenic Speciation in Rice and Rice Products Using High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination (/media/131512/download?attachment).
Toxic and nutrient elements	As, Cd, Cr, Pb, Hg, Mn, Ni, Cu, Zn, Se, Mo	C-008.01	EAM 4.7 Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion (/media/131679/download?attachment).
Toxic and nutrient elements	Iodine	C-009.01	EAM 4.13 Inductively Couple Plasma-Mass Spectrometric Determination of Iodine in Food Using Tetramethyl Ammonium Hydroxide Extraction (/media/131514/download?attachment).

FDA Foods Program Compendium of Analytical Laboratory Methods: Microbiological Methods

The FDA Foods Program Compendium of Microbiology Methods includes the [Bacteriological Analytical Manual \(BAM\)](https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam) ([/food/laboratory-methods-food/bacteriological-analytical-manual-bam](https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam)) and microbiology methods validated under the [Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens](https://www.fda.gov/media/83812/download?attachment) ([/media/83812/download?attachment](https://www.fda.gov/media/83812/download?attachment)) but not yet entered into the BAM. FDA's Bacteriological Analytical Manual presents 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 they are added to the BAM. During this time, the new methods will be [listed below](#) until their addition to the BAM. ^

Microbiological methods are validated under the MDVIP at four levels (or their equivalents): Top ()

Level 1: Emergency Use; Level 2: Single Laboratory Validation; Level 3: Single Laboratory Validation Plus Independent Laboratory Validation Study; and, Level 4: Full Collaborative Multi-laboratory Validation (MLV) Study (10 labs). Virtually, all methods included in the microbiological methods portion of the Compendium have MLV status. For a list of other microbiological methods used by the FDA, which have not reached multi-laboratory validation status, please see “[Other FDA Microbiological Methods of Interest \(/food/laboratory-methods-food/other-analytical-methods-interest-foods-program\)](/food/laboratory-methods-food/other-analytical-methods-interest-foods-program).”

BAM Link and Validated Methods Pending Addition to the BAM

Matrix	Analyte(s)	Name of Method/Resource	Validation Status
Multiple	Foodborne pathogens	Bacteriological Analytical Manual (BAM) (/food/laboratory-methods-food/bacteriological-analytical-manual-bam)	BAM
Multiple	<i>Salmonella</i>	Screening of <i>Salmonella</i> in Foods and on Environmental Surfaces by Real-Time Quantitative PCR (qPCR) (/media/168834/download?attachment)	MDVIP Level 4 (multi-laboratory)
Multiple	<i>Listeria</i>	Molecular Verification of <i>Listeria</i> spp. isolates and Molecular Identification of <i>Listeria monocytogenes</i> Serogroups Using Real-Time PCR (qPCR) (/media/165293/download?attachment)	MDVIP Level 4 (multi-laboratory)
Tattoo inks	Nontuberculous mycobacteria	Isolation and Identification of Nontuberculous Mycobacteria in Tattoo Inks: See BAM, Chapter 23A.	MDVIP Level 4 (multi-laboratory)
Multiple	<i>Salmonella</i>	Confirmation of <i>Salmonella</i> isolates by Real-time Polymerase Chain Reaction (PCR): See BAM, Chapter 5.E.9.c.	MDVIP Level 4 (multi-laboratory)
Multiple	<i>Salmonella</i>	<i>Salmonella</i> Serotype Prediction Using the GalaxyTrakr SeqSero2 Workflow: See BAM, Chapter 5.E.11	MDVIP Level 4 (multi-laboratory)
Soft fruit	Norovirus and Hepatitis A	Concentration, Extraction, and Detection of Norovirus and Hepatitis A virus in Soft Fruit: See BAM, Chapter 26	MDVIP Level 4 (multi-laboratory)
Molluscan shellfish	Norovirus and Hepatitis A	Concentration, Extraction, and Detection of Norovirus and Hepatitis A virus in Molluscan Shellfish: See BAM, Chapter 26	MDVIP Level 4 (multi-laboratory)  ^{Top}

Matrix	Analyte(s)	Name of Method/Resource	Validation Status
Animal foods	<i>Salmonella</i>	Screening of <i>Salmonella</i> in Animal Food by Loop-mediated Isothermal Amplification (LAMP): See BAM, Chapter 5.C.28.	MDVIP Level 4 (multi-laboratory)
Scallops, finfish	Norovirus and Hepatitis A	Concentration, Extraction, and Detection of Norovirus and Hepatitis A virus in Scallops and Finfish Meat: See BAM, Chapter 26	MDVIP Level 4 (multi-laboratory)
Agricultural water	<i>Cyclospora cayetanensis</i>	Dead-End Ultrafiltration (DEUF) for the Detection of <i>Cyclospora cayetanensis</i> from Agricultural Water; see BAM, Chapter 19C.	MDVIP Level 4 (multi-laboratory)
Agricultural water	<i>Cyclospora cayetanensis</i>	Recovery and Detection of <i>Cyclospora cayetanensis</i> from Agricultural Water; see BAM, Chapter 19C.	MDVIP Level 4 (multi-laboratory)

Was this helpful?