



Science and Research Key Initiatives

**A Framework for Aligning Science and Research Activities with
the FVM Strategic Plan**

**U.S. Food and Drug Administration
Office of Foods and Veterinary Medicine
*FY 2016 - FY 2025***

Advancing regulatory science is one of the U.S. Food and Drug Administration's (FDA or the Agency) core missions directed towards protecting human and animal health. As a science- and evidence-based agency, the FDA must have access to the best scientific data and resources in order to support informed regulatory decision-making. In support of achieving this overarching aim, scientific expertise and research are two of the key foundations of the work conducted within the Foods and Veterinary Medicine (FVM) Program. Human and animal food safety, animal health, and nutritional science are the primary drivers of research efforts within FVM. Agency efforts such as setting preventive controls, investigating new pathogens and chemical hazards, and ensuring safe consumer products are supported by such research activities as the development of novel models and tools, the adoption of new technologies, and the application of innovative strategies to deal with emerging public health threats.

All FVM Program activities are carried out with the end goal of protecting and promoting human and animal health

FVM PROGRAM SCIENCE AND RESEARCH INTEGRATION

The FDA Office of Foods and Veterinary Medicine (OFVM), was created in 2009 to lead a functionally-unified foods and veterinary medicine program designed to enhance the Agency's ability to meet today's great challenges and opportunities in food and feed safety, veterinary medicine, nutrition, and other critical areas. These goals were outlined in the FVM Program Strategic Plan released in 2012. As a science-based Agency, it was also recognized that the success of FVM's strategic plan was dependent on a unified collaborative regulatory science and research enterprise. To oversee this effort, the FVM Program implemented a Science and Research Team (SRT) lead by the Chief Science Officer and Research Director (CSO/RD) within OFVM and created the Science and Research Steering Committee (SRSC). This committee, under the leadership of the CSO/RD, is composed of senior science and research leaders from the operating units of the FVM Program—the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). It also has representation from Office of Regulatory Affairs (ORA), the National Center for Toxicological Research (NCTR), the Office of the Chief Scientist, the Coordinated Outbreak Response and Evaluation (CORE) Network, and the Office of International Programs.

As defined in its charter, The SRSC is the operational arm of the FVM Executive Council for science and research and is charged with providing oversight to all FVM research-related activities. Specifically, the SRSC's role is to lead, coordinate and unify natural science research and methods development strategies. Key components of the mission include:

- Developing and implementing an FVM Science and Research action plan, with Key Initiatives designed to strengthen and maintain core science and research capabilities
- Developing and implementing a common framework and process for prioritizing FVM research
- Developing and implementing a unified analytical methods development and validation program that is aligned with FVM priorities
- Developing and communicating improved processes for technology transfer of research and methods to FVM program offices
- Aligning the roles and responsibilities of each laboratory operating unit across FVM
- Optimizing use of laboratory staff and resources across FVM

The fiscal year (FY) 2016 – FY 2025 FVM Program Strategic Plan reaffirms the commitment to food and product safety and to support a healthier food supply through four fundamental goals:

GOAL 1 – FOOD SAFETY: Protect America’s consumers and animals from foreseeable hazards

GOAL 2 – NUTRITION: Foster an environment to promote health and safe food choices

GOAL 3 – ANIMAL HEALTH: Protect human and animal health by enhancing the safety and effectiveness of animal health products

GOAL 4 – ORGANIZATIONAL EXCELLENCE: Continuously improve the leadership, management, staffing, and organizational capacity of the FVM Program to protect public health

Four guiding principles underlie each of these goals:

- **PUBLIC HEALTH IS THE FIRST PRIORITY:** All FVM Program activities are carried out with the end goal of protecting the consumer and promoting public health.
- **PARTNERSHIPS WITH OTHERS IS THE KEY TO SUCCESS:** The FVM Program must partner and collaborate with a wide array of stakeholders in all of its program areas to ensure that roles and responsibilities are clear, that standards are scientifically sound and workable across our diverse food system, and that high rates of compliance and good public health outcomes are achieved.
- **SCIENTIFIC EXPERTISE AND RESEARCH ARE THE FOUNDATIONS OF THE FVM PROGRAM’S WORK:** Because food, animal health, and nutrition science drive much of what the FVM Program does, maintaining the quality and credibility of the FVM Program’s science base is a central priority.
- **OPERATING OPENLY AND TRANSPARENTLY IS A CORE PRINCIPLE:** The FVM Program is committed to open communication and engagement to inform rulemaking and other activities, generate high levels of

compliance with public health standards, and build the public confidence that is critical to the Program's success.

As highlighted in these guiding principles, it is imperative that the FVM Program maintain a strong science infrastructure, clearly identify its research needs and priorities, and collaborate with other public health and research agencies in the Federal and State government, academia, foreign regulatory counterparts, and private industry to effectively meet its mission of protecting and promoting public and animal health and for the Agency to implement relevant provisions of the FDA Food Safety Modernization Act (FSMA).

FVM PROGRAM SCIENCE AND RESEARCH KEY INITIATIVES

In alignment with, and in support of, the FY 2016 – FY 2025 FVM Program Strategic Plan, these Science and Research Key Initiatives have been established by senior FVM scientific leadership to chart a path forward for protecting and promoting human and animal health under the same overall goals.

FVM STRATEGIC GOAL 1 – FOOD SAFETY

KEY INITIATIVE: PROTECT AMERICA'S CONSUMERS AND ANIMALS FROM FORESEEABLE HAZARDS ACROSS THE GLOBAL FARM-TO-TABLE CONTINUUM

Ensuring that the food consumed by humans and animals is wholesome, safe, and free of contamination are key in promoting public health. Implementation of an integrated approach to research will position the FVM Program to more efficiently address the issues threatening the food supply in the coming decades. Prevention of foodborne illness has many facets, and all must be based upon the best scientific data available. Science-based, prevention-oriented standards are needed at each step in the food production process – from production and processing, to transportation and storage, to handling and preparation in consumers' homes. FVM research programs are far-reaching, engaging in extensive partnerships both within and outside the federal government; addressing harmonization of methods and sampling approaches; supporting the development of new enforcement tools; and enhancing the coordination of ORA field laboratories, as well as surveillance and compliance personnel in CFSAN and CVM. The leveraging of new/innovative scientific methods, such as whole genome sequencing, will continue to enhance enforcement and tracking efforts.

Operational Objectives:

- 1.1 Reduce the risk of chemical, allergen, and radiological exposures in food and feed products that pose public health or regulatory concerns

- 1.2 Reduce the risk of microbial hazards in food and feed products
- 1.3 Enhance food defense throughout the supply chain by developing methods and survey strategies to reduce the risk of intentional (malicious) introduction of hazardous chemicals, microbial agents, or toxins
- 1.4 Enhance food defense by developing chemical and molecular methods for preventing the introduction of mislabeled, counterfeit, or economically adulterated products into the marketplace
- 1.5 Provide regulatory tools and resources necessary to ensure safety of genetically-modified organisms (GMOs)
- 1.6 Develop preventive control strategies for hazards in FDA regulated products
- 1.7 Enhance detection and response to foodborne illness outbreaks and other food/feed incidents
- 1.8 Strengthen or create partnerships, with other governmental agencies and domestic/ foreign entities, to enhance the effectiveness and efficiency of food/feed safety efforts
- 1.9 Enhance the safety of food/feed additives and generally recognized as safe (GRAS) substances

FVM STRATEGIC GOAL 2–NUTRITION

KEY INITIATIVE: SUPPORT HEALTHY AND SAFE CHOICES IN FOOD AND OTHER CONSUMER PRODUCTS

FVM research plays a vital role in helping to provide evidence-based approaches to defining nutrition-related risk factors and improving the nutritional status of people and animals. Communication is critical to the success of this effort, so that consumers and producers can make more informed decisions. Activities are broad, and they include developing methods for the monitoring of the composition of foods, as well as providing a scientific basis to promote the development of new products and the reformulation of existing ones. Another important area of research within the FVM program is the evaluation of issues related to cosmetics safety and labeling.

Operational Objectives:

- 2.1 Provide and support accurate nutrition information and evidence-based recommendations

- 2.2 Assess emerging nutrition science and changes in the composition of foods in the marketplace
- 2.3 Provide a broad science base to facilitate new products and product formulations to promote a healthier food supply
- 2.4 Improve data-driven surveillance, detection, and responses to human illnesses associated with dietary supplements, including the development of screening methods
- 2.5 Provide regulatory tools and resources necessary to ensure safety of cosmetics

FVM STRATEGIC GOAL 3 – ANIMAL HEALTH

KEY INITIATIVE: PROTECT ANIMAL AND PUBLIC HEALTH BY HELPING TO ENSURE THE SAFETY AND EFFECTIVENESS OF ANIMAL HEALTH PRODUCTS

The FVM program uses a comprehensive life-cycle approach to integrate pre-approval and post-approval functions (surveillance, compliance, adverse event monitoring and reporting) for animal health products. FVM research encompasses a broad spectrum of veterinary products that the Agency regulates, providing a strong scientific basis in support of the approval of new animal health products. Enhancing knowledge in regulatory science and new/innovative technologies is crucial in this endeavor, spanning a broad mission space that includes antimicrobial resistance, drug residues in edible animal products, and genetically-engineered organisms.

Operational Objectives:

- 3.1 Ensure safe and effective animal drug products, and reduce the risk of harm from unsafe use of marketed drugs
- 3.2 Reduce the risk and availability of substandard/illegally marketed animal drugs
- 3.3 Promote the judicious use of medically important antimicrobials in food animals to minimize the development of resistance
- 3.4 Strengthen detection, surveillance, and responses to incidents related to FDA-regulated animal health products
- 3.5 Ensure the safety of food products derived from genetically-engineered animals, and provide for the detection of these products in the marketplace

FVM STRATEGIC GOAL 4 – ORGANIZATIONAL EXCELLENCE

KEY INITIATIVE: *ENHANCE OFVM'S SCIENCE AND RESEARCH RESOURCES AND ACTIVITIES FOR OPTIMAL PUBLIC HEALTH BENEFITS*

To successfully implement and carry out all of the requirements of FSMA, as well as to provide other diverse mission-critical scientific support, FVM research programs depend upon coordinated institutional expertise, capacity building and optimization, and communication with diverse stakeholders from all levels of public and private sectors through the programs described below. Embedded within these programs are processes that establish a comprehensive Method Development, Validation, and Implementation Program (MDVIP) that embraces many FVM activities (e.g. risk analytics and hazard identification, which are coordinated with resource prioritization and allocation; horizon-scanning and evaluation of emerging technologies and innovation). Continuing development of a culture of collaboration with other research and health agencies in the Federal and State governments, academia, private industry, and foreign regulatory bodies will expand scientific capabilities and allow the FVM Program to benefit from scientific advances being made across the globe.

Operational Objectives:

- 4.1 Achieve risk-based resource allocation utilizing risk analysis and tracking of impact metrics
- 4.2 Optimize FVM scientific and organizational capacity to enhance detection, prevention, and response strategies to identified hazards
- 4.3 Maintain and strengthen mission-critical science capabilities through workforce development, technological modernization, and innovation
- 4.4 Enhance stakeholder engagement and leverage external resources
- 4.5 Develop data sharing capacity and reporting coordination with other governmental and non-governmental entities
- 4.6 Facilitate harmonization with internal and external laboratory certification guidelines/standards
- 4.7 Establish a methods portal to allow access, by external entities, to current regulatory methods being used within the FVM Program, including state validated methods

IMPLEMENTATION

These Key Initiatives, Operational Objectives, and other activities will be implemented through operational planning, risk-based resource planning/management, and action planning at the office/branch/division level. Research objectives will continue to be prioritized and strategically aligned annually, accompanied by periodic assessment of completed research projects to assess impact and efficiency of resource utilization. Objectives and activities will be reassessed biennially, accompanied by reexamination of broader Key Initiatives.