



FDA Foods and Veterinary Medicine Program Strategic Plan 2012 – 2016

Developed by the
Office of Foods
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs

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Letter from the Deputy Commissioner

I am pleased to present, on behalf of the FDA's Foods and Veterinary Medicine Program, our Strategic Plan for 2012-2016. As the title indicates, this plan takes into account all the activities within the jurisdictions of the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) and supported by the Office of Regulatory Affairs (ORA).

The Foods and Veterinary Medicine Program enjoys enormous opportunity but also faces significant challenges in carrying out its public health and consumer protection mission. Whether working in the areas of food safety, nutrition or animal health, employees at CFSAN and CVM experience this every day, as do FDA's field staff in ORA who carry out critical inspection, laboratory analysis and other work in support of the Foods and Veterinary Medicine Program.

FDA's stakeholders are also keenly aware of the opportunities and challenges we face. Many in the food industry and the consumer community came together to secure the enactment of the FDA Food Safety Modernization Act of 2011 (FSMA), which gives FDA the new job of building a modern, prevention-oriented food safety system suited for today's globalized food supply. These groups are now wondering how we can accomplish all that FSMA requires. Likewise, the public's interest in the areas of nutrition and nutrition information grow every day, as does the importance of animal health to the food system and consumers.

Public expectations are high in all the areas in which FDA works, and FDA employees work hard to meet those expectations as fully as possible, even in a world of inevitably scarce resources. Success in this environment requires a strategic plan to guide our hard work and keep us focused on the most important things we need to accomplish in order to fulfill our public health and consumer protection mandates. With this in mind, the senior leadership of the Foods and Veterinary Medicine Program, drawing on input from many expert staff and managers, prepared this draft strategic plan for 2012 through 2016.

The plan outlines seven strategic program goals, each encompassing its own key objectives, as well as nearly 100 specific initiatives aimed at achieving our goals and objectives. This plan illustrates the breadth and complexity of the work we do and calls out the initiatives that the leadership team considers most important to our success. We know that success depends in part on the availability of resources, especially to implement FSMA, but we think that mission clarity for ourselves and our stakeholders regarding what we're trying to achieve and how are crucial and necessary first steps.

We have carefully considered the various internal and public comments that were received after the posting of the draft version of this plan in September 2011. These comments have helped us to strengthen the plan as well as the day-to-day operations of the program. We continue to welcome comments on the work of the FVM Program, and we will not hesitate to modify the specific elements of the plan as circumstances warrant. The leadership of the Foods and Veterinary Medicine Program is strongly committed, however, to the central underlying theme of the plan, which is our duty to make the best use of the tools and resources Congress has given us to protect and promote the public health.

*Michael R. Taylor
Deputy Commissioner for Foods*

Executive Summary

The Foods and Veterinary Medicine (FVM) Program encompasses the wide range of responsibilities and activities of the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM) and the related field activities of the Office of Regulatory Affairs (ORA).

Carrying out FDA's food safety, nutrition, and animal health activities becomes more challenging every year as globalization, advances in science and technology, and shifts in consumer expectations drive change throughout the human and animal food and animal drug systems. At the same time, foodborne illness continues to have a substantial impact on public health with an estimated 48 million illnesses occurring each year, and diet-related diseases and obesity remain a significant burden to the nation's health. As public health and regulatory challenges intensify and consumer expectations rise, the success of FDA's FVM Program becomes even more important.

Congress recognizes the unique challenges faced by FDA in the area of food safety in the 21st century and last year gave the agency a modern legislative mandate to meet these challenges by enacting the FDA Food Safety Modernization Act of 2011 (FSMA). FSMA directs FDA to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize food and feed hazards from farm-to-table.

With new mandates and authorities come greater responsibilities, including the obligation to make optimal use of FVM resources. It is now incumbent on the FVM Program to determine how it can best use its authorities, human capital, and other resources effectively and efficiently to protect consumers and promote public health.

The 2012 – 2016 FVM Program Strategic Plan charts a direction for the future. The Program has assessed its current capabilities, developed a new mission and vision for the unified FVM Program, and identified key goals and objectives to advance food safety, nutrition and animal health in the years to come. In working to meet the goals of this plan, the FVM Program will strive for transparency with stakeholders and seek opportunities for the public and private sectors to contribute ideas and expertise that can improve Program effectiveness.

FVM Program Vision: Protect consumers and promote the public health by safeguarding America's food supply and enabling consumers to choose healthy diets.

FVM Program Mission: Secure high rates of compliance with science-based food safety and labeling standards by implementing integrated, prevention-oriented and risk-based programs to:

- Protect the safety and security of foods for humans and animals,
- Regulate the safety and effectiveness of animal drugs, and
- Ensure that food labels contain useful and reliable information.

2012 – 2016 Strategic Priorities of the FVM Program

Cross Cutting Goal: Improve effectiveness and efficiency across all levels of the FVM Program

- Objective 1. Improve management and program effectiveness and make optimal use of all FVM Program resources.
- Objective 2. Develop and implement an evidence-based resource planning model that connects performance measures and outputs to public health outcomes.
- Objective 3. Develop and apply public health metrics and goals for risk-based food safety priority setting.
- Objective 4. Establish a process and management structure to enhance risk-based decision making throughout the FVM Program.

Program Goal 1: Establish science-based preventive control standards across the farm-to-table continuum

- Objective 1. Adopt science-based regulations that protect the food and feed supplies from contamination.
- Objective 2. Provide clear and current direction to industry to ensure effective implementation of preventive control standards.
- Objective 3. Evaluate and improve the effectiveness of preventive control standards.

Program Goal 2: Achieve high rates of compliance with preventive control standards domestically and internationally

- Objective 1. Improve FVM Program intelligence on industry and the supply chain.
- Objective 2. Conduct domestic inspections to verify compliance with standards.
- Objective 3. Improve assurance that imported foods and feeds meet preventive control standards.
- Objective 4. Effectively implement new and existing enforcement tools.
- Objective 5. Improve the collaboration among CFSAN, CVM and ORA headquarters and field staff, as well as with Federal, State, local, tribal and territorial partners on inspection and compliance efforts.

Program Goal 3: Strengthen scientific leadership, capacity, and partnership to support public health and animal health decision making

- Objective 1. Establish and implement centralized planning and performance measurement processes.
- Objective 2. Improve information sharing internally and externally.
- Objective 3. Maintain and strengthen mission-critical science capabilities.
- Objective 4. Cultivate expert institutional knowledge.

2012-2016 Strategic Priorities of the FVM Program

Program Goal 4: Provide accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity

- Objective 1. Update the Nutrition Facts label.
- Objective 2. Implement menu and vending machine labeling regulations.
- Objective 3. Improve consumer access to and use of nutrition information.

Program Goal 5: Encourage food product reformulation and safe production of dietary supplements

- Objective 1. Reduce sodium content in the food supply.
- Objective 2. Reduce industrially produced *trans* fat in the food supply.
- Objective 3. Improve the safety of dietary supplement products and the supply chain.

Program Goal 6: Improve detection of and response to foodborne outbreaks and contamination incidents

- Objective 1. Improve response to foodborne outbreaks and contamination incidents.
- Objective 2. Investigate and adopt innovative technologies and processes to detect and investigate foodborne outbreaks and contamination events.
- Objective 3. Enhance implementation of the Reportable Food Registry (RFR), including response strategies.
- Objective 4. Conduct effective risk communications related to outbreaks and contamination incidents.

Program Goal 7: Advance animal drug safety and effectiveness

- Objective 1. Increase access to safe and effective animal drugs and reduce risk of harm from unsafe use of marketed animal drugs.
- Objective 2. Reduce availability of substandard and illegally marketed animal drugs.
- Objective 3. Foster the judicious use of medically important antibiotics in food animals to minimize the development of antimicrobial resistance.

Introduction

American consumers have high expectations of the FDA. They expect that the food they purchase at the supermarket will be safe, and that the FDA, Centers for Disease Control and Prevention (CDC), U.S. Department of Agriculture (USDA), and Environmental Protection Agency (EPA), as well as state, local, territorial and tribal regulatory and public health authorities, will work together to both protect the food supply from dangers threatening public health and to support a healthier food supply. Industry has similar high expectations. For example, food processors and producers expect that FDA's regulations and guidance will serve as a reliable standard for food safety, and farmers expect that the drugs they use to keep animals healthy will be safe and effective. These stakeholders and others place their confidence in the FDA, relying on the agency to continue to uphold effective safety and labeling standards that will maintain the confidence of consumers worldwide.

In addition to meeting the longstanding expectations of stakeholders, the FDA must also meet new legislative mandates. Congress last year recognized the unique challenges faced by FDA in the area of food safety in the 21st century, and gave the agency a modern legislative mandate to meet these challenges by enacting the new FDA Food Safety Modernization Act of 2011 (FSMA). FSMA directs FDA to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm-to-table.

FDA's New Role in Protecting Food and Feed Safety

On January 4, 2011, President Obama signed the FDA Food Safety Modernization Act of 2011 (FSMA) into law, the first major overhaul of food safety legislation in more than 70 years. This act gave FDA new and enhanced mandates and authorities to protect public health, redefining the role of the FVM Program in safeguarding America's food supply. These new mandates and authorities include:

- A new legislative mandate to require science-based preventive controls throughout the farm-to-table continuum.
- New tools for inspection, compliance and outbreak response.
- New authority to recall certain food products.
- New authorities and tools to ensure imported products meet U.S. standards.
- New levels of collaboration among government agencies, both domestic and foreign, to achieve public health goals.

Through FSMA, FDA has the mandate and authority to construct a modern food safety system that protects food from farm-to-table, establishes shared responsibility for food safety among all participants, and strengthens accountability for prevention domestically and internationally. FSMA has given the FVM Program a new statutory framework that increases its ability to protect consumers and promote the public health. This 2012 – 2016 FVM Program Strategic Plan takes this new statutory framework into account and places high priority on adequate and timely implementation of FSMA.

This strategic plan reflects FDA’s current thinking about the activities that will be key to building a modern food safety system, while also addressing the other challenges posed by the current food safety, nutrition and animal health environments and meeting the expectations of FDA’s stakeholders. Over the next five years, the activities in this strategic plan will be the focus of the Foods and Veterinary Medicine (FVM) Program, which includes the work of the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the related activities of the Office of Regulatory Affairs (ORA).

Scope and Guiding Principles

Currently, there are many consumer and industry trends affecting the FVM Program. These include:

- New food technologies are changing the composition of America’s food supply,
- Globalization presents significant food safety challenges,
- The proportion of the American population vulnerable to foodborne illness is growing,
- Emerging foodborne pathogens are affecting the food supply,
- Intentional contamination is a growing concern,
- New technologies are changing the landscape of the animal drug industry, and
- Obesity and chronic disease are major health concerns for the U.S. public

Keeping the above trends in mind, the FVM Program developed its strategic priorities around three critical operations:

Protecting the safety and security of foods for humans and animals

In a dynamic and ever-growing global marketplace, many challenges compel the FVM Program to shift the way public health risks associated with food for both humans and animals are addressed. Contamination incidents and outbreaks of foodborne illness have a substantial impact on public health – an estimated 48 million foodborne illnesses occur every year resulting in an estimated 128,000 hospitalizations and 3,000 deaths.ⁱ These illnesses disrupt the food system at great economic cost and undermine public confidence in the food supply. Due to changes in the way food and feed products are produced and distributed, increases in the volume and complexity of imported products, and the ongoing risk of emerging pathogens, the FDA must undergo a paradigm shift in the way it safeguards America’s food supply.

ⁱ CDC. 2011. Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC’s 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.

Regulating the safety and effectiveness of animal drugs and feed

Safe and effective animal drugs and food/feed additives play an important role in protecting animal health and the safety of America's food supply. The FVM Program is committed to safe and effective regulation of these products for food-producing and companion animals. Specifically, the program must focus on providing timely pre-market review of new animal drugs, ensure that approved drugs are being used appropriately, and put measures in place to minimize the illegal sale of unapproved drugs. These efforts will contribute to a food supply that is safe for both humans and animals, and protect billions of poultry, cattle, swine and minor animal species, as well as more than 150 million companion animals in the U.S.

Ensuring that food labels contain reliable information that empowers consumers to make healthful choices in their diet

According to CDC, seven out of 10 deaths in the U.S. are caused by chronic diseases. Heart disease and stroke are the first and third leading causes of death, accounting for more than 30 percent of deaths nationwideⁱⁱ, and more than one-third of adults have two or more of the major diet-related risk factors associated with heart disease and stroke including high blood pressure, high cholesterol, diabetes and obesity.ⁱⁱⁱ Obesity is another major public health concern. Two-thirds of adults and one-third of children are overweight or obese in the U.S., and about one-third of Americans have hypertension.^{iv} With those figures in mind, the FVM Program should continue its efforts to empower consumers to make healthful choices in their diets through effective, informative nutrition labeling and outreach, while simultaneously encouraging the food industry to provide more healthful products.

In addition to the high priority initiatives identified in this plan, the FVM Program conducts many other important food safety, nutrition, cosmetic and animal health activities. These include review of infant formula notifications, pre- and post-market regulation of ingredients and packaging, monitoring for chemical contaminants, authorization of nutrient content and health claims, cosmetics safety and labeling, and ongoing regulatory, enforcement, research, communications, education and outreach activities. These programs will continue to operate and receive appropriate management attention to function effectively and efficiently within the bounds of available resources.

The development of this strategic plan was guided by several guiding principles:

- **Public health is the first priority:** All FVM Program activities are carried out with the end goal of protecting and promoting public health.

ⁱⁱ Centers for Disease Control and Prevention. Deaths: Final Data for 2005. *NVSR*. 2008;56 (10) 2008-1120

ⁱⁱⁱ Centers for Disease Control and Prevention. Racial/Ethnic and Socioeconomic Disparities in Multiple Risk Factors for Heart Disease and Stroke—United States, 2003. *MMWR*. 2005;54(5):113–117.

^{iv} Centers for Disease Control and Prevention. Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, Trends 1960-1962 Through 2007-2008.

Centers for Disease Control and Prevention. Prevalence of Obesity Among Children and Adolescents: United States, Trends 1963-1965 Through 2007-2008.

- **Partnering with others to build prevention-based systems is the key to success:** The FVM Program must partner with a variety of stakeholders to ensure that safety is built into food production and processing from farm to table so that we prevent foodborne illness before it begins.
- **Scientific expertise and innovation are the foundations of the FVM Program's work:** Food, animal health and nutrition science drive much of what the FVM Program does, from setting preventive controls, to investigating new pathogens and emerging nutrition information.
- **Government transparency is the national standard:** The FVM Program is committed to operating with transparency and providing other government entities, as well as private, non-profit, and academic sectors, with the opportunity to provide input to the Program on issues of concern and innovation.

This strategic plan includes a new vision and mission statement, a cross-cutting goal, and seven program goals requiring action and dedicated effort over the next five years. These goals, and their supporting objectives and initiatives, serve as the FVM Program's major priorities and strategic solutions for addressing the food safety, nutrition and animal health-related challenges facing our country today and in the years to come. With the recognition of these priorities, the FVM Program begins laying the groundwork for a modern program that taps the best science and makes optimal use of resources to protect consumers and promote public health in America.

Strategic Direction of the FVM Program

Vision

Protect consumers and promote the public health by safeguarding America’s food supply and enabling consumers to choose healthy diets.

Mission

Secure high rates of compliance with science-based food safety and labeling standards by implementing integrated, prevention-oriented and risk-based programs to:

- Protect the safety and security of foods for humans and animals,
- Regulate the safety and effectiveness of animal drugs, and
- Ensure that food labels contain useful and reliable information.

Cross-Cutting Goal – Improve effectiveness and efficiency across all levels of the FVM Program

To successfully implement FSMA and meet the challenges associated with today’s global food system, the FVM Program must change the way it does business. This includes creating new organizational components that can address FSMA mandates for risk-based decision making, as well as changes in structure and process that can improve program management and ensure optimal use of resources. These improvements are different from the remainder of the goals in this strategic plan due to their internal nature and overarching focus on the work systems and business practices of the FVM Program. As described here, these changes comprise a “cross-cutting goal” that has implications for all remaining program goals and objectives.

Objectives:

CC.1 – Improve management and program effectiveness and make optimal use of all FVM Program resources.

A major focus of the FVM Program during the period 2012-2016 will be to improve program management and effectiveness through an integrated operating model and unified leadership structure, with a strong focus on program-wide strategic planning and risk-based priority setting and resource allocation.

Key Initiatives

CC.1.1: Ensure integrated planning and policy development and efficient, timely decision making for the FVM Program.

CC.1.2: Manage risk-based priority setting and resource allocation and other strategic management functions on an integrated, Program-wide basis.

CC.1.3: Enhance mission-driven priority setting and resource allocation across all lab-based research and methods development programs.

CC.1.4: Consolidate the coordination and management of key cross-cutting external functions, including communications, intergovernmental affairs, and international affairs.

CC.2 – Develop and implement an evidence-based resource planning model that connects performance measures and outputs to public health outcomes.

The FVM Program must be able to answer questions about where it is investing its resources and how those investments are improving animal health and public health and protecting consumers. Without a robust system in place to capture and analyze the public health data and outcomes associated with each program area and its activities, determinations about how to better invest resources to improve health and safety are not sufficiently informed. The current methodology of tracking performance measures and program outputs needs to be updated to incorporate how those efforts affect public health. The new model, which will be operated by a proposed new Resource Planning and Strategic Management staff, must recognize and reinforce the public health value of the range of activities conducted by the FVM Program and enable leaders to make risk-based, systematic resource allocation decisions to better protect and enhance public health. By changing what and how activities are measured, the FVM Program will more effectively drive continuous improvements in public health.

Key Initiatives

CC.2.1: Complete design of the resource planning model and a supporting activity-based reporting system.

CC.2.2: Integrate results of resource planning into annual budget formulation and execution processes.

CC.2.3: Utilize the resource planning model to inform workforce planning and implementation.

CC.2.4: Continuously evaluate and refine the resource planning model.

CC.3 – Develop and apply public health metrics and goals for risk-based food safety priority setting.

The FVM Program will identify the critical risks affecting food and feed safety, identify and prioritize goals based on the current landscape, and develop metrics that can be used to measure public health outcomes. With the establishment of accepted public health priorities, the FVM Program can then conduct targeted data collection and use baseline data to develop intervention strategies tied to meaningful, measureable outputs. As these intervention strategies are identified, they will be communicated throughout the organization so functional areas within the FVM Program can link their efforts to these priorities. And as implementation progresses, ongoing evaluation will be conducted to measure whether public health outcomes are indeed improving and adjustments will be made where necessary in strategy or resource allocation.

Key Initiatives
CC.3.1: Conduct periodic surveillance of the food safety environment and identify the most significant foodborne hazards and targets for the FVM Program.
CC.3.2: Perform collection and in-depth data analysis on selected hazards and targets.
CC.3.3: Develop meaningful intermediate outcomes targets.
CC.3.4: Implement continuous evaluation and measurement of efforts to reduce hazards and refine public health objectives.

CC.4 – Establish a process and management structure to enhance risk-based decision making throughout the FVM Program.

Risk is not the only factor the FDA must consider when making food safety decisions, but it is an extremely important factor. The FVM Program must transform its approach to collecting, analyzing and managing risk information to enhance the way it safeguards America’s food supply. It will take time to collect and incorporate robust risk data from a variety of sources, build the necessary decision tools to ensure successful use, and outline the internal processes enabling a systems-based approach. A new management structure, supporting processes and permanent staff positions must be created to launch a systems approach to risk-based decision making. In doing so, the FVM Program will be able to make better use of its resources at all levels of the organization, and make a fundamental cultural and process shift towards data-driven, risk-based decision making across the FVM Program.

Key Initiatives

CC.4.1: Establish a management structure, principles, guidelines, and procedures to foster and support risk-based decision making.

CC.4.2: Update IT infrastructure to support risk-based decision making throughout the FVM Program.

CC.4.3: Implement integrated data exchange with counterpart public and private organizations to enhance risk-based decision making.

CC.4.4: Conduct internal outreach and communications around new risk-based decision-making processes.

Program Goal 1 – Establish science-based preventive control standards across the farm-to-table continuum

Between 2012 and 2016, the FVM Program will focus its efforts on comprehensive prevention by introducing a series of new safety standards and practices aimed at preventing all foods and feed from becoming contaminated. These standards will be grounded in the latest food safety research and science, and will be informed by experts in the FVM Program, the food and feed industry, and the Federal, academic, animal health and public health arenas. By setting science-based preventive control standards for the way industry produces, processes, distributes, stores, transports and markets food and feed items, the FVM Program will define the responsibility of the operators throughout the food system to ensure the safety of products that enter into commerce. In addition, by paying special attention to food handler education and food safety in the retail environment, and consumer education in homes, prevention measures will cover the farm-to-table continuum. Given the risk of intentional contamination, the FVM Program will also continue playing an important role in food defense by setting standards for protecting the food and feed supply from tampering or other deliberate actions. And with the mindset of continuous improvement in its food and feed safety efforts, the FVM Program will continue to conduct research and evaluation on the effectiveness of its preventive control standards and partner with agricultural and industry suppliers, distributors and marketers to improve their knowledge of regulations, guidance, hazards and mitigation strategies.

Objectives:

1.1 – Adopt science-based regulations that protect the food and feed supplies from contamination.

Science-based preventive control standards will apply broadly and consist of a combination of regulations, guidance, model codes and consumer advice to address multiple points of the food supply chain, from farm-to-table.

Key Initiatives
1.1.1: Set preventive control standards for food/feed processing facilities.
1.1.2: Set preventive control standards for produce safety.
1.1.3: Set preventive control standards for safe food transport.
1.1.4: Continue to set standards for uniform Food Code adoption, and encourage enrollment, implementation and accountability for FDA Retail Food Program Standards.
1.1.5: Set preventive control standards for intentional contamination.
1.1.6: Set recordkeeping standards for administration of drugs to food producing animals.

1.2 – Provide clear and current direction to industry to ensure effective implementation of preventive control standards.

The FVM Program will work with a variety of partners (e.g., trade associations, other government agencies, and academia) to ensure that targeted, sector-specific guidance is regularly provided to industry. This will provide industry with the most up-to-date information on regulatory standards and assist with successful implementation of preventive controls standards. Targeted outreach and training efforts will help improve industry’s implementation of preventive control standards.

Key Initiatives
1.2.1: Work with a variety of partners to provide targeted guidance regarding preventive controls.
1.2.2: Issue hazard-specific performance standards.
1.2.3: Work with a variety of partners to conduct training, education and outreach to help ensure effective implementation.

1.3 – Evaluate and improve the effectiveness of preventive control standards.

In collaboration with appropriate Federal and State organizations, the FVM Program will analyze, measure, and report on the food industry’s compliance with specific preventive control standards and their effectiveness in improving food safety. Findings from these studies will inform efforts to improve industry compliance as well as identify needs for future preventive control standards.

Key Initiatives
1.3.1: Establish metrics for evaluating the effectiveness of preventive control standards.
1.3.2: Evaluate the effectiveness of preventive control standards in collaboration with Federal and State organizations.
1.3.3: Conduct scientific research to support development of new standards and guidance.

Program Goal 2 – Achieve high rates of compliance with preventive control standards domestically and internationally

The FVM Program can no longer rely on simply tracking its activities and outputs as the means for measuring success; it must transition to tracking the *impact* its activities have on the public health, including animal health. Improving health must be at the heart of all compliance operations in order to ensure that the entire compliance toolkit – from guidance development and inspections, to enforcement actions – is leveraged towards opportunities with the largest impact. This requires improving the knowledge and data that the FVM Program has on the global supply chain, and shifting the way Program personnel think about and conduct inspections. Measuring the number of inspections conducted each year can only be a small part of a broader strategy. The driving force should be a field staff that makes real-time resource allocation decisions from inspection to inspection, adjusting the depth of evaluation based on the nature and complexity of the processes employed at a facility, the inherent risk of the foods produced by a facility, and a facility’s food safety track record. Investigators must be empowered to strike a balance between comprehensiveness and quantity of inspections, adjusting inspectional frequencies and methodologies to promote prioritized distribution of resources and adequate coverage for each industry. In order to address import concerns with a mindset of comprehensive prevention, the primary burden to verify the safety of human and animal food and animal drugs coming in at the border must be shifted to manufacturers, processors and their importers under FDA oversight. And with new authorities and tools granted by Congress, the FVM Program will determine the best processes and procedures to enforce preventive control standards to maximize prevention of problems before they occur.

Objectives:

2.1 – Improve FVM Program intelligence on industry and the supply chain.

In addition to improving the quality of registration, risk and supply chain data, the FVM Program will focus on sharing data – when appropriate – with states and other trusted regulatory partners, recognizing the necessity for partnerships and collaborations. The Program will also engage industry, when necessary, to obtain data that can inform risk-based decision-making.

Key Initiatives
2.1.1: Improve the quality, accuracy, timeliness, and completeness of registration data.
2.1.2: Improve knowledge of risk factors and preventive practices in key sectors of the food/feed industry.
2.1.3: Work with industry to foster state-of-the-art tracing systems.

2.2 – Conduct domestic inspections to verify compliance with standards.

The FVM Program will work with Federal, State, local, tribal, and territorial regulatory and public health partners as well as members of industry to establish a fully integrated, risk-based domestic food and feed safety inspection system that ensures adequate oversight of industry and implementation of preventive controls. These efforts will help to ensure that inspections are conducted as efficiently as possible and in a uniform manner.

Key Initiatives
2.2.1: Develop an integrated Federal/State food and feed safety inspection work-plan to improve inspection efficiency and achieve inspection goals.
2.2.2: Improve processes for risk-based selection of domestic inspection targets.
2.2.3: Adopt risk-based approaches to conducting inspections that maximize public health benefit by ensuring high rates of compliance.
2.2.4: Establish and update training for Federal, State, local, tribal and territorial regulatory and public health officials.
2.2.5: Implement the Manufactured Foods Regulatory Program Standards to ensure the consistent quality of inspections and other elements of state regulatory programs.

2.3 – Improve assurance that imported foods and feeds meet preventive control standards.

New import safety models will hold foreign suppliers, processors, and others in the supply chain, including importers, accountable for making sure that the foods and feeds brought into the U.S. are safe. All import safety activities, including foreign inspections and border interventions, will be prioritized and targeted based on information about identified risk factors. Finally, the FVM Program will coordinate with, and accept and incorporate pertinent data from, internal and external sources, allowing more informed decisions to be made using risk data.

Key Initiatives
2.3.1: Enforce importer accountability through implementation of the foreign supplier verification program requirement.
2.3.2: Implement an accredited third-party certification program that ensures the rigor, objectivity, and credibility of certifications from third party audits.
2.3.3: Implement the voluntary qualified importer program.
2.3.4: Leverage international partners and increase work on joint regulatory programs with foreign counterparts to improve assurance of food and feed safety.
2.3.5: Establish a process to determine appropriate foreign inspection targets based on risk and resource availability.

2.4 – Effectively implement new and existing enforcement tools.

The FVM Program must swiftly and aggressively use its enforcement tools to protect public health when significant food or feed safety problems are identified. In order to do this transparently and judiciously – and ensure that industry is provided with the appropriate due process – the FVM Program will establish and refine the processes for using new authorities granted by Congress.

Key Initiatives
2.4.1: Implement the administrative detention authority as needed.
2.4.2: Implement the suspension of registration authority as needed.
2.4.3: Implement the mandatory recall authority as needed.
2.4.4: Streamline processes for use of existing judicial enforcement tools.

2.5 – Improve the collaboration among CFSAN, CVM and ORA headquarters and field staff, as well as with Federal, State, local, tribal and territorial partners on inspection and compliance efforts.

Mechanisms that promote effective collaboration and communication within the FVM Program, as well as with Federal, State, local, tribal and territorial officials, will be implemented to achieve strategic objectives. Leveraging resources of all component organizations will remain a key determinant to success for the FVM Program.

Key Initiatives
2.5.1: Enhance risk-based work planning processes and collaboration on inspection assignments.
2.5.2: Establish streamlined communication and data sharing within the FVM Program and with all regulatory and public health partners to improve the effectiveness of preventive control inspections, related laboratory work, and other compliance efforts.
2.5.3: Establish streamlined communications and procedures to support use of new administrative tools and existing enforcement tools for identified violations.

Program Goal 3 – Strengthen scientific leadership, capacity, and partnership to support public health and animal health decision making

Implementation of an integrated approach to research will position the FVM Program to more efficiently address the issues threatening the food supply and animal health in the decades to come. Strategically and operationally linking research needs to the agency’s regulatory goals will create focused synergy and momentum for the FVM Program and will increase the ability of the agency to achieve its goals. Fostering a culture of collaboration with other research and health agencies in the Federal government, State government agencies, academia, with private industry and with foreign regulatory bodies will expand scientific capability and permit the FVM Program to benefit from the great strides being made across the country and globally. With transparent, collaborative processes for prioritizing science and research needs, the FVM Program can achieve a clear and consistent focus on its goals and leverage the regulatory and research capabilities of partners to help meet its highest priorities. These efforts will require significant investments in cutting edge technologies that strengthen science and technology infrastructure with the future in mind. And as expert scientists continue to be recruited and trained, the FVM Program will continue to improve its technological, laboratory and analytical capabilities and build expert institutional knowledge.

Objectives:

3.1 – Establish and implement centralized planning and performance measurement processes.

Based on established animal health, public health and regulatory goals, the FVM Program will develop and implement processes to identify and prioritize critical research needs. It will allocate resources accordingly, monitor performance and make on-going adjustments as needed to maximize the contribution of the research program to achieving the Program’s goals.

Key Initiatives
3.1.1: Establish and implement FVM Program science research priority setting and operational planning processes.
3.1.2: Continually evaluate and report performance metrics.
3.1.3: Harmonize methods development and validation across the FVM Program.
3.1.4: Plan and implement ongoing collaborative activities among science and research elements of programs and centers.

3.2 – Improve information sharing internally and externally.

The FVM Program will cultivate a collaborative communications mindset in its science and research functions by promoting internal information sharing, and adapting IT systems to facilitate such sharing. Developing effective methods to keep the public informed of advances in food safety, nutrition and animal health research will strengthen the bond among the FDA, other government agencies, academia, industry and consumers.

Key Initiatives

3.2.1: Effectively communicate research plans and results within the program and to the public.

3.2.2: Develop centralized IT infrastructure to collect, analyze and share data with program offices.

3.2.3: Evaluate the impact of publications and presentations on the scientific and regulatory community.

3.2.4: Improve communication with food and feed importers to provide rapid notification of test results.

3.2.5: Share risk-based data on high-risk firms, farms and importers with foreign regulatory bodies.

3.2.6: Collaborate with external bodies in the exchange of information to facilitate the efficient evaluation of innovative technologies to meet the therapeutic and production needs of new animal drugs

3.3 – Maintain and strengthen mission-critical science capabilities

The FVM Program will have to maintain current science and research capabilities and strengthen its ability to address emerging technologies and needs.

Key Initiatives

3.3.1: Identify and invest in disciplines and specialties that are critical to carrying out the FVM Program’s mission.

3.3.2: Identify and invest in emerging disciplines, sciences, and technologies to mitigate future risks in food safety, promote animal health and support a healthier food supply.

3.3.3: Maintain and enhance the science and technology infrastructure to support day-to-day operations.

3.4 – Cultivate expert institutional knowledge.

In addition to continuing to fill its ranks with the best scientists in the field, the FVM Program will develop integrated training requirements and invest in programs to nurture the science and research expertise it needs to operate effectively in modern food safety, nutrition and animal health environments.

Key Initiatives

3.4.1: Identify and fill science leadership positions.

3.4.2: Develop and implement integrated FVM Program training requirements and training programs for cross-functional staff.

3.4.3: Track development and advancement of science and research expertise for internal workforce.

Program Goal 4 – Provide accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity

Food products sold in the United States have to be labeled so consumers can understand the products' nutritional qualities and use that information to improve their diets. The FVM Program will continue to work with industry and consumer groups to determine the best methods for conveying nutrition information on food items, menus and vending machines. Similar efforts will be pursued in pet food labels to protect and enhance animal health. By improving the way nutrition information is communicated to the public and by promoting awareness and education around these initiatives, the FVM Program can help improve the way consumers make dietary choices for themselves and their pets to ultimately enhance public health and animal health.

Objectives:

4.1 – Update the Nutrition Facts label.

The nutrition facts label will be updated in light of the most current information about nutrition and health, including potentially giving greater prominence to calorie declarations. The manner in which serving size information, daily values and key nutrients are communicated will also be updated.

Key Initiatives

4.1.1: Publish proposed rules updating the nutrition facts label and serving sizes.

4.1.2: Publish final rules updating the nutrition facts label and serving sizes.

4.2 – Implement menu and vending machine labeling regulations.

Appropriate nutrition information needs to be available for all foods sold in retail settings. By making calorie and other nutrition information readily available at the point of purchase such as in restaurants, similar retail food establishments and on vending machines,

consumers can be equipped with the right information to make better choices regarding what they eat.

Key Initiatives
4.2.1: Publish final menu and vending machine labeling regulations.
4.2.2: Collaborate with states, localities and other partners to ensure high rates of compliance.

4.3 – Improve consumer access to and use of nutrition information.

The FVM Program will contribute its expertise to educate consumers and improve the way they interpret and use nutrition information. As evidence-based approaches for informative labeling in food and feed products are developed, consumers will be able to make healthier choices about the food they eat or the pet food products they select that can support improved health and well-being in people and animals.

Key Initiatives
4.3.1: Explore front-of-pack nutrition labeling opportunities.
4.3.2: Collaborate with public/private sector parties on nutrition education.
4.3.3: Implement updated standards for the labeling of pet food including nutrition and ingredient information.
4.3.4: Implement standards for animal feed ingredients.
4.3.5: Publish final rule defining and permitting use of the term “gluten free” in the labeling of foods.

Program Goal 5 – Encourage food product reformulation and safe production of dietary supplements

In addition to undertaking initiatives that empower consumers to make better health choices, the FVM Program is committed to using its scientific leadership and influence and, when appropriate, regulatory tools to promote a healthier food supply for American consumers. This includes fostering the development of healthier food products and improving safety oversight of dietary supplements.

Objectives:

5.1 – Reduce sodium content in the food supply.

The FVM Program is committed to encouraging the food industry to reduce the amount of sodium included in packaged foods and served in restaurants. In order to inform decisions about how best to reduce sodium content, the FVM Program will research and analyze all relevant considerations, including the role of sodium in taste, safety and other important attributes of food products, as well as consumer behavior.

Key Initiatives
5.1.1: Conduct modeling to assess sodium intake resulting from varying levels of salt added to foods.
5.1.2: Consider options to identify and implement sodium reduction targets.
5.1.3: Collaborate with CDC and USDA to monitor sodium intake.

5.2 – Reduce industrially produced trans fat in the food supply.

The FVM Program will continue its efforts to reduce artificial *trans* fat in the food supply.

Key Initiatives
5.2.1: Complete and publish updated <i>trans</i> fat intake assessment.
5.2.2: Implement options for further reduction of <i>trans</i> fat in the food supply.
5.2.2: Collaborate with CDC and USDA to monitor <i>trans</i> fat intake.

5.3 – Improve the safety of dietary supplement products and the supply chain.

The program will continue executing a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, and other relevant statutes and regulations.

Key Initiatives
5.3.1: Develop and implement strategic, risk-based, and innovative compliance and regulatory strategies to address dietary supplement safety issues.
5.3.2: Advance post-market surveillance systems in the regulation of dietary supplements.
5.3.3: Advance pre-market oversight of dietary supplements by finalizing and implementing new dietary ingredient (NDI) guidance.

Program Goal 6 – Improve detection of and response to foodborne outbreaks and contamination incidents

While the FVM Program is focused primarily on prevention, illness outbreaks and contamination incidents will continue to occur due to the complex and dynamic reality of the food system. As a critical element of current and future prevention of food and feed safety problems, the FVM Program will enhance its efforts to promptly detect, contain and learn from such outbreaks and incidents. This will include dedicating necessary resources and expertise to achieve success, and creating new ways to work in a closely integrated fashion within FDA, and with animal health and public health agencies and regulatory partners at Federal, State, local, tribal and territorial levels. Improved data collection, analysis, sharing and communication both within government and with industry and consumer stakeholders will be key elements of this effort.

Objectives:

6.1 – Improve response to foodborne outbreaks and contamination incidents.

In order to appropriately deal with outbreaks of foodborne illness and feed contamination incidents, the FVM Program will establish and operate a group of full-time, multidisciplinary experts with the skills and resources necessary to plan and carryout rapid, effective emergency outbreak responses, in collaboration with all FVM Program operating units and Federal, State, local, tribal and territorial partners. This group will also plan and conduct targeted follow-up investigations to identify root causes and inform future prevention efforts.

Key Initiatives
6.1.1: Operationalize the Coordinated Outbreak Response and Evaluation (CORE) Network.
6.1.2: Develop metrics to evaluate response to foodborne outbreaks and contamination incidents.
6.1.3: Continually improve response to foodborne outbreaks and contamination incidents.
6.1.4: Use data from foodborne outbreak and contamination incident investigations to inform prevention efforts.

6.2 – Investigate and adopt innovative technologies and processes to detect and investigate foodborne outbreaks and contamination events.

New approaches that minimize the amount of time required for FVM Program field staff to obtain records for collecting, analyzing and visualizing trace-back results are needed.

Similarly, new approaches and technology for managing and sharing epidemiologic, laboratory and environmental data during foodborne outbreaks and contamination events require development.

Key Initiatives
6.2.1: Identify and prioritize systems, process and research needs related to improving outbreak detection and response.
6.2.2: Implement enhanced processes and IT systems for collecting, monitoring, analyzing and sharing data with Federal, State, international, and industry laboratories, public health agencies and regulatory offices.
6.2.3: Implement approaches for improving technical input, communications and coordination with industry during outbreak investigations.

6.3 – Enhance implementation of the Reportable Food Registry (RFR), including response strategies.

By improving the ways industry reports and FDA responds to contamination incidents that have the potential to cause adverse health consequences, the FVM Program can better protect public health, including animal health, and improve targeting of future inspections and prevention efforts.

Key Initiatives
6.3.1: Develop standard operating procedures for CFSAN, CVM, and ORA to standardize and streamline the process used to respond to reportable food events.
6.3.2: Implement consumer notifications for grocery stores related to posting of reportable/recalled food notifications.

6.4 – Conduct effective risk communications related to outbreaks and contamination incidents.

The FVM Program will increase public awareness of food safety incidents, outbreak and contamination events, and implement effective risk communications so consumers can take appropriate action and make informed choices.

Key Initiatives

6.4.1: Conduct research to strengthen the science that supports effective risk communication.

6.4.2: Use research findings to develop and update policies and standard operating procedures for communicating risks.

6.4.3: Expand FDA capacity to develop, disseminate and oversee effective risk communications.

Program Goal 7 – Advance animal drug safety and effectiveness

The FVM Program protects human and animal health by conducting pre-market review and approval, and post-market surveillance and compliance oversight of animal drugs, devices and additives used in animal feed. In addition to carrying out these central, health-related responsibilities, the FVM Program fosters the efficient development of new animal drug products and the availability of drugs for minor use and minor species, and enhances knowledge in emerging regulatory science and technology. To increase access to safe and effective animal drugs, the program works to decrease the prevalence of unapproved animal drug products marketed in the U.S. and reduce unsafe use of legally marketed animal drugs. In addition, the FVM Program must work to inform the public and shape public policy regarding the appropriate, judicious use of medically important antimicrobial drugs in food-producing animals.

Objectives:

7.1 – Increase access to safe and effective animal drugs and reduce risk of harm from unsafe use of marketed animal drugs.

The FVM Program will expeditiously approve quality, safe, effective, properly-labeled new animal drug products through a science-based approach in a regulatory environment. After a drug is approved, post-approval activities will ensure continued effectiveness through monitoring product usage, product defects, and adverse events.

Key Initiatives

7.1.1: Optimize new drug evaluation functions and ensure user fee timeframes, goals and commitments are met.

7.1.2: Enhance the development of drugs for minor use and minor species.

7.1.3: Enhance the capabilities of the Adverse Drug Event (ADE) pharmacovigilance surveillance system.

7.2 – Reduce availability of substandard and illegally marketed animal drugs.

The FVM Program is concerned about the number of unapproved animal drug products that are being sold and marketed to animal owners and veterinarians. To reduce the risk of harm from substandard and illegally marketed animal drugs, the program will identify new regulatory frameworks and enforcement strategies to combat this growing area of concern.

Key Initiatives

7.2.1: Develop risk-based frameworks that assure quality and safety for animal drug products that are currently being marketed without FDA approval.

7.2.2: Develop and implement an enforcement strategy that addresses the illegal compounding of new animal drugs and removes unsafe, ineffective or copycat animal drugs from the market.

7.3 – Foster the judicious use of medically important antibiotics in food animals to minimize the development of antimicrobial resistance.

The FVM Program will inform the public and help shape public policy regarding the use of medically important antimicrobial drugs in food-producing animals and continue its efforts to minimize the development of antimicrobial resistance by fostering judicious use of medically important antibiotics.

Key Initiatives

7.3.1: Issue final guidance on the judicious use of medically important antimicrobial drugs in food-producing animals and simplify the process for voluntarily phasing out non-judicious uses.

7.3.2: Conduct outreach and education with external stakeholders to implement the judicious use guidance recommendations.

7.3.3: Evaluate public health impact and develop strategies to address the extra-label use of drugs in food-producing animals.

7.3.4: Evaluate the use of antimicrobials in ethanol production.

Conclusion

The FVM Program Strategic Plan outlines an ambitious agenda for meeting today's food safety, nutrition and animal health challenges. While other important FVM Program activities will continue, the goals, objectives and key initiatives outlined here will guide the Program's leadership, managers and staff in setting priorities and managing the FVM Program. This Plan will also enable the FVM Program's many stakeholders to see the full breadth of the key initiatives the Program is pursuing and the purposes for which the Program is pursuing them.