NASDA Model
Food Safety Modernization Act
Preventive Controls for Animal Food
Implementation Framework

Working Document for Review and Discussion Purposes
Subject to Revision as Needed

Prepared by:
National Association of State Departments of Agriculture
Food Safety Modernization Act Preventive Controls for Animal Food
Technical Working Group
August 29, 2018 Update

Although the contents of the chapters of this framework have been discussed with FDA through a cooperative agreement between FDA and NASDA (Federal Award Identification Number: U01FD005934), we stress that this document is written from a state’s perspective, with the goal of providing guidance and basic information to any state contemplating development of a state program. We are thankful for the contributions of FDA staff and their significant interaction with state animal food safety professionals during the development of this framework. The federal/state dialog definitely improved the overall quality of our efforts.
Table of Contents

Introduction ................................................................................................................................. 4

Background ............................................................................................................................... 7

Chapter 1: Alignment and Consistency ...................................................................................... 15
  1. Executive Summary ............................................................................................................. 16
  2. Background ......................................................................................................................... 16
  3. Purpose ............................................................................................................................... 16
  4. Current Harmonization Efforts and the PCAF Framework: .................................................. 18
  5. Harmonized Approach to Building Future Programs .......................................................... 20
  6. Roles and Responsibilities ................................................................................................. 21

Chapter 2: Foundation of Law .................................................................................................. 22
  1. Executive Summary ............................................................................................................. 23
  2. Background ......................................................................................................................... 23
  3. Purpose / Scope ................................................................................................................... 23
  4. Roles and Responsibilities ................................................................................................. 24
  5. Regulatory Foundation ....................................................................................................... 26
  6. Fundamental Components of a State Program .................................................................... 26
  7. Steps to Evaluate the Regulatory Foundation for a State Program ..................................... 26
  8. Other Considerations ......................................................................................................... 32

Chapter 3: Infrastructure and Financial Resources ................................................................. 33
  1. Executive Summary ............................................................................................................. 34
  2. Background ......................................................................................................................... 34
  3. Purpose ............................................................................................................................... 35
  4. Scope of New Funding to Support Development of State PCAF Program ......................... 35
  5. Infrastructure Needs: .......................................................................................................... 36
  6. Roles and Responsibilities ................................................................................................. 40
  7. Resources ........................................................................................................................... 40

Chapter 4: Regulator Training .................................................................................................. 42
  1. Executive Summary ............................................................................................................. 43
  2. Scope/Purpose ...................................................................................................................... 43
  3. Background ......................................................................................................................... 43
  4. Roles and Responsibilities ................................................................................................. 48
  5. Related Documents and Resources: .................................................................................. 51

Chapter 5: Education and Outreach ......................................................................................... 52
  1. Executive Summary ............................................................................................................. 53
  2. Purpose ............................................................................................................................... 53
  3. Background ......................................................................................................................... 53
  4. Outreach and Education Plan ............................................................................................ 55
NASDA Model Animal Food Safety Implementation Framework

Introduction

The National Association of State Departments of Agriculture (NASDA) National Implementation Framework (Framework) for the Preventive Controls for Animal Food Regulation (PCAF) contains the fundamental and essential components for the operation of a state animal food safety program that can fully implement the FDA’s Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Animal Food regulation (Preventive Controls for Animal Food regulation or PCAF regulation). The PCAF regulation was published as a final rule in September 2015 and is found in Title 21 of the Code of Federal Regulations part 507 (21 CFR part 507).

The PCAF regulation, as well as this framework, establishes preventive actions to ensure the safety of animal food in an effort to protect animal and human health. The goal of the PCAF Framework is to provide the foundational knowledge and support to any state considering implementation of a FSMA-aligned animal food safety program.

The PCAF Framework includes the following foundational chapters discussing each key area required for a state to successfully implement a FSMA-aligned animal food safety program including:

- Chapter 1: Alignment and Consistency
- Chapter 2: Foundation of Law
- Chapter 3: Infrastructure and Financial Resources
- Chapter 4: Regulator Training
- Chapter 5: Education and Outreach
- Chapter 6: Inspection Program Planning
- Chapter 7: Laboratory Support
- Chapter 8: Enforcement
- Chapter 9: Dispute Resolution

Twelve state Departments of Agriculture and universities, NASDA, the Association of American Feed Control Officials (AAFCO), and the FDA were actively involved in the development of the PCAF Framework in an extensive collaborative and consensus building effort through a

---

1 Most state animal food safety programs (i.e. state programs) use the terms “animal feed”, “commercial feed” or “feed” in their laws and regulations. A decision was made to utilize the term “animal food” in this document to provide consistent terminology throughout and to more closely align with the terminology in the PCAF regulation. Animal food, as used in this document, has the same meaning as the term “animal food” as defined in 21 CFR 507.3, “food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.”
Technical Working Group (TWG). Many states have a current program that regulates animal food, and experts for the TWG were sourced from these programs. The TWG consisted of members of states with differing size programs and from programs that were based in state departments of agriculture and university systems. TWG members chose to participate in the effort by authoring specific sections or chapters. All states were involved and briefed through NASDA regarding the development of this model framework.

The TWG authored these foundational chapters to allow any state program to have available to them a full discussion of the basic components needed for implementation of the PCAF Regulation. The Framework is written from the perspective of states taking the role as the major implementation arm for the PCAF regulation, and is written for the guidance of state animal food programs.

Although each chapter in the Framework has been reviewed with FDA through a cooperative agreement between, FDA and NASDA (Federal Award Identification Number: U01FD005934), this document is written from a 50-state perspective, with the goal of providing guidance and basic information to any state contemplating development of a PCAF program as a component of the state’s program. Some states may already have within their programs many of the components discussed.

Other states may need to seek fundamental changes in their programs, or may choose to implement only one or some activities under the PCAF regulation (education, training, outreach, inspection, etc.). The decision on the scope of implementation completed by the state will be at the state level; however, the chapters, herein, will provide the essential core components needed for a complete program in support of the PCAF regulation. For the purposes of these chapters, the term ‘state’ includes any state or territorial agency.

The FDA’s Operational Strategy for Implementing the FDA Food Safety Modernization Act\(^2\) spells out some of FDA’s FSMA implementation strategies – from a federal perspective. While the FDA has been involved with the review of the PCAF Framework, this should be viewed as a NASDA document – offering advice to the states (i.e., it is not an FDA document \textit{per se}). We appreciate the advice, counsel and recommendations from our FDA colleagues as they measurably improved the PCAF Framework chapters. This document is considered a living document, one that is destined to be improved over time to allow for improvements to account for advances in technology and experience with implementation. The revision schedule of this document will be decided after its initial release.

\(^2\) [http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm395677.htm](http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm395677.htm)
The mutual state and federal goal for the FSMA animal food safety program is to provide animal and human health protection through a preventive, science-based partnership and integrated regulatory program. The goal of the PCAF Framework is to provide the foundational knowledge and support to any state considering implementation of such a FSMA-aligned animal food safety program.

Without the commitment from the NASDA members and the voluntary involvement of the state staff members, this document would not yet be in draft form. Many thanks are extended to the NASDA members for their willingness to allow NASDA to use their staff members as technical experts on this project. Equally, we thank those individual contributors, who assisted us as writers, commenters, and reviewers. Your knowledge and passions have made this effort more rewarding. Thank you also to the FDA staff for their contributions. The dialog definitely improved the overall quality of our efforts.

For further information on this document contact Janell Hendren, Associate Director of Public Policy and Food Safety Programs, at janell@nasda.org or Bob Ehart, NASDA Senior Policy and Science Advisor, at bob@nasda.org.
Animal Food Regulation
In the United States, animal food has a long history of regulation. Animal food has been regulated at the federal and state level for over one hundred years. FDA’s authority was established in 1906, and some state agencies had regulations in place prior to that as evidenced by the establishment of AAFCO in 1909. Federal and state government agencies each have responsibilities to ensure the safety of animal food. Ensuring the safety of the animal food is part of both federal and state regulatory agencies mission to protect animal and human health. The FDA is responsible for ensuring that all animal food moving in interstate commerce, except those under the United States Department of Agriculture (USDA) jurisdiction, are safe, wholesome, and labeled properly. State agencies are responsible for ensuring that animal food, within their jurisdictions, is safe and in compliance with State laws and regulations.

FDA’s original authority over animal food was established in the Pure Food and Drug Act of 1906. In 1938, the authority was broadened with the passage of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act provides FDA with its oversight authority for animal food. FDA passes regulations, which can be found in the Code of Federal Regulations, to implement the authorities in the FD&C Act.

State animal food programs develop their own laws, regulations, and ordinances that establish their oversight authority for animal food based on the procedures of that state. Many state animal food programs have animal food responsibilities that include animal and human health protection, consumer protection (e.g., enforcing compliance with regulations to prevent the spread of bovine spongiform encephalopathy (BSE) and for ensuring safe production of medicated animal feed), and support of the state’s agricultural industry. AAFCO develops uniform regulations, standards, definitions, and enforcement policies related to the manufacture, labeling, distribution, and sale of animal food. In efforts to harmonize state laws and regulations, some states have chosen to adopt, some or all, of the AAFCO model regulations.

Food Safety Modernization Act (FSMA)
Why FSMA?
While the United States has been privy to one of the safest food supplies, there were a number of significant foodborne illness outbreaks that resulted in human and animal illness, and in some cases death, between 2005 and 2010. On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) was signed into law with broad bipartisan support
and support from the food industry and consumer groups. This law enables better protection of animal and human health by helping to ensure the safety and security of the human and animal food supply. The law had four primary areas of focus: prevention; import safety; inspection, enforcement, and response; and integration. The law shifted the focus from primarily reacting to food safety problems to preventing them. The law also provides FDA with new enforcement authorities to help achieve higher rates of compliance with risk based, prevention-oriented safety protocols, and to better respond to and contain problems when they do occur. In addition, the law gives FDA important new tools to better ensure the safety of imported human and animal foods and directs the Agency to build an integrated national food safety system in partnership with State, local, tribal, and territorial authorities.

While there have been efforts by both regulators and industry to advance food safety, significant human and animal food safety challenges persist in today’s complex, dynamic, and global food system. Today’s food supply is highly diverse and increasingly complex, with many new foods in the marketplace that pose new food safety challenges. New pathogens are emerging, and we have seen commonly known pathogens appear in foods where they have not been traditionally seen. In addition, we continue to see common animal food safety hazards that are not being controlled. When illness outbreaks occur, they can have devastating impacts on animal and human health and impose substantial economic disruption and cost on the human and animal food industry. The food safety challenge is only compounded by globalization and the increasing amount of imported human and animal food.

FSMA builds on past experience and the strong foundation provided by the current food safety system, but it also marks a historic turning point for food safety. FSMA directs FDA to build a food safety system for the future that makes modern, science- and risk-based preventive controls the standard across all sectors of the food system; meets the food safety challenges of the global food system; and establishes stronger partnerships for food safety across all levels of government and with the private sector to ensure optimal use of public and private resources.

As part of the efforts to implement FSMA, FDA has passed four regulations that build the foundation for modern day animal food safety. Those regulations are:

- Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (a.k.a. Preventive Controls for Animal Food or PCAF), 21 CFR part 507
- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (a.k.a. FSVP), 21 CFR part 1, subpart L
- Sanitary Transportation of Human and Animal Food, 21 CFR part 1, subpart O
- Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 21 CFR part 1, subpart M

Why the PCAF regulation?
Of the four foundational FSMA regulations, the regulation that will have the most immediate impact on the animal food industry and state regulators is the PCAF regulation. The PCAF regulation applies to animal food facilities that manufacture, process, pack, or hold animal food in the United States and that are required to register as food facilities with the FDA under section 415 of the FD&C Act. The PCAF regulation established a baseline of current good manufacturing practice requirements to ensure that animal food is protected from contamination. The PCAF regulation also establishes a prevention oriented system for the animal food industry by requiring facilities to have a food safety plan and to conduct a hazard analysis and implement appropriate preventive controls to ensure control of hazards that can impact both animal and human health.

As regulators, we are obligated to protect the safety of the U.S. food supply. As animal food regulators, we know that the safety of the animal food supply is necessary to ensure protection of both animal and human health. Animal food can cause harm to an animal if it contains a hazard. In some cases, the animal food may also be a source of a hazard that can impact human health, such as through consumption of food derived from animals (e.g., meat, milk, and eggs) or through handling the animal food (e.g. pet food).

Ensuring the safety of animal food is complex in light of several factors. While human food manufacturers must consider the impact of their food on a single species (humans), animal food is made for a wide variety of species. Animal food is made for food-producing animals, pet animals, wild animals, zoo animals, and laboratory animals. Many animals consume one food as their sole source of nutrition. Therefore, the food that they consume must be nutritionally adequate and not a source of a hazard that could cause the animal illness or death. Animal foods are also handled and fed in a wide variety of settings. Some foods are handled on farms or in feed mills and would not typically be handled by humans. Other foods, like pet foods, are handled in homes and often in the kitchen. If a pet food is contaminated with a pathogen of human health concern, this could result in secondary contamination of human food-contact surfaces or human food. Humans could become ill from the pathogen through handling the pet food or through these secondary contaminations.

While the U.S. animal food supply has a history of safety, there are also instances where the presence of hazards has resulted in significant instances of animal illness and death and in some cases human illness. Examples of animal food hazards that have led to animal and human illness and death include: mycotoxins, dioxins, industrial chemicals such as melamine and cyanuric acid, nutritional deficiencies and toxicities, animal drugs, and microbial pathogens:

**Mycotoxins:** Aflatoxins, as an example of mycotoxins, are naturally occurring and are produced by many species of the fungus Aspergillus on certain agricultural commodities. Since their discovery in the early 1960’s, aflatoxins have been shown to be toxic to animals and humans when consumed above certain levels. Aflatoxins have also been shown to be carcinogenic to laboratory test animals. After consumption, aflatoxins are
metabolized by the liver to a reactive intermediate and eliminated as aflatoxin M1 in milk or as aflatoxicol in urine. High level aflatoxin exposure produces acute damage and cirrhosis of the liver as well as cancer of the liver. It appears that no animal species, including humans, is immune to the acute toxic effects of aflatoxins. In 2005, there was a major recall of dog food because it was contaminated with aflatoxins. The FDA received reports from 4 states of illness in over 40 dogs, including 23 deaths, associated with the consumption of the contaminated pet food. In addition, the company’s contaminated pet food was exported to at least 29 foreign countries. The source of this contamination was traced to local corn, which had been contaminated with aflatoxins before entering the pet food facility.

**Dioxins:** Dioxins have been linked to adverse health effects in humans, such as cancer, immune suppression, and reproductive or developmental effects. Dioxin is a concern in food-producing animals because human dioxin exposure in the United States comes primarily from the consumption of animal products. In 1997, the USDA’s Food Safety and Inspection Service, through their dioxin sampling survey, identified dioxins in poultry tissue. Through a multi-agency investigation, the FDA traced this contamination to high levels of dioxins present in an anti-caking agent (ball clay) used in animal food. That same year, FDA issued a statement to users of ball clay products in animal feed requesting those companies to cease the use of ball clay products in animal feeds and feed ingredients. In 2002, a foreign government identified high dioxin levels in a mineral product intended for animal food imported from the United States. The source of the dioxin was related to the high temperature used in the mineral manufacturing process. In 2003, another dioxin incident in minerals was identified as a result of an FDA food sampling assignment. In this case, the mineral premix manufacturer purchased a trace mineral that was a by-product of a metal smelting process. Dioxin contamination is not limited to the U.S. animal food supply. Incidents of dioxin contamination in Belgium in 1999 and Ireland in 2009 led to significant financial impacts due to the exposure of animals directly through consumption of the animal food and to humans who would consume the meat derived from the animals. These combined incidents were estimated to have a financial burden of over $759 million. These incidents raised public awareness of the problem of dioxin contamination in animal food.

**Melamine and Cyanuric Acid:** In 2007, there was a massive pet food recall due to adulteration of pet food with melamine and cyanuric acid. These substances were intentionally added to imported wheat gluten and rice protein concentrate for economic reasons. Melamine was added to wheat gluten and rice protein concentrate by the suppliers to create a falsely high estimate of protein in their products. While melamine by itself is relatively nontoxic to mammals, the melamine used to adulterate the wheat gluten and rice protein concentrate in this incident had been combined with cyanuric acid, creating a mixture that became toxic. When the animals ingested the
adulterated food, the mix of these two chemicals was absorbed into the blood stream and ultimately created an accumulation of crystals in the tubules of the animals’ kidneys, leading to kidney failure and death in many animals. The addition of these substances to pet food affected a large number of pet food facilities in the United States and created a nationwide problem by causing illness and death in many dogs and cats. During the investigation to find the root cause of the illnesses, the investigation found that products containing these adulterants had also been incorporated into the diets of food-producing animals (swine and aquaculture fish). These situations with food-producing animals emphasized the potential link between adulterated animal food (and ingredients) and the potential for adverse effects on human health.

**Nutritional deficiencies and toxicities:** Many animals consume one food as their sole source of nutrition. Therefore, the food that they consume must be nutritionally adequate and balanced. If not nutritionally adequate and balanced, the food presents a safety hazard to the animals. Nutrient deficiencies or excesses can raise safety concerns. Because different species have different nutritional needs, certain quantities of a nutrient that are needed by one species of animal could pose a health risk to another species of animal. Therefore, animal food hazards include both nutrient deficiencies and toxicities. There is a history of animal food incidents resulting in recall of the animal food and in animal illnesses and deaths from nutrient deficiencies or toxicities. Examples of nutrient related hazards in animal food include low levels of thiamine in cat food; high levels of vitamin D in dog food; low levels of vitamin D in food for swine; high levels of vitamin D in food for guinea pigs, fish, and other animal species; high levels of calcium and phosphorus in food for broiler chickens and turkeys causing the death of several hundred young birds; high levels of salt in food for broilers; high levels of protein/urea in food for cattle; and high levels of copper in food for sheep. Many of these animal foods with nutrient imbalances (deficiencies or toxicities) resulted in a recall of the affected animal food, and in some cases serious illness or death in the animals consuming the food. Because food for food-producing animals is often sent in large batches, if a batch is deficient in a required nutrient or has excess of a nutrient that can lead to a toxic condition, the result can have a significant impact to a single farm. Nutrient deficiencies and toxicities in livestock food tend to be localized events with potential for serious impacts. However, nutrient deficiencies and toxicities in pet food can be national events due to the distribution pattern, and small package sizes, common to pet food.

**Animal drugs:** In the United States, animal drugs require approval by FDA before they can be marketed for administration to animals. While animal drugs can be safely and effectively used in accordance with their regulations, animal drugs can be chemical hazards introduced into animal food such as through an ingredient containing residues or through drug carryover or cross contamination during manufacturing. Drugs can be
approved for one species but have toxic effects if included in food for a different species. For animal drugs used in food-producing animals, FDA establishes a tolerance for the drug residue in human food as part of the approval process. Animal drug residues detected in food derived from food-producing animals (i.e., animal tissues such as meat, milk, and eggs) are considered a hazard for human food if an established animal drug tolerance is exceeded.

An example of an ingredient-related hazard is drug contamination in an animal food result from using a raw material that contains drug residues. Depending on the chemical property of the drug, residues of certain drugs may become concentrated during animal food manufacturing and processing. Two examples of types of drugs that can become concentrated during manufacturing are antibiotics and pentobarbital. In 2013, two companies recalled various pet treats after antibiotic residues were found upon testing of the treats by regulatory laboratory. In 2014, FDA issued an import alert for poultry jerky-type treats due to the presence of antibiotic and/or antiviral residues as a result of positive test results for these residues in jerky treats from certain countries. Pentobarbital is a component of euthanasia solutions that are used to humanely kill animals. Pentobarbital is stable in tissue, aqueous environments, and resists degradation at rendering temperatures. There are reports of pentobarbital toxicosis in domestic species, zoological animals, and wildlife. In 2015, cases of toxicosis linked to pentobarbital in horsemeat resulted in the death of two animals and illness of a third in a wildlife preservation center in the United States. In 2017, pentobarbital in dog food resulted in illness in four dogs and the death of a fifth dog.

Many feed mills manufacture animal food that contains one or more approved animal drugs. These medicated feeds are subject to 21 CFR part 225 – Current Good Manufacturing Practice for Medicated Feeds, which require, in part, that facilities making medicated feed take steps to ensure adequate cleanout of their equipment in order to maintain proper drug levels and to avoid unsafe contamination of animal food with drugs. Flushing of equipment and sequential production of medicated feed are two commonly practiced procedures for preventing unsafe contamination from drug carryover. Failure to perform proper equipment cleanout procedures or failure to adequately follow the procedures could result in contaminated animal food that may cause illness or death in animals. For example, incomplete clean-out from a previous batch of animal food manufactured with monensin (which is particularly toxic to horses) has been the source of contamination in animal food. In 2014 and 2015, monensin contamination of animal food resulted in the death of horses and layer hens.

**Microbial pathogens**: Microbial contamination of animal food is also a high concern, not only for animals consuming the contaminated food, but also for humans that handle that contaminated animal food. Microbial contamination is primarily a concern with pet
food because it has the potential to be directly contacted by humans. There have been reported outbreaks in which people have become ill, and even hospitalized, from microbial contamination of pet food. Two examples of Salmonella illness in humans that were linked to pet food occurred in 2007 and 2012. In 2007, a rare serotype of Salmonella, *S. Schwarzengrund*, was identified as being the cause of human illness and the Salmonella source was linked to a pet food. After the initial recall and stoppage of production for five months, there were additional reports of illness in humans from the pet food. This led to a larger recall of approximately 23,109 tons of dry pet foods, representing 105 brands. While no pets were reported sick, 79 people in 21 states were reported ill due to the handling of pet food contaminated with this Salmonella strain. In April 2012, epidemiologic and laboratory investigations conducted by officials in local, state, and federal animal and human health, agriculture, and regulatory agencies linked a *Salmonella Infantis* outbreak to contaminated dry dog food produced by a single production facility. A total of 49 people (47 individuals in 20 states and 2 individuals in Canada) were reported infected with *Salmonella Infantis*. Among the 24 human patients with available information, 10 were hospitalized. The results from product testing by multiple agencies along with production codes provided by ill persons, led to multiple recalls by several companies with animal food products manufactured at the implicated production facility. The recalls included 17 brands representing over 30,000 tons of dry dog and cat food produced at the facility. This was the second documented outbreak of human salmonellosis linked to dry pet food in the United States.

These are just some of the hazards that have the potential to be associated with animal food. Steps must be taken to ensure the safety of the animal food. Implementation of the hazard analysis and preventive controls requirements of the PCAF regulation is one way that the animal food industry can improve food safety in the U.S. We as regulatory officials have a role in helping to ensure the proper implementation of the PCAF regulation by the industry as part of our responsibility to protect animal and human health and ensure the safety of the animal food supply.

**Impact of PCAF rule on State Animal Food Programs**

Many states have established animal food programs. These programs are individualized to the needs of that state and can vary widely. Animal food programs can be a part of the state’s department of agriculture or part of a state’s university system. These programs vary in size and in operations.

There are core areas of work that many state programs currently conduct under their program. These areas include licensing and registration, label reviews, and inspections and sampling. Inspections are performed both under the state’s authority and in some cases under contract with FDA. Prior to the passage of the PCAF regulation, inspections were primarily focused on compliance with regulations to prevent the spread of BSE and regulations to ensure the safe
production of medicated animal food. Many states also have robust sampling programs that are used to detect the presence of contaminants (e.g., mycotoxins) or to ensure consumer protection through comparison of analytical results with label guarantees (e.g., nutritional content verses label guaranteed analysis).

As the animal food supply becomes more complex through globalization and increased complexity of animal foods, the regulatory landscape has shifted to account for the introduction of hazards. FDA and state agencies have partnered together to oversee the animal food supply, and the new PCAF regulation requires continued partnership to ensure that the regulatory community is prepared to oversee compliance with the new regulations that provide the platform for animal food safety in the United States. To be able to perform this body of work, state programs will have to transition to a prevention oriented system that includes oversight of the implementation of current good manufacturing practices (CGMPs) and the control of animal food safety hazards. This transition could include updates to a state program’s regulatory foundation, a new approach to implementation of current good manufacturing practices beyond just medicated feed, redirecting sampling and testing to focus on animal food hazards, training or hiring staff that have technical skills necessary for reviewing complex food safety plans, or training or hiring staff capable of conducting outreach to the industry in an effort to gain compliance with the new regulations.
# Table of Contents

1. Executive Summary

2. Background

3. Purpose

4. Current Harmonization Efforts and the PCAF Framework

5. Harmonized Approach to Building Future Programs

6. Roles and Responsibilities
1. Executive Summary
This chapter describes the importance of alignment and consistency in implementing the PCAF regulation across state programs. While state programs need to have flexibility in developing their PCAF program, alignment with the intent and requirements of the PCAF regulation is essential for uniform and consistent application of the regulation. Animal food safety regulators have a long history of participating in efforts to increase harmonization, such as through active participation in AAFCO and their committees, and voluntary participation in the Animal Feed Regulatory Program Standards (AFRPS). These harmonization efforts while different from the intent of the PCAF Framework provide a strong foundation and context for state animal food programs to build a successful PCAF implementation program. States should take a harmonized approach to building PCAF programs by following a foundational step-wise approach, which will require additional resources to fully and successfully implement. To aid in harmonization efforts and building towards the future, implementation of the PCAF regulation must be a shared responsibility between FDA, state programs, NASDA, and AAFCO.

2. Background
Consistency among state agencies engaged in animal food safety inspection programs will enhance the national goal of increasing animal and human health protection. A state program has a primary role in the implementation of the PCAF regulation in that state and as a part of an integrated food safety system (IFSS). Efforts, such as those through AAFCO and the AFRPS, have long been underway to develop harmonization and alignment in animal food safety programs. Individual states can leverage existing harmonization and alignment efforts as they consider different approaches to implementation of the PCAF regulation. For example, AAFCO has developed draft model bill language to assist states in harmonizing existing state statutory and regulatory frameworks to include the PCAF regulation.

Depending upon the existing statutory and regulatory animal food safety authority and the priorities of an individual state program, different analysis and action steps may be necessary. Some states may choose to expand existing programs; others may consolidate programs; some may create unique programs; and some may forgo implementing the PCAF regulation and changing authorities at this time. There will be a need for some states to have a transitional period between the compliance date of the PCAF regulation and the date the state agency is able to implement the PCAF regulation (including conducting inspections) under their own authority.

3. Purpose
Individual chapters of the PCAF Framework address specific elements a state animal food safety program will need to fully implement the PCAF regulation. This chapter outlines current efforts that are ongoing to promote uniformity and consistency across animal food regulatory programs. These current efforts, including active participation in AAFCO and NASDA and
implementation of AFRPS can be leveraged to ensure there is a foundation for effectively implementing the PCAF regulation and for ensuring it is uniformly and consistently applied across state programs.

The PCAF regulation is new for both the animal food industry and regulators. However, the process of implementing regulatory programs are not in their infancy. Most states have well-established programs that have a well-established history of animal food regulation. Programs implementing the PCAF regulation may vary due to the different agricultural, legislative, and administrative approaches that exist from state to state. These state programs reflect a state’s animal food industry, consumers, stakeholders, and general public interests. Each state will need to work through its own system for implementing the PCAF regulation. For the PCAF regulation to be successful, states will need options and flexibility when approaching implementation. Flexibility is important for state programs with few or limited resources, and flexibility is needed to foster innovative approaches to implementation across all program sizes. Depending on various factors and internal conditions, different states may have different priorities with respect to implementation of the PCAF Framework. As many state programs are currently not identical, state programs can be expected to take various approaches to how they carry out implementation of the PCAF regulation as well.

Alignment with the intent and requirements of the PCAF regulation is essential for uniform and consistent application of the regulation for state programs to successfully prevent animal food safety hazards and associated human or animal illness or injury. There are many partners within an integrated food safety system that need to work in an integrated system to achieve animal food safety. FDA shepherds the national implementation of the PCAF regulation to ensure that it is being followed and is being applied appropriately and uniformly as envisioned by the US Congress in the FSMA legislation. The animal food industry needs to know what to expect for implementation and that the industry is being treated uniformly, both from state to state and from state to FDA. States need to know they are focusing their resources and attention appropriately and effectively.

As state programs consider implementation of the PCAF regulation, the PCAF Framework allows flexibility for implementation. However, utilizing a systematic approach to implementation is needed to build a successful program that is protective of animal and human health. Even though state programs differ, if each one is in alignment with the PCAF regulation, the alignment will create the consistency needed to implement the PCAF regulation successfully.

The need for consistent alignment with the PCAF regulation is reflected in the need for ongoing education, outreach, and training as part of a long-term strategy and commitment for ensuring high rates of compliance with the regulation. State programs should focus on a core set of
shared goals: know the regulation, know how to apply the regulation, and know the human and animal health significance.

Alignment of a state programs’ activities with the PCAF regulation supports the shared goal of gaining compliance with the PCAF regulation, and the PCAF regulation supports a goal that the FDA and states share: protecting human and animal health and preventing foodborne illness. This shared focus is at the core of the recommendations outlined in the PCAF Framework. The PCAF Framework provides various recommendations with human and animal health as the ultimate goal. State programs should focus on their ability to support market access for the animal food industry, the individuality and regional distinctiveness of the industry, and the flexibility needed for state programs to be innovative in their successful implementation of the PCAF regulation.

4. Current Harmonization Efforts and the PCAF Framework:

The focus of the PCAF Framework, AFRPS, and AAFCO committee products such as Model Bill and Regulations and Quality Assurance/Quality Control Guidelines for Feed Laboratories vary in application; however, collectively they are designed to promote uniformity and consistency among state programs.

The overall goal of the PCAF Framework is to provide the foundational knowledge and support to any state implementing a FSMA-aligned animal food safety program. Human and animal health benefits of a PCAF regulation program can be accomplished through multiple approaches—e.g., education, outreach, training, technical assistance, inspection, and enforcement. Protection of human and animal health through implementation of the PCAF regulation is what matters, so there can be flexibility in how to achieve it. This concept is also reflected within the PCAF regulation itself as is evidenced by the flexibility provided within the regulation. If the PCAF regulation is to be applied uniformly and consistently, alignment with the regulation needs to be assured—among states and within a state. Elements, structures, processes and practices all must align with the shared goal to implement a FSMA-aligned animal food safety program.

Much of the PCAF framework calls for self-assessment, identifying questions programs should ask themselves. The answers are not intended to verify adherence to a specific program standard; instead they are intended to point to areas where a program needs to act to ensure alignment with the PCAF regulation. Because consistency of implementation is the intention, the framework is based on the work that creates that consistency.

Under some circumstances, such a foundation may be created by adopting voluntary regulatory program standards. One of the foundational principles of IFSS, as envisioned by the Partnership for Food Protection, is the implementation and uniform application of model standards so that
federal and state agencies conduct inspections under the same set of standards. Standards provide a consistent, underlying foundation that is critical for uniformity across state and federal agencies to ensure the credibility of the programs under an IFSS. Following a recommendation to create program standards for animal food at the 2010 PFP 50-State Workshop (A United Approach to Public Health), AAFCO formally requested to partner with FDA to create the AFRPS in 2010. The passage of FSMA in 2011 further supported the need for program standards with key pieces of the legislation requiring enhanced partnerships and integration of regulator partners. The enhanced partnerships and integration called for by FSMA will allow FDA to rely on inspections and data collected by other agencies to support regulatory activities and further the idea of an IFSS.

The voluntary AFRPS, first published in 2014, provide a uniform foundation for the design and management of state programs responsible for the regulation of animal food. This is consistent with the principles of the FSMA and the fundamental goal of AAFCO and FDA to provide a mechanism for developing and implementing uniform and equitable statutes, regulations, and standards to enhance the protection of the nation’s animal food supply. The AFRPS is composed of eleven standards that serve as an objective framework to evaluate and improve components of a State program. The standards cover the State program’s regulatory foundation, training, inspection program, auditing, feed-related illnesses or death and emergency response, enforcement program, outreach activities, budget and planning, laboratory services, sampling program, and assessment and improvement of standard implementation. While implementation of the AFRPS is voluntary, state programs who are implementing (or have implemented) the AFRPS have built many of the foundational elements that can be used to support and speed implementation of the recommendations in the PCAF Framework.

The development of state jurisdictional laws and regulations are based on the public policies, legislative and administrative landscapes, agricultural conditions and available resources. Enforcement of laws and regulations is most effective if administered uniformly and equitably. AAFCO adopted a Model Commercial Feed Bill and Regulations as regulatory guidance for states when establishing its jurisdictional laws and regulations. The AAFCO Model Bills and Regulations are published in the AAFCO Official Publication (AAFCO OP), which is available electronically and in hardcopy (contact AAFCO for an electronic copy of the Model Bill and Model Regulation). Standards of reference are also established in the AAFCO OP, allowing members and others to cite an official source. The AAFCO OP provides a wide range of resources designed for uniformity and states are encouraged to consult it regularly in program development.

The overarching goal of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards, definitions and enforcement policies for
regulating the manufacture, labeling, distribution and sale of animal food; result in a safe, effective and useful animal food. The AAFCO Model Bill and Regulations are one way in which AAFCO promotes uniformity and consistency by providing uniform guidance to individual members when establishing their jurisdictional laws and regulations. Although the AAFCO Model Bill and Regulations have not been passed into law in all the states, the subject matter covered within does represent the official policy of the Association. The AAFCO Model Bills and Regulations are endorsed by a variety of groups representing the animal food industry including the American Feed Industry Association, National Grain and Feed Association, Pet Food Institute, National Rendering Association and many others. The AAFCO Model Bills and Regulations Committee is tasked with providing timely and sound recommendations to the AAFCO Board of Directors so that fair and just model bills and regulations are maintained and advocated by AAFCO regarding the production, labeling, distribution, and sale of commercial feed and production of noncommercial feed. In addition to the Model Bill and Regulations, AAFCO provides the states with additional efforts to support harmonization such as through publications (e.g. labeling guides, sampling guides), development of standardized laboratory testing methods and proficiency testing guidelines, and the development of education, training, and outreach.

The focus of these different harmonization documents (PCAF Framework, AFRPS, and the work of AAFCO) vary in application; however, collectively they are designed to promote uniformity and consistency among state programs. The AAFCO, through their Model Bill and Regulations and other work, provides uniformed guidance to individual members when establishing their individual jurisdictional laws and regulations. The AFRPS ensures a uniform and consistent approach to the state program among jurisdictions, and the PCAF Framework the foundation and flexibility for effectively implementing the PCAF regulation and for ensuring it is uniformly and consistently applied.

5. Harmonized Approach to Building Future Programs

Although many states have established animal food programs, most states have not updated or modified their programs to build a PCAF program. The PCAF Framework provides a uniform and consistent approach to building a PCAF program, but states are going to need additional resources to ensure a harmonized approach to building a program that can ensure effective implementation of the PCAF regulation.

Many State regulatory agencies currently participate in established collaborations with FDA under contracts, cooperative agreements, or partnerships. The current funding sources provided by FDA have allowed the development of a number of uniform and consistent approaches to certain aspects of state programs, such as inventory development, training programs, and outreach programs. As a result of work done by state programs under their own authority or from current or previous FDA funding, state programs may already have some of
the individual components needed to develop and implement a PCAF program. However, additional resources are needed to fully develop a PCAF program. To ensure a harmonized approach to building a PCAF program, participating agencies will need a funding instrument, such as a grant or cooperative agreement, which addresses three fundamental steps.

The first step is for a state program to conduct an assessment of current demands, capacities, and capabilities to implement the PCAF regulation and the recommendations in this framework and identify any existing gaps. After the gaps are identified, the next step would be for the state program to develop the necessary strategies to address the gaps. This step would include development of strategies to address program functions such as outreach, inspectional and compliance approaches, training, administrative support, and laboratory preparedness. The last step is to implement these strategies. Implementing these strategies would result in a state having a fully developed PCAF program that included industry outreach and education programs, a risk-based inspection program, and mechanisms for continuous improvement. The result of the funding would be state animal food programs that are designed to protect human and animal health by ensuring the safety of the animal food supply. Please see Appendix 1 for suggested activities associated with each of these three steps. The final requirements for FDA funding would be negotiated between FDA and the States when funding is appropriated, a funding announcement is made, and applications accepted.

6. Roles and Responsibilities

As outlined in the PCAF Framework, implementation of the PCAF regulation is a shared responsibility among FDA, state programs, and the organizations dedicated to supporting state programs (NASDA and AAFCO). Each chapter of the PCAF Framework provides recommended roles and responsibilities for state programs, FDA, and NASDA and AAFCO (where appropriate). Without coordination, shared responsibility, and new or additional resources, implementation of the PCAF regulation will not be successful. Responsible entities should build off existing harmonization efforts to create uniformity and consistency while developing the individual elements of a PCAF regulation implementation program as outlined in this Framework.
# NASDA Model Animal Food Safety Implementation Framework

## Chapter 2: Foundation of Law

### Table of Contents

1. Executive Summary................................................................. Error! Bookmark not defined.
2. Background .................................................................................. Error! Bookmark not defined.
3. Purpose / Scope ............................................................................ Error! Bookmark not defined.
4. Roles and Responsibilities............................................................... Error! Bookmark not defined.
5. Regulatory Foundation ................................................................... Error! Bookmark not defined.
6. Fundamental Components of a State Program ................................. Error! Bookmark not defined.
7. Steps to Evaluate the Regulatory Foundation for a State Program.... Error! Bookmark not defined.
8. Other Considerations...................................................................... Error! Bookmark not defined.
1. Executive Summary

This document is an internal deliberative document not intended to provide legal advice. This document provides background materials and information for the purpose of facilitating conversation between states and their legal counsel about establishing a program.

This chapter provides a toolset for a state’s analysis of the legal authority and considerations necessary for implementing or amending a regulatory framework for a state program, including the PCAF Regulation, as promulgated by the FDA.

Each state has a variety of mechanisms available to adopt, develop, or amend a state program. If a state intends to implement or align an existing program with a federal regulation, each state must develop an individual solution (statutory and regulatory) that incorporates the scope of program activities (e.g., outreach and education, registration and/or licensing, inspection, compliance, and enforcement, etc.).

2. Background

State programs have historically been involved in animal food safety regulation, including programs with oversight of pet food, medicated feed, and bovine spongiform encephalopathy (BSE) regulations. These programs typically reside in state departments of agriculture, although some reside in university systems, departments of health, or in a combination of those agencies. Currently over 75% of state programs are involved in the federal BSE and Medicated Feed Contract Inspection Program. The current number of state programs enrolled in the Animal Feed Regulatory Program Standards (AFRPS) Cooperative Agreement is available on FDA’s website.³ If states seek to align existing or implement a new program to align with the PCAF regulation, each state will need to determine how to do so in the context of their existing state authority and agency responsibility.

3. Purpose / Scope

The Foundation of Law chapter addresses the legal and regulatory components that must be in place for a state animal food program to implement, administer, or align an program with the PCAF regulation published in September 2015 (21 CFR part 507). This chapter references other pertinent chapters of the PCAF Framework, developed through NASDA. This chapter should be considered as part of a compendium of resources for states to use in implementing a program aligned with the final PCAF regulation.

³ Current number of states involved in the feed standards is at:
https://www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/regulatoryprgmstnds/ucm475063.htm#AF2
4. Roles and Responsibilities

State Agency Responsibilities

Regarding existing programs, States fit into several categories:

- States with animal food control programs
  - Administered by the state department of agriculture
  - Administered by the state university or health agency
- States with existing human food safety authority for manufactured foods, where animal food is considered within the mandate of human food.
  - Administered by the state department of agriculture
  - Administered by the state department of health or other similar agency
- States considering future authorities and institutional relationships
- States not yet considering future authorities and institutional relationships

Depending upon the existing statutory and regulatory animal food safety authority, different analysis and action steps may be necessary. Some states may choose to expand existing programs; others may consolidate programs; some may create unique programs; and some may forgo changing authorities at this time. While the emphasis of this document is to assist states considering modifying or aligning an existing state program, states should consider creating authorities to address all programs impacted by FSMA, including the four foundation animal food regulations and FSMA regulations specific to human food\(^4\), instead of a piecemeal approach.

States are responsible for analyzing their existing state legal authority and determining the structure under which a program, aligned with the PCAF regulation, can be modified or developed. In this process, the states will benefit from an evaluation of the foundation of law and regulations in their state to verify that the state program is aligned with the authority in its existing state law and any regulations. States should also look to the AAFCO Model Bill and Regulations to modify and update existing state laws. The AAFCO Model Bill and Regulations provide a standard to help promote uniformity among states and include model harmonization language for states to adopt the PCAF Regulation by reference. Refer to 7.3 in this chapter for more detail on the AAFCO Model Bill and Regulations harmonization language. In this regard, states should compare their basic state animal food safety authority to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or other state food safety authority to determine whether basic animal food safety authority is present, such as adulteration. In addition, some states with existing programs may benefit from a review of the voluntary AFRPS, Voluntary National Retail Food Regulatory Program Standards; Manufactured Food (for human consumption) Regulatory Program Standards for guidance. If additional legal authority is needed, the state is

\(^4\) The FSMA regulations that have been published and are specific to human food are the Preventive Controls for Human Food regulation (21 CFR part 117), Produce Safety Rule (21 CFR part 112), and the Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR part 121).
responsible for drafting appropriate statutory and/or regulatory language for a program which is aligned to the PCAF Regulation.

Congress made substantial changes to existing federal food safety authority when FSMA passed, and the act was signed into law. Food safety is in everyone’s best interest. Animal food safety is an important component of this authority and protects both human and animal health. As state legislative changes seek to bring state laws into alignment with federal law, adequate resources to implement the federal law will be necessary. If a state chooses not to participate, primary enforcement authority will remain with FDA in that state. See the Financial Support Chapter for more information on the need for adequate funding to implement a state program.

FDA Responsibilities
In addition to federal rulemaking to establish science-based standards for the safe manufacturing, processing, packing, and holding of animal food, FDA is responsible for setting national policies related to animal food safety, including publication of guidance documents. FDA develops national policy in close consultation with state regulatory partners and other interested stakeholders. FDA also develops and delivers training curriculum for federal and state personnel implementing this regulation under FDA authority. FDA will need to provide follow-up auditing of inspection programs and inspection staff as applicable and appropriate. FDA is responsible for providing scientific support through the availability of subject matter experts and laboratory expertise and support (e.g., accreditation and methodology).

FDA has indicated that in shaping the operational strategy for gaining industry compliance with the PCAF regulation, they will collaborate with state animal food regulatory partners to develop broader surveillance capacity through inspectional, sampling, and data collection activities.

In addition, it is desired that FDA should work with NASDA, AAFCO, other partners as needed, and the states to develop a series of model authorities and regulations to ensure the state programs have a process for determining substantial comparability and alignment with the PCAF regulation.

Other Responsibilities
NASDA and their cooperative agreement partners will coordinate with the states and be active facilitators of information and resources to assist states in adopting and maintaining necessary legal authority.

Organizations such as the National Conference on State Legislatures (NCSL), the Council of State Government (CSG) and/or the National Agricultural Law Center can assist AAFCO, FDA, NASDA, and the states in monitoring the progress of state legislation across the nation related to the PCAF Regulation implementation.
5. **Regulatory Foundation**

The final PCAF regulation and the authorities in FSMA represent the regulatory foundation for a state program. The adoption of FSMA statutory and regulatory provisions or the promulgation of comparable state statutory and regulatory authority should complement any existing animal food safety regulatory authority, held by the state agency or state university.

6. **Fundamental Components of a State Program**

States that do not already have animal food safety regulatory authority within the agency (i.e., animal feed program authority) and plan to implement the PCAF regulation must ensure that four primary components are present. The four crucial components include: statutory authority; ability to adopt regulations to implement the PCAF regulation; appropriate inspectional and enforcement authority, and mechanisms for adjudicative functions.

7. **Steps to Evaluate the Regulatory Foundation for a State Program**

The first decision is whether a state desires to implement a new, or align an existing program that incorporates the PCAF regulation in its entirety or in part.

Each state should carefully review the existing statutory authority and current regulations to identify changes necessary to implement or align their program to include the PCAF regulation. The analysis should include additional considerations of data collection privacy, inspection and enforcement, as well as related food safety programs for medicated feeds and human food by-products and other facets to ensure compliance. These fundamental areas are discussed in the following sections.

7.1 **State Decision to Align or Implement a PCAF Program**

Each state should carefully review the statutory changes FSMA has created including the new authority in the PCAF regulation to determine whether the state will fully implement or align with the PCAF regulation, or to forgo establishing or aligning a program under state authority.

Established state programs may wish to align their current program with the new PCAF regulation. Many states have established programs with regulatory authority that is aligned with federal requirements for adulteration, medicated feed CGMPs, Veterinary Feed Directives (VFDs), BSE requirements, animal food approved food additives, generally recognized as safe (GRAS) ingredients, and/or ingredient definitions, as well as other state food safety requirements (e.g., elements of the AAFCO model bill).

In the absence of independent state authority, a state could implement a program under FDA commissioning or credentialing authority. By operating a program through federal commissioning and credentialing, the state would most likely only be able to use existing staff and resources. Operating a program under commissioning and credentialing may not provide
the same benefit as a state’s own legally authorized program. Under programs authorized by commissioning and credentialing, FDA takes a more active role in inspection schedules and priorities, rather than the state agency, and enforcement and compliance decisions are made by the FDA rather than the state.

Some states may consider the option of performing PCAF inspectional activities under FDA authority, as seeking state authority, drafting rules, and aligning a program may take more time than is available between the publishing of the PCAF regulation and the implementation dates for enforcement of the PCAF regulation. Commissioning and credentialing may be an interim solution or a longer-term solution, depending upon timing and interest at the state level.

**Authority to Adopt Federal Code and Regulations**
Regardless of the adoption method, each state seeking to implement the PCAF regulation will need to develop their regulation based on the state’s Administrative Procedures Act (APA). Each state has its own APA that establishes procedure and requirements for regulations and regulatory activities. Some states allow adoption of federal regulations by reference while others require specific language for adoption. Some states permit automatic adoption of critical rule changes while other states require specific consideration of each change. Each state should carefully review their ability to adopt the PCAF regulation to ensure there is a mechanism to keep the regulation current with federal changes.

Some states may choose to amend their existing state authority to incorporate FSMA as it amends the FD&C Act, or pass that aligns state law with the PCAF regulation and other related FSMA regulations of the FD&C Act. Finally, others may enter into a cooperative agreement with FDA and subsequently promulgate state rules aligned with the PCAF regulation.

**7.2 Determination of Needed Agency Authorities in State Law**
Traditionally, the state legislature must grant an agency the appropriate authority to establish a regulatory program. Authority in some states may be extremely broad and applicable to all animal food produced in the state. Other state legislatures might provide specific and limited authority to an agency, or divide authority between agencies. If a state has broad statutory authority, this may be sufficient to allow a state to develop or align a program without obtaining additional statutory authority.

AAFCO developed draft model bill language to assist states in harmonizing existing state statutory and regulatory frameworks to include applicable elements of the PCAF regulation authorities as they relate to animal food safety.

Furthermore, several state programs are currently enrolled in the AFRPS cooperative agreement. The AFRPS Standard 1 – Regulatory Foundation, directs the state program to
conduct an evaluation of the scope of their legal authority and determine whether they have a regulatory foundation that is adequate to protect human and animal health by ensuring the safety and security of animal food. As a result, some state programs may have already made a determination about the status of needed authorities in their state law. Some states may need to consider whether they need to conduct a reevaluation based on the date of their last evaluation.

Review of Basic Animal Food Safety Authority
Many states currently have basic broad animal food safety laws incorporating authorities similar to or identical to the FD&C Act. States should carefully review the basic provisions such as authority to take regulatory action on animal food adulteration.

Review for Animal Food Safety Authority
Since many states already have a program, most states have the legal authority to enter the animal food facility, gather evidence, collect and analyze samples and take enforcement actions for violations comparable to federal authority and regulations. Many states also have authorities to hold or detain adulterated animal food through a withdrawal from distribution, stop-sale, or seizure process. The state may wish to review the FSMA provisions and consider alignment of new food safety authorities established under the FD&C Act, including the copying of records, mandatory recall authority, and inspection fees.

States without an existing program will need to consider how to implement these basic inspectional and enforcement authorities within their jurisdiction.

States will also need to consider how they will incorporate all components of the CGMP and hazard analysis and risk-based preventive controls requirements in the PCAF regulation into their statute or regulatory authority.

Authority to Enter into Agreements
States should review their legal authority to enter into agreements with other state agencies, non-governmental organizations (e.g. laboratories, universities) and the federal government, such as FDA. If intrastate Memorandums of Understanding (MOUs) are utilized, their underlying authority and language should be affirmed by their legal divisions to ensure that they are not only appropriate, but authorized by state statutes. State agencies should work to enact, through State Legislatures, additional needed legal authorities as identified.

Review Protection of Information Authority
Each state should carefully examine existing authorities regarding what information can be protected as confidential. Many states have adequate statutory authority to protect proprietary
practices and confidential business information. The animal food facilities regulated under the state program may claim information should be protected from disclosure.

Many states may already collect information under a program that is subject to public accessibility, Freedom of Information Laws (FOIL), Freedom of Information Acts (FOIA), or state Sunshine Laws, which create concerns about privacy and protection of confidential business information. Inconsistencies between federal and state protections of confidential information could result in regulatory partners not being able to share information, hindering the ability to protect animal and human health.

State agencies may exchange non-public animal food information with FDA by entering into a Single Signature 20.88 Long-Term Food Information Sharing Agreement (ISA). The ISA allows for the head of the state agency to affirm that the non-public information provided by FDA will not be disclosed with anyone outside of their agency without written confirmation from FDA and that such information can be released to the public. Under this confidentiality agreement, the state agency is committing to protect the non-public information that FDA shares with individuals in that agency. This may include information for which public disclosure is prohibited by law, and information compiled for enforcement purposes. Any request to share this information outside of the state agency must be approved in advance by FDA. A database of state and local agencies that have entered into an ISA is on FDA’s website.5

Authority to Adopt Federal Statutory Requirements
States differ widely on the authority to adopt federal statutory language into law. Each state should examine legal authorities and determine what options it has to expand or exercise jurisdiction and become involved in activities related to the PCAF regulation. For example, the state must consider whether it is in the best interest of the state to adopt the FSMA regulations in its entirety, only adopt the PCAF regulation in its entirety or seek limited PCAF regulation authority to implement a program.

7.3 Adoption of Appropriate State Regulations

Adoption of the US Code and the Code of Federal Regulations by Reference
Many state agencies have adopted parts of 21 CFR that relate to animal food safety. Some states are able to adopt CFR provisions by reference, while other states have to adopt the language word for word. Some states are able to adopt the CFR in a manner that automatically includes provisions that are adopted at a future date, while other states must adopt the CFR as

5 Database of agencies with 20.88 Single Signature Agreements
http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=singlesignaturefood&displayAll=true
it exists on a certain date and must make updates when additional provisions are added at a later date. It will be important to verify which CFR provision and the date of the last update of the code for the purposes of determining authority under the PCAF regulation. The failure to have proper legal foundation, and maintain updates as the regulation is updated or changed over time, presents significant risk of fragmented state animal food safety requirements.

The authority to adopt regulations in state statutory language may impact the ability to tailor jurisdiction and regulations to the state’s priorities. While some may consider only adopting certain provisions of the PCAF regulation; however, partial adoption could increase the complexity of the state program and could cause confusion in the regulated community. For example, a state that adopts only the CGMP requirements in Subpart B of the PCAF regulation would not encompass the definitions, training requirements and recordkeeping requirements outlined in the associated subparts.

The AAFCO Model Commercial Feed Bill and Regulations also provide state programs a regulatory guidance when establishing its jurisdictional laws and regulations. In 2017, AAFCO approved harmonization language for states to use if a state program is interested in adopting the PCAF Regulation by reference in the state’s feed law or regulation. The language is:

**AAFCO Model Commercial Feed Bill**  
**Section 10 (c) Food and drug rules.** Federal regulations contained in Title 21, Code of Federal Regulations, part 507, not otherwise adopted herein, also are adopted as feed rules of this state.

**AAFCO Model Regulation 11 Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls**  
(b) Pursuant to Section 10 of the Act, the________ adopts the requirements of Title 21, Code of Federal Regulations, part 507.

Due to the above changes to adopt the PCAF regulation by reference, the AAFCO Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients and associated checklist in the AAFCO OP were deleted and replaced with an html reference link and a citation to the CGMP’s Title 21, Code of Federal Regulations, 507.14-507.28, which are the CGMP requirements found in subpart B.

The intent of the AAFCO approved harmonization language is to offer a method that facilitates alignment of state authority with PCAF regulation requirements. Model language will help ensure consistent state authority.

**Methods of Regulation Adoption**  
Since rule adoption is an integral part of developing a regulatory program, each state should carefully plan for an adoption schedule that will permit continuing alignment to the
requirements of the PCAF regulation. Each state should consider the usual time required for rule adoption under their state’s administrative procedures and requirements and should factor in adequate time to appropriately implement the program or to seek separate means of implementation.

7.4 Determine the State Agency Responsible
State programs are authorized and administered by state departments of agriculture, state universities, departments of health, or a combination of those agencies. In most instances, these state programs will assume responsibility for aligning their existing program with the PCAF Regulation.

For agencies that have not had animal food safety authority in the past, but now seek authority to develop a state program, the state program seeking authority must determine responsibility for the major components of the program as a function of the current and potential roles of the appropriate state agencies.

In states where jurisdiction is split between agencies for certain functions or where the primary food safety agency does not anticipate implementing a program, an MOU may be the appropriate mechanism to transfer specific and limited authority or responsibility to another agency. Some states authorize a MOU, Memorandum of Agreement, or some other contractual agreement.

States should also consider what agency or program area will assume responsibility for human food by-products for use as animal food. By-products of human food production are a common source of ingredients in animal food diets. The PCAF regulation contains streamlined provisions for human food by-products for use as animal food (See 21 CFR 507.1(d) and 507.12). States should also consider how their human food and animal food programs will share oversight at facilities that produce both human food and human food by-products for use as animal food. Refer to Appendix 2, Human Food By-Products for Use as Animal Food, for more information.

7.5 Develop a Timeline
Establish and execute a plan and timeline to develop a state program.
A state plan should consider the amount of time needed to obtain authority, adopt the PCAF regulation, ensure preparation for inspectional, enforcement and laboratory activities (e.g., training, and updating inspectional and enforcement tools), and ensure an adjudication procedure is in place. The plan should consider legal, legislative, environmental, and political situations such as the timing of state legislative sessions. Although 46 state legislatures meet annually, four legislatures (Montana, Nevada, North Dakota and Texas) only hold sessions every other year.
8. Other Considerations

Identifying Regulated Businesses
Many state programs have a preexisting registration or licensing system in place for identifying animal food manufacturing or distribution activities within their state. However, these systems may not be able to identify animal food business information that is relevant for determining applicability, exemptions, and business size under the PCAF Regulation.

The PCAF regulation applies to facilities that are required to register under Section 415 of the FD&C Act because they manufacture, process, pack, or hold animal food for consumption in the United States. Establishments that are exempt from registration are exempt from the PCAF regulation. The food facility registration exemptions can be found in 21 CFR 1.226, with associated definitions in 21 CFR 1.227. Furthermore, the PCAF Regulation has additional exemptions identified in 21 CFR 507.5.

The state program should review its feed license list as well as businesses that were previously exempt from state feed licensing or registration to determine if those businesses now qualify and need to register with FDA as a food facility under section 415 of the FD&C Act and comply with the PCAF regulation. Previously exempt businesses that may now qualify include farms that distribute animal food, including ingredients, to other animal producers and businesses, warehouses, manufacturers, and distributors.

States should consider the current establishments and business information captured by their state animal food registration or licensing system and compare that to the information that will be necessary to identify whether and how the PCAF regulation applies to the establishment.

Qualified Facilities
Within FSMA statutory language and the PCAF regulation, some facilities will be considered qualified facilities. Instead of developing a food safety plan, these facilities will be required to submit an attestation to FDA. To meet the attestation requirement, facilities have the option of stating that they are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. This attestation may be based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

State regulatory partners should consider what documentation from their food safety program would represent compliance with State food safety laws and regulations. State regulatory partners may wish to provide education to qualified facilities about state documentation that may be appropriate for use in an attestation.
NASDA Model Animal Food Safety Implementation Framework  
Chapter 3: Infrastructure and Financial Resources  

Table of Contents  

1. Executive Summary ........................................................................................................... 34  
2. Background ....................................................................................................................... 34  
3. Purpose ............................................................................................................................. 35  
4. Scope of New Funding to Support Development of State PCAF Program .................. 35  
5. Infrastructure Needs: ........................................................................................................ 36  
6. Roles and Responsibilities ............................................................................................... 40  
7. Resources ......................................................................................................................... 40
1. Executive Summary
This chapter defines and examines the needs for a resource and infrastructure assessment before a state program implements the PCAF regulation. Taking into account the various types and sizes of state programs throughout the US, this chapter is an overview of how an agency would strategize its program to implement the PCAF regulation so the state can develop and implement a program to best fit their needs. This chapter also discusses additional financial support that will be required for states to develop a PCAF program. When applicable, the chapter references topics that have been discussed in other chapters (for example, Chapter 2: Foundation of Law). By the end of the chapter, the state program should have a clear understanding of the aspects of an infrastructure assessment and resources needed to enhance their program, as well as the financial expectations to meet these needs.

2. Background
NASDA and AAFCO have estimated that the initial overall cost of funding required for states to develop and/or implement a national animal food safety program to be a minimum of $20 million annually. Determining infrastructure and programmatic needs in states is intrinsically linked to obtaining the resources and funding necessary to develop and implement programs capable of inspecting and enforcing the PCAF regulation. State agencies should be cognizant of the potential for increased facility, equipment and administration costs associated with implementing new programs. Consistency among state agencies engaged in animal food safety outreach/education or inspection programs will enhance the national goal of increasing human and animal health protection. Accurate assessments of infrastructure coupled with systematic growth in state programs will contribute to the consistency and uniformity needed to successfully implement the PCAF regulation.

State regulatory programs will require both short-term and long-term financial support to successfully develop, and/or implement a sustainable, comprehensive PCAF program. A comprehensive program will address the recommendations in the PCAF Framework and includes components such as outreach, education, inspection, compliance, and enforcement. While each state will elect to implement their programs in slightly different fashions – consistent with their state procedures – the goal must be uniform and consistent programs allowing safe animal food to be distributed across the nation.

Any State agency that partners with FDA to implement the PCAF regulation at the State level will require resources to establish the foundational training, outreach and education, inspection, compliance, enforcement, laboratory, and administrative programs necessary to implement the PCAF regulation.

In recognition of the resources needed to sustain a program with the capacity and capability of educating, facilitating, and determining compliance with the PCAF regulation, multi-year funding using a grant, cooperative agreement or similarly designed flexible funding vehicle
should be utilized to provide financial support to build the necessary infrastructure and capacity.

Current financial vehicles such as the FDA animal food safety inspection contracts alone will not suffice to provide the funding necessary to build infrastructure, capacity and capability to establish a FSMA animal food safety program.

3. Purpose
This infrastructure assessment is an evaluation conducted by the state program to identify any possible gaps in core program areas that need development or improvement to successfully implement the PCAF regulation. For any area or function of the core program in which a gap is identified, costs need to be estimated and an improvement plan should be put in place and reviewed/updated on an annual basis.

The goal of the proposed funding model is to establish a flexible means to determine adequate funding for state programs that is proportional to program needs and to the volume of regulated industry. The funding will be used to develop and/or expand infrastructure, capacity and capability to conduct outreach, training, education, inspections, compliance and enforcement on animal food manufacturing facilities subject to the PCAF regulation.

4. Scope of New Funding to Support Development of State PCAF Program
In addition to existing state program funding, many State regulatory agencies currently participate in established collaborations with FDA under contracts, cooperative agreements, or partnerships, (e.g., animal food safety inspection contracts, Animal Feed Regulatory Program Standards, FDA Food and Egg Contracts and the Cooperative Agreement Program for Produce Safety).

Current FDA contracting practices result in a participating State agency receiving a fixed-price reimbursement for inspection or sampling/analytical activities based on a yearly negotiated unit cost. The contract model is not the ideal financial vehicle required for states because a fixed-price reimbursement for inspections does not allow states to develop the infrastructure, capacity and capability necessary to institute animal food safety programs in support of the FSMA regulations.

FSMA animal food safety program funding should be based on programmatic needs, multi-year to allow for appropriate growth, and providing continued funding adequate to support the long-term sustainability of State animal food programs. Funding will vary from state to state. In the short term, FDA and States will need to agree on what step of development (see chapter 1) the state is currently operating to assess the resources needed to progress as well as the size and complexity of facilities to be inspected, including an assessment of outreach and education needs. Long term, sufficient funding to maintain infrastructure needs for all states is necessary
with consideration for additional funding prioritized to meeting regulatory needs such as inspectional frequency of states with inventories that are large, complex, and high-risk. Individual funding instruments (grants, cooperative agreements) should offer no less than 5 years of funding to enable efficient and effective long-term planning for States and FDA.

Addressing the broader scope of animal food safety programs, State agencies should be offered a flexible, comprehensive funding model with which they can customize their funding to meet short and long term programmatic needs, and receive funding on a timetable that mirrors their plans for developing comprehensive programs. The added measures of flexibility created by using a flexible, comprehensive model will allow states to customize funding which will, in turn, result in more effective utilization of FSMA appropriations.

If, for example, historical programs (e.g. Medicated Feed Program, BSE, or tissue residue) are to continue rather than being folded into new funding categories, the funding model must be able to accommodate that. Also, if additional programs are added (e.g. veterinary feed directive or other FSMA regulations), additional flexibility to incorporate new program dimensions into a new funding matrix/rubric should be anticipated.

State programs that elect to participate and are selected to receive funding to continue historical or additional programs and add PCAF work should have the option to receive additional funding specifically for: industry outreach and education; regulator training; and inspectional activities including provisions for analytical support as necessary.

5. Infrastructure Needs:

5.1 Staffing: Determine the number of staff needed, which could include both full time and part time employees (AFRPS Standard 8) needed to accomplish program goals based on volume of inspections, funding constraints, and anticipated demands (time and effort). AFRPS Standard 8 provides a model a state program can use to calculate their staff needs. The determination should include the staff needed in the following areas:

a. Inspections and investigations (including re-inspections and surveillance activities)
b. Sampling activities (including sampling conducted by the state program) (see Chapter 4, Outreach/Education and Chapter 5, Inspection Program Planning);
c. Auditing (e.g., financial, inspection, metrics)
d. Outreach
e. Compliance and enforcement.

Please refer to the discussions in Chapter 5: Outreach/Education and Chapter 6: Inspection Program Planning for a detailed discussion on these program areas.
5.2 Technology Systems or Solutions: To meet the long-term needs of a state’s technology system requirements, the technology systems or solutions utilized must be able to address the state’s current needs as well as have the capability to interface with the systems or solutions of other programs and agencies. States also require a technology system that can expand to encompass future projects and workloads in all program areas that a particular state agency regulates. This system would not only function with a state program and FDA contract work, but may also function with other program areas such as seed, fertilizer, and pesticide. A system may also need to interface with other federal programs such as USDA and EPA. The information and data housed in these systems could be shared with partnering agencies in numerous ways, thus it is essential that the technology capture timely and accurate data, provide a mechanism by which to share, and contain security measures that ensure information integrity and privacy. The state’s technology system should be capable of capturing, reporting, and retaining the following data:

a. Facility inventory control
b. Inspection and investigation assignment
c. Compliance and enforcement activities
d. Sample data including capturing, reporting, and retaining sample collection data; sample control data; and sample analysis data.
e. Employee training

5.3 Technology Equipment: The technology equipment needs to be compatible with the technology system or solution a state program uses. The technology system/solution cannot function properly without the appropriate equipment. Technology changes fast and a program must be able to adapt. When assessing technology equipment needs, the state program should recognize that both the functional and physical lifespan of most electronics is 3 to 4 years. While the Technology System or Solution mentioned above in section 4.b will provide capable resources for data collection, the technology system or solution is not a replacement for the standard operating systems necessary for most technology equipment and is typically not included in the basic equipment price. The review of the technology equipment needs for the state program to implement the PCAF regulation should consider the potential for the following types of equipment:

a. Laptops
b. Tablets
c. Data security measures
d. Physical security measures to protect hardware or data
e. Data storage capabilities (e.g., short and long term data storage)
f. Wi-Fi or Wireless capabilities for on-site functions.
g. Wi-Fi enabled Smart Phone
5.4 Training and Educational Resources: The training and educational needs evaluation should begin by looking at the functions your staff is currently trained to do, and how you can utilize them to accomplish immediate goals first. Required training needed for staff to satisfy the program and inspection goals should be a high priority. In the long term, continuing education needs should be looked at for staff to stay current on changes in regulations and industry practices. State staff responsible for conducting inspections and investigations for compliance with the PCAF regulation should have completed training consistent with that provided in:
   a. FDA Regulator CGMP and Preventive Controls Training
   b. Food Safety Preventive Controls Alliance Course- PCAF Course (or other preventive controls qualified individual training)

5.5 Inspection Equipment, Materials, and Supplies: Prior to the start of inspections for compliance with the PCAF regulation, an evaluation of the equipment, materials, and supplies needed to conduct inspections should be made. The implementation of the PCAF regulation, and the possible increase of inspection staff needed to accomplish program goals, may require the purchase of additional equipment and supplies to make sure staff is adequately equipped to carry out inspection goals. Implementation of the PCAF regulation does not require new types of inspection equipment. However, the addition of inspection personnel will require an increased inventory of the necessary equipment, material, and supplies. AFRPS appendix 8.3 provides a general list of equipment, materials, and supplies that should be available for state program staff that conduct inspections and sample collections. Necessary equipment used by field inspectors, listed below, falls into three general categories and individual items within these categories and should be included in the infrastructure assessment:
   a. Vehicles
   b. Sampling equipment (probes, bags, forms, etc.)
   c. Personal protective equipment

5.6 Laboratory support (internal or via contract): A state program should have access to laboratory support to complement their inspectional and compliance activities related to the PCAF regulation. Laboratory support could come from a laboratory located within the state program or could be a contract laboratory. The infrastructure assessment of laboratory support should include:
   a. Adequate facilities (space, utilities, meets safety and security needs, etc.)
   b. Adequate personnel and training (sufficient full time equivalent employees (FTEs) with desired competencies)
   c. Equipment and instrumentation acquisition and maintenance
d. Quality management system that meets programmatic requirements (e.g., ISO 17025 accreditation)
e. Laboratory Information Management System compatible with needs

*Please refer to the discussions in Chapter 7: Laboratory Support for a detailed discussion on laboratory infrastructure.*

5.7 Facilities: During the self-evaluation, the state program may need to consider whether additional facility space is needed. The expansion of the program’s responsibilities into the PCAF regulation may require additional space to accommodate any increases in staffing and laboratory activities. The infrastructure assessment’s evaluation of facilities should consider:

a. Potential for expansion (through purchase or lease) of existing structures or building facilities. Types of facilities to consider:
   i. Administrative
   ii. Field
   iii. Laboratory facilities; and

b. Classroom facilities for:
   i. Training regulatory staff
   ii. Educating or conducting outreach to the regulated industry.

5.8 Program Support: The implementation of the PCAF regulation may require additional or new types of administrative support. Program support will be needed to sustain the PCAF requirements of a program long term. The infrastructure assessment of program support should include:

a. Human Resources: Implementation of the PCAF regulation will add additional daily requirements to both your inspection and administrative staffs. The changes in inspection priorities, reporting requirements, and technology skills may demand a change in job descriptions and capabilities, thus requiring a higher salaried position.

b. Information Technology: Increased devices and capabilities coupled with newer complex solutions will require IT support that is available, knowledgeable, and dedicated to your systems.

c. Legal Support: Legal and regulatory components must be in place to implement, administer, or align a state program with the PCAF Regulation. A state program’s evaluation should consider the legal support resources needed to obtain the necessary inspection and enforcement authorities, and the need for legal support needed during implementation, such as resources needed to review compliance and enforcement cases.
6. Roles and Responsibilities

State Agency

The state agency conducts periodic and annual resource and infrastructure assessments to evaluate current and anticipated needs for implementing the PCAF regulation into their state program. The state agency then develops a strategic implementation assessment plan to address any identified gaps.

The State program should develop and maintain the infrastructure, capacity and capability to initiate and maintain a FSMA animal food safety program in accordance with the requirements of any funding obligation. The participating state agency should, as appropriate, coordinate and share information relative to animal food safety program activities such as outreach, education, training, and inspections with both federal and state partners.

Federal

FDA will provide assistance in the form of guidance documents and other technical sources of information to state agencies. The guidance and technical information should be used by the state agency to assess the impact of the PCAF regulation on the infrastructure and programmatic needs of the state program.

FDA recognizes that funding will be needed to support state programs developing a PCAF program. It will be necessary for FDA to evaluate funding for State PCAF programs consistent with the flexible model as outlined in this document or similar models that provide the same degree of flexibility to accommodate program objectives, degree of participation, size of industry, and expectations founded on risk-based assessments. FSMA mandates that FDA should provide support, guidance and oversight of funding and ongoing project accomplishments as appropriate. FDA’s standard practice is to share information with their state partners regarding the funding process (to the extent permissible by law, particularly during periods of open competition), during and throughout the duration of the project.

Associations

Associations, such as NASDA, AAFCO and others as appropriate, will facilitate the exchange of information to assist State programs in obtaining financial support, and provide assistance as appropriate during and throughout FSMA implementation.

The animal food industry, academia, and national associations representing animal food (e.g. AAFCO and NASDA) should serve as a resource to inform a state agency’s infrastructure assessment (e.g. new manufacturing technology, preventive controls, validation studies, and analytical needs).

7. Resources

Estimated feed establishments (from FDA website: https://www.accessdata.fda.gov/scripts/BSEInspect/view/bse_help.cfm) with possible funding
categories to build a financial model. The funding opportunities are likely similar each year, with differing amounts being available/needed depending upon the year within the implementation (e.g., the proposed 5 year plan).

FDA Animal & Veterinary Website
Food Safety Modernization Act (FSMA) website
Animal Feed Regulatory Program Standards (AFRPS)
NC State University Feed Science Program and Feed Mill Education Unit
NASDA Model Animal Food Safety Implementation Framework

Chapter 4: Regulator Training

Table of Contents

1. Executive Summary..............................................................................................................43
2. Scope/Purpose......................................................................................................................43
3. Background ..........................................................................................................................43
4. Roles and Responsibilities.....................................................................................................48
5. Related Documents and Resources .....................................................................................51
1. Executive Summary
This chapter outlines the need for state programs to develop a comprehensive training program for the implementation of the PCAF regulation. This chapter recognizes that many state programs have a history of training animal food regulators, especially inspection staff. State programs should have a training program for inspection staff that ensures consistency and uniformity across inspections. As state programs evaluate their current training program, or seek to develop a training program, they should consider how the training program will be developed or updated to include training for staff conducting inspections under the PCAF regulation.

2. Scope/Purpose
A competency-based training regimen for state program professionals is strategically important to the success of a state program. Training is a necessary component of any program, and states have training programs in place to ensure appropriate training of their program staff. States and FDA have worked collaboratively to educate and train animal food regulatory professionals to ensure we have a trained workforce to ensure compliance with animal food regulations, which is necessary to protect animal and human health.

This chapter outlines many of the currently available training programs and opportunities for collaboration on training development. The purpose of this chapter is to create a baseline to assess resource needs and plan training activities. This training is necessary to achieve consistency in inspectional approach and regulatory strategies that can be implemented by state animal food inspectors conducting PCAF inspections. While training may be needed in various positions within a state program, this chapter focuses on a training program for inspection staff.

3. Background
Training for animal food regulators has been well established due to the long history of regulation of animal food at both state and federal levels. Many state programs have developed their own training plans to train their regulatory staff. Some state programs leverage the training programs that FDA has created to train animal food regulators. Prior to performing PCAF inspections, inspectors will need to have specialized training to ensure comprehension of the new regulation and consistency in inspectional approach. There are several training initiatives that have been developed, or are being developed, to provide a state program with a foundation to develop, or enhance, its inspection training program for inspectors.

Current Training Initiatives
While many of the needs for PCAF regulation training are new, a number of training initiatives already underway can be leveraged in a state’s training program, such as:
AAFCO

Association of American Feed Control Officials’ (AAFCO) involvement with both the Basic Inspector Training Seminar (BITS) and Advanced Inspector Training Seminar (AITS) helps create a consistent training environment for the successful implementation of regulatory consistency of state animal food inspectors.

BITS supplies both the new and experienced inspector with essential proficiencies in safety, product sampling, label auditing, inspection of facility’s manufacturing product, biosecurity procedures and professional skills the inspector will use during review of regulatory compliance with the seed, feed, and fertilizer retailers and manufacturers in their state. This training is collaboration between three associations: AAFCO, the Association of American Plant Food Control Officials (AAPFCO) and the Association of American Seed Control Officials (AASCO). Included with BITS, inspector manuals are handed out by all three associations. The AAFCO Feed Inspector’s Manual can be found on the AAFCO website under publications.

AITS is focused training in animal food investigative techniques, animal nutrition, animal drug calculations, intense label auditing, and emergency response with dialogue on the current regulatory concerns and actual situations. The demonstrated knowledge attained will complement the experienced state feed control official’s abilities to perform state feed regulatory work.

National Curriculum Standards and the Partnership for Food Protection

States are actively engaged in many capacities in the FDA’s initiative to create the National Curriculum Standards (NCS). States currently participate in the NCS development through the Partnership for Food Protection (PFP) Training and Certification Work Group. The PFP is a cooperation between Federal, State, Local, and Territorial Officials. Some state personnel are members of the PFP’s Training and Certification Workgroup which is helping to direct the NCS process. The overall approach of the NCS is to create comprehensive, coordinated training to address regulatory implementation needs. A clear training pathway will be in place for state and federal personnel. Training efficiencies will be built-in including online and blended learning activities along with instructor-led skills courses. While, participation in face-to-face courses may require funding for travel, on-line courses will also be available to minimize travel costs.

http://www.aafco.org
The NCS can be leveraged, as appropriate, and assist the state in saving training time and cost.

The NCS consists of two primary components: (1) Competency Framework and (2) Curriculum Framework. Taken together, these two frameworks define the performance expectations of the human and animal food regulatory profession.

These two frameworks will help animal feed control officials:

- Ensure consistent performance expectations;
- Identify training gaps and inform training curricula;
- Catalog existing learning events (training, courses, etc.); and
- Create career-spanning professional development learning paths.

The NCS features a competency assessment tool, which can be used to conduct self-assessments, or assessments of others, to determine how individuals measure up against the NCS. Competency gaps identified through these assessments can then be addressed through various learning experiences (e.g., on-the-job training, courses). The NCS also allows training developers to know which competencies need to be addressed in their training materials, and allows developers to submit their course(s) for inclusion on the site.

The Curriculum Framework identifies the training content areas needed by regulatory and laboratory personnel to conduct animal food safety activities. The Curriculum Framework includes core FDA Regulator courses that will be recommended for states to effectively implement an integrated program. Because the NCS is being developed and updated to include FSMA regulations, including the PCAF regulation, the Curriculum Framework addresses the change in the inspection approach especially the knowledge needed for assessing animal food safety plans.

Once the NCS is complete, the product will be available to all regulatory personnel, including both federal and state animal food safety inspectors, with the goal to ensure that inspections are consistent throughout the United States. There is a group working on the NCS dedicated to developing the appropriate content for animal food, and that group’s first priority is the animal food inspector. The NCS has been established and training is under development. Currently, there are 25 courses that will be required for the Entry Level animal food inspector and 11 courses for the Basic Level animal food inspector.

Training material produced by various entities will be reviewed and approved for placement within the NCS Curriculum Framework. The animal food safety training paths and specific courses will be vetted (through a formal course review process) and placed in the curriculum so
that a standardized approach is used. The NCS will assist in consistency and delivery of knowledge regarding animal food safety requirements while at the same time build long-term competency. This will allow state agency decision-makers to identify the most cost-effective animal food safety training options that meet their programmatic needs.

The NCS is also envisioned to eventually contain a credential component. This portion of the NCS is still under development and may take significant time prior to implementation. Getting an inspector credentialed could take a considerable amount of time and effort. Once an inspector is credentialed, there will be a need for continuing education to maintain them.

**AFRPS Standard 2: Training**
The AFRPS Standard 2: Training describes the elements of training for inspectors to ensure they have the knowledge, skills, and abilities to competently inspect animal food facilities, conduct investigations, gather evidence, collect samples, and take enforcement actions. The standard outlines the need for a training plan that ensures inspectors receive training to perform their work assignments and includes curriculum for basic and advanced training (that includes course work and field training) and continuing education upon completion of training. As states develop their training plans, they may incorporate AAFCO’s BITS and AITS courses, college courses, and FDA courses to fulfill coursework requirements of AFRPS Standard 2.

**National Certified Investigator and Inspector Training**
An additional learning resource that can be used to fulfill inspectional needs is the National Certified Investigator and Inspector Training – Basic Program by The Council on Licensure, Enforcement and Regulation (CLEAR). This fee-based training has 10 modules that cover the essential elements of good investigations and inspections for regulatory personnel. This is not required training but has proven to be very beneficial to the inspectors that have attended. The locations of the training move around the country. Cost to attend the course could be reduced if an event was held near or in your state.

**FDA regulator training**
In support of their contracts and cooperative agreements with the states, FDA has created training opportunities for animal food inspectors that include the following courses:

- Grain and feed mill inspections VM101,
- Bovine Spongiform Encephalopathy (BSE) VM213,
- Current good manufacturing practices (CGMP) for medicated feed inspections VM206.

---

7 [https://www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/regulatoryprgmstndss/ucm475063.htm](https://www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/regulatoryprgmstndss/ucm475063.htm)
8 [http://www.clearhq.org](http://www.clearhq.org)
Current and future training will consist of courses offered through AAFCO, on-line training courses through FDA’s Office of Training, Education, and Development (OTED), and in person courses held by FDA’s OTED. Face-to-face training will be offered based on OTED’s Annual Training Needs Survey and program implementation to determine the number of personnel needing to take different animal food courses.

**FSMA Training**

FSMA introduced new mandates for FDA to provide training and support to states. Specifically, Section 209 of FSMA (Section 1012 of the FDC Act or 21 USC 399c) articulates Congress’s expectation for training and support to the States. Section 209 of FSMA spells out FDA’s responsibilities to set standards based on science and develop training to include inspectional approach, regulatory strategies, sampling procedures, best practices, and improve upon the system-based approach to an inspection. The section also provides opportunities like the PCAF Framework that promotes State partnerships and provides for adequate training to successfully inspect the regulated industry under the PCAF regulation.

These FSMA components set the stage for the utilization of state resources in an integrated fashion to accomplish animal food safety and animal and human health goals.

The purpose of a state program’s PCAF training plan is twofold:
- To identify the immediate steps that can be taken to prepare staff at different levels and program functions for implementation of the PCAF regulation, and
- To understand and provide input to the FDA process for developing a long-term National Curriculum and training system for animal food safety regulatory staff that will include animal food safety training.

The state’s training plan should build on current course offerings and examine the development of a training framework that will assist in implementation of the PCAF regulation while strengthening the competencies of state personnel, with the primary focus on inspection staff. Ultimately, the current FDA curriculum development process will incorporate all animal food safety training so priorities that meet foundational, short term goals can be the initial focus for a state program. Training can be phased to align short-, mid-, and long-term needs that support capacity development efforts.

The benefits of using a training framework includes system-wide comparability, uniformity, quality, improved animal and human health, and economic savings through targeted, competency-based animal food safety training across state and federal agencies.
4. Roles and Responsibilities

State Agency Responsibilities

State programs that intend to implement the PCAF regulation must include a training component for their program. State programs without an existing training program should consider developing a plan that incorporates basic animal food inspection knowledge, skills, and activities in addition to the PCAF regulation training needs. State programs with an existing training program should consider how they will implement a training program specific to the PCAF regulation.

In development of a training program for the PCAF regulation, the state program may need to consider both a short term and longer term strategies.

Short term strategies are those that need to be put into place by states to quickly implement training to support the PCAF regulation. Short term strategies can address the needs to convert existing staff from current inspection activities to those necessary to perform inspections of both the CGMP and PC requirements of the PCAF regulation. The short term strategies may also address the need to hire and train new staff with limited animal food experience. During initial implementation, states may choose to stagger training between the CGMP and hazard analysis and risk-based preventive controls (PC) requirements of the PCAF regulation. A system for identifying training needs should be used to determine and prioritize the delivery of training. The activities that should be considered in short term strategies include:

- Ensuring regulatory staff meet a predetermined level of education and/or experience
- Providing recommended, existing training to appropriate staff
- Tracking staff training and managing records
- Identifying and sharing best practices with other states
- Creating mechanisms to measure training effectiveness
- Working collaboratively with stakeholder advisory groups to identify strategic direction and training priorities

Long term strategies are those that are needed to develop a comprehensive training program that considers the overall needs of the state program. The training should address all animal food safety training needs of the program, including those of the PCAF regulation. A comprehensive training plan can leverage materials developed by other entities including AAFCO (e.g. BITS and AITS), NCS, FDA (e.g., courses available through OTED), and CLEAR (e.g., National Certified Investigator and Inspector Training) or by the program if they are implementing AFRPS Standard 2: Training. The long term strategy should consider:

- Coursework and field experience for basic inspectors
- Coursework and field experience for advanced inspectors
- Necessary coursework and field completion prior to conducting inspections, including PCAF inspections
• Continuing education
• Learning management system needs to track completion of training

In development of a training program, a state program should consider whether they will leverage training developed by other entities (e.g., FDA or other state agencies) or will be responsible for the development and delivery of training. If a state program will develop and deliver the training internally, they will need to ensure they have educational experts who are familiar with adult learning concepts, the necessary subject matter expertise to develop the training, and that they have skilled instructors to deliver the training. Resources are available through the International Food Protection Training Institute (IFPTI)\textsuperscript{9} that are focused on adult learning and instructor skill training. If a state program chooses to develop and deliver their own training for the PCAF regulation, there is a need to ensure consistency with the concepts and key messages that are found in FDA training courses to ensure consistent and uniform inspections for compliance with the PCAF regulation.

A sustainable training program is necessary to address the critical role that training plays in building state agency workforce capacity around animal food safety. This training is necessary to achieve consistency in inspectional approach and regulatory strategies that can be implemented by state animal food inspectors conducting animal food safety inspections, including PCAF inspections.

**FDA Responsibilities**

FDA is responsible for developing training for animal food safety regulatory staff responsible for implementing the PCAF regulation at both the state and federal level. To ensure knowledge of the PCAF regulation and uniformity and consistency in inspectional approach, FDA has overseen development or developed three primary courses intended for animal food safety regulatory staff involved with implementation of the PCAF regulation. Consistent with FDA’s desire to build an integrated food safety system, these courses were developed with input from state animal food safety regulatory personnel. These courses include:

- Food Safety Preventive Controls Alliance – PCAF course
- Current Good Manufacturing Practice for Animal Food Regulators (VM102)
- Preventive Controls for Animal Food Regulators (VM220)

**Food Safety Preventive Controls Alliance – PCAF course:** FDA partnered with the Food Safety Preventive Controls Alliance (FSPCA) to develop an FDA recognized curriculum to satisfy the requirements for training to become a preventive controls qualified individual (PCQI). This course is offered through the FSPCA and is not restricted to regulatory personnel. The course is typically offered to include both industry and regulatory personnel in the same course. For

\textsuperscript{9} \url{https://ifpti.org/}
industry, the course is optional as completion of the course is not required and there are other methods to become a PCQI. For regulators, the course is required training for all regulators completing PC inspections under an FDA contract or cooperative agreement. The FSPCA PCAF course is offered as a 2.5 day course or blended learning web and in-person format, covering the principles of a food safety system. When funds have been made available, FDA provided funding for many state personnel to attend the FSPCA training.

**Current Good Manufacturing Practice for Animal Food Regulators (VM102):** FDA has developed a Current Good Manufacturing Practice for Animal Food Regulators Course that provides content required for the regulation of facilities that fall under the CGMP requirements of 21 CFR Part 507 (primarily subpart B, with related requirements in subparts A and F). This course was made available for an initial round of regulators in 2016 and is being offered through OTED’s course catalog each fiscal year. To attend this course, participants must complete the required prerequisites, which are available online. The online prerequisite courses for attending VM102 include Grain and Feed Mill Operations (online in 2017 and before 2017 - face to face) and Regulatory Foundations of CGMPs for Food for Animals (online). The primary audience for this course is inspection staff; however, there may be benefits to other animal food safety staff with FDA and state programs to attend the course. The course is a 3.5 day in person training.

**Preventive Controls for Animal Food Regulators (VM220):** The Preventive Controls for Animal Food Regulators Course (VM220) is under development and should be available in 2018 as well as one online prerequisite course. To attend this course, participants must complete the required prerequisites. The prerequisite courses for attending VM220 include CGMP for Animal Food Regulators course (VM102), Regulatory Foundations of PCs for Food for Animals (online), and FSPCA Preventive Controls for Animal Food (before 2018 – face to face and blended in 2018 - both online and face to face). A list of these courses can be found in OTED’s LMS called Pathlore. The primary audience for this course is inspection staff; however, there may be benefits to other animal food safety staff with FDA and state programs to attend the course. This course is expected to be delivered only as an in person training.

In the future, the two FDA regulator courses (Current Good Manufacturing Practices for Animal Food Regulators – VM102 and the Preventive Controls for Animal Food Regulators – VM220) will be offered regionally by a FDA trained instructor cadre consisting of both state and federal staff that are tasked with training the inventory of Federal, State, Local, Tribal and Territorial animal food regulators. FDA is responsible for, and committed to, developing a PCAF training curriculum that meets the needs of both federal and state animal food safety regulatory personnel. FDA is also responsible for ensuring that the content of the PCAF curriculum is

---

10 [https://orauportal.fda.gov/stc/ora/psciiis.dll?linkid=720650&mainmenu=ORA&top_frame=1](https://orauportal.fda.gov/stc/ora/psciiis.dll?linkid=720650&mainmenu=ORA&top_frame=1)
maintained and updated to ensure accuracy and consistency with the PCAF regulation and scientific data.

While this document attempts to address all current relevant training, other training opportunities continue to be developed and made available to regulatory staff. Therefore, as these options are made available, revisions will be made to this document to keep it current with pertinent training options.

5. Related Documents and Resources:
https://www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/regulatoryprgmstnds/ucm475063.htm
http://www.clearhq.org
https://ifpti.org/
https://orauportal.fda.gov/stc/ORA/psciis.dll?linkid=720650&mainmenu=ORA&top_frame=1
NASDA Model Animal Food Safety Implementation Framework
Chapter 5: Education and Outreach

Table of Contents

1. Executive Summary........................................................................................................................................... 53
2. Purpose ............................................................................................................................................................. 53
3. Background ...................................................................................................................................................... 53
4. Outreach and Education Plan ......................................................................................................................... 55
5. Outreach Plan Target Audience ................................................................................................................... 56
6. Outreach Plan Delivery ................................................................................................................................... 58
7. Funding ............................................................................................................................................................ 63
8. Responsibilities .................................................................................................................................................. 63
1. Executive Summary
Because of the complexity of the PCAF regulation and the application of new requirements to the animal food industry, state programs will need to develop an outreach program to support successful implementation. Although some states have previously conducted outreach programs, the PCAF regulation will require stronger connection between the state programs and stakeholders. The state program should develop an outreach plan that identifies the various audiences, outreach needs for the audience, the methods to deliver the outreach, and the messages needed for the individual audiences. While the primary audience for outreach is the regulated industry, there are several other groups that should receive outreach such as livestock producers, trade associations, and consumers. States should consider a variety of ways to deliver outreach, including one-on-one contacts by inspectors, the state program’s websites, meetings with stakeholders, workshops, and webinars. In addition, states should consider novel approaches to outreach, such as by requiring continuing education credits, incentive programs, and upstream outreach. An education-before-regulation concept incorporates a preferential use of education to encourage compliance, while maintaining the ability to use enforcement to ensure implementation of regulations if necessary. While PCAF outreach is a shared responsibility between regulatory partners, state programs are often in the best position to conduct outreach because state personnel are often in the regulated facilities. With PCAF regulation outreach to stakeholders, state programs continue to be dedicated to advancing food safety and animal and human health protection.

2. Purpose
Successful implementation of the PCAF regulation includes education and outreach activities that provide regulators and the regulated communities with knowledge of the regulation’s CGMP and PC requirements. Industry will need to know how to comply with the PCAF regulation, maintain its ability to conduct self-assessments, and take immediate corrective actions as needed.

This chapter describes the education and outreach needs of the animal food industry and other audiences that should be included in a state program’s model education and outreach program (outreach program). This chapter does not include the detailed messaging that will be needed to conduct outreach. This chapter also does not cover regulator training for inspections, as that topic is covered in Chapter 4: Regulator Training.

3. Background
FSMA, specifically the PCAF regulation, has fundamentally changed the way the U.S. has to approach animal food safety. With the PCAF regulation, both industry and regulators need to think in concrete terms about an approach to producing safe animal food that relies on prevention. Most of the animal food industry has not been required to operate under CGMPs prior to the passage of the PCAF regulation, except for firms making medicated feeds. The
industry has not been required to implement hazard analysis and risk-based preventive controls (PC); however, some pet food manufacturers and ingredient manufacturers (e.g., renderers) have voluntarily implemented preventive programs such as hazard analysis and critical control points (HACCP).

Industry trade associations have made a notable effort in making their members (mostly large and small facilities) aware of the PCAF regulations. But a significant number of small and very small facilities are not members of the trade associations, so they are not familiar with the CGMP and PC requirements of the PCAF regulation. These operations also have the least amount of resources to implement the planning and changes required by the PCAF regulation.

The presence of state inspectors in animal food facilities, and the knowledge the officials have of animal food regulation, including the PCAF regulation, puts the state inspectors in the best position to assist with outreach and education to the animal food industry. Most of the facilities impacted by the PCAF regulation are already in contact with their state program. However, there are facilities that were not previously in contact with the state program that the PCAF regulation now also covers. To ensure successful implementation of the PCAF regulation, it will be important for state programs to provide outreach to facilities that had not been under state oversight before (e.g., human food by-product manufacturers, single ingredient manufacturers). While some state programs have contracts with FDA to do inspections under FDA authority, most animal food inspections are conducted by state officials that have the authority under their state’s law to take action if they find an adulterated or misbranded animal food.

Compliance with animal food regulations traditionally has been driven by enforcement actions. But we realize that education can also encourage compliance. An education-before-regulation concept incorporates a preferential use of education to encourage compliance, while maintaining the ability to use enforcement to ensure implementation of regulations if necessary. Protecting animal and human health is of the utmost importance; as such, compliance must be achieved and enforcement actions should be used as necessary to ensure the protection of animal and human health. A state program’s outreach program will rely on public information to explain the PCAF regulation (and where appropriate other FSMA related regulations).

While the state program may be the primary outreach contact for animal food facilities, there are other entities that conduct outreach that can be leveraged. AAFCO conducts industry outreach workshops and is routinely called upon to serve as a contact point on animal food related issues. FDA and industry trade associations also provide outreach on the PCAF regulation. Another outreach source that can assist industry is university extension agents.
4. Outreach and Education Plan

An organization’s outreach is defined as an activity of providing services to any populations who might not otherwise have access to those services. One goal of an outreach program is to deliver and impart knowledge. A significant volume of knowledge is needed to ensure that the PCAF regulation is fully understood. Activities must facilitate cooperation to ensure successful implementation and compliance with the regulation. Knowledge transfer to the industry will be of major importance but will also present major challenges in reaching small and very small facilities. An equally important goal of outreach, especially when it comes to developing a compliance program, is to familiarize the regulated industry with the regulatory process of inspection, compliance, and enforcement activities.

Outreach will be a key component of a state program’s PCAF regulation implementation. The outreach will be used to deliver the knowledge and help achieve an overall goal of increasing and maintaining industry compliance with the PCAF regulation. Communications with industry will depend on a few key principles. State agency outreach is a continuing responsibility and must be made available to industry and needs to be documented to measure effectiveness. Outreach for the PCAF regulation will initially focus on making industry aware of the applicability of the PCAF regulations and work to gain industry compliance. After the initial phase, outreach will focus on assisting the industry with gaining and maintaining compliance.

While state programs have been conducting outreach to animal food stakeholders for many years, outreach on the PCAF regulation may be new to many state programs. Activities necessary for PCAF regulation outreach should be included in a state program’s outreach plan. Outreach plans should at a minimum include the objectives of an outreach plan, the target population, types of outreach activities (including delivery), and objective of a specific outreach activity. States participating in the AFRPS have been working to develop outreach plans as outlined in Standard 7: Outreach Activities. Those outreach plans can be modified to include outreach on the PCAF regulation. While some state programs may have formal outreach programs, others conduct outreach in a less formalized manner. Those states should consider developing formalized outreach plans that include PCAF regulation outreach.

AFRPS Standard 7: Outreach Activities provides two formats (a chart and a paragraph) for an outreach plan. NASDA will be developing an operational plan for this document that will provide the key objectives and messages to start a PCAF regulation outreach plan. Outreach plans should deliver the knowledge needs identified in this document with an appropriate delivery method.

A state program’s outreach plan will use an action item for delivering educational needs (knowledge) to each audience identified in the outreach plan. The vision is the majority of the industry outreach will be provided one-on-one by state animal food inspectors. Other
audiences will be served with the rest of the delivery methods. The state program should set up a process to benchmark a percentage of the communication work plan completed by the state program each year. It is critical to reach the maximum number of affected animal food facilities.

5. Outreach Plan Target Audience

5.1 Overview
The state program’s outreach efforts include identifying and connecting with animal food industry stakeholders, with the primary audience being the regulated industry. The regulated industry stakeholders represent diverse industry groups, manufacturing practices, and operation sizes. Outreach should be designed so individual audience members recognize themselves as the target of the outreach and to encourage industry to comply with the PCAF regulation by taking proactive steps in advance of inspections, thus avoiding regulatory enforcement action.

All outreach audiences will need to know where to obtain knowledge about the PCAF regulation, including availability of education and training. Communication about education and training availability will need to be done locally, regionally, and nationally.

5.2 Outreach Needs by Audience
State agencies
State program staff, regulatory and non-regulatory (including managers and information officers) that may interact with the animal food industry should have basic knowledge of the PCAF regulation and how to apply it. One means for state program to obtain the basic knowledge of the PCAF regulation is to attend the FSPCA- PCAF course. State program staff that interact with the animal food industry also need an awareness of state activity to gain industry compliance (see section 6.3). For example, if a state program implements other PCAF regulation compliance support programs, such as Continuing Education (CE) credits, staff will need operational knowledge of those programs.

Inspectors are the primary entity within the state program that will be delivering education and outreach to the regulated industry. Their knowledge will be gained through regulator training, as described in Chapter 4: Regulator Training.

Regulated Animal Food Facilities
The primary audience for a state program’s outreach program for the PCAF regulation is the regulated animal food industry. Educational materials should be focused on helping the regulated industry gain knowledge to understand the animal and human health significance of the PCAF regulation, the components of the regulation, and the applicability of the regulation to regulated facilities. In general, animal food facilities will need knowledge of hazards,
common validations, effective control steps, and historical recalls. The material could also include information that helps to simplify applying the regulation such as by providing advice on recordkeeping requirements or examples of food safety plans. One source for the animal food industry to gain this knowledge is the FSPCA-PCAF course. FDA has also developed guidance documents on several PCAF topics, and industry will need to know how to find them. An example education material a state program can provide to facilities is examples of egregious violations that would result in a significant animal and human health threat and subsequently result in a failed inspection. Such examples could empower the facilities to succeed at compliance. The state will need to make information on how to find educational materials available in their outreach.

The PCAF regulation requires that each individual involved in manufacturing, processing, packing, or holding of animal food have knowledge of animal food safety and animal food hygiene, as well as personal hygiene, and the knowledge necessary to be qualified to do his or her job. Industry has developed animal food personal hygiene safety training, but that training may not be available to all animal food facilities. A state program’s outreach program should include information that makes a facility knowledgeable about this requirement.

Some ingredient manufacturers and human food by-product generators are not aware they are in the animal food business. Human food by-product generators should be familiar with federal and state human food regulations (including those promulgated under FSMA), but they may not be aware that they need to include animal food in their hazard assessments. These facilities will need educational materials similar to those required by manufacturers who make complete animal food. Because they often do not consider themselves to be animal food manufacturers, in addition to knowledge of the PCAF regulation, they will need foundational information on other aspects of animal food regulation including labeling, ingredient nomenclature, and animal nutrition.

There are some animal food facilities that are exempt from certain portions of the PCAF regulation, such as either the CGMP or PC requirements. Examples of these facilities include farms making their own animal food and retail feed stores. Some of these facilities have not traditionally been in a state program’s animal food facility inventory or been inspected by either the state program or FDA. These facilities may have a general lack of understanding of animal food regulation. These facilities will need knowledge of the applicable portions of the PCAF regulation that apply to them, which is likely to include personal training and training in animal food safety and animal food hygiene. Even though these facilities may be exempt from certain requirements of the PCAF regulation, in the interest of animal and human health, voluntary adoption and especially early adoption of the PCAF regulation by these facilities should be encouraged, supported through activities to engage industry and support compliance (see section 6.3), and verified through inspections.
Livestock Producers and other state program stakeholders
Some animal food firms are exempt from the requirements of the PCAF regulation because they are not required to register with FDA as an animal food facility under section 415 of the FD&C Act. For example, a farm that makes the animal food fed to the animals under that farm’s management would be exempt from the PCAF regulation because they are exempt from registration. While these farms may be exempt, they still need to have knowledge about the safe production of animal food, which could include knowledge about the requirements of the PCAF regulation. In addition, part of supporting an integrated food safety system, farmers purchasing complete feed should also be aware if their suppliers are complying with current animal food safety regulations. Unsafe animal food can impact their animals and may impact the food supply if the unsafe animal food contaminates the meat, milk, or eggs from their animals.

Engagement with livestock producer associations, Extention Agents, universities, animal food trade associations, veterinarians, human food processor trade association, and consumers (especially pet owners) will need to be included in the state program’s outreach. These groups can assist in the development of educational materials, leveraging private educational resources, encouraging implementation of the PCAF regulation, and state program funding support. Some of these entities will also need to be engaged to reach very small firms as well as mobile operations manufacturing animal food on farm. Some may need access to the FSPCA-PCAF course or to a state CE program.

6. Outreach Plan Delivery
6.1 Outreach Delivery Overview
State programs should leverage existing outreach plans when considering methods for delivery of outreach. The delivery methods could be a mix of both traditional delivery methods (e.g., personal interaction, websites, or meetings) and novel approaches (e.g., Cooperative Extension Animal Food Safety Specialist). A state program should consider adding new activities to engage and support industry compliance as a way of broadening their overall education and outreach efforts.

6.2 Outreach Delivery Methods
6.2.1 Inspector one-on-one
State animal food inspectors are a primary contact point and primary source of outreach to animal food firms. State inspectors will primarily deliver outreach in a face-to-face manner during the course of an inspection. State inspectors have the ability to direct firms to resources to develop and foster a food safety culture. Through personal interaction with the firm, they can also help identify areas where an animal food manufacturer needs help to determine compliance with the CGMP and PC requirements prior to and after a facility has reached its compliance date.
6.2.2 State Website: Many state programs already have a website. State programs should consider adding information related to the PCAF regulation. A website needs to be developed that will be easy to use and will guide state regulators and industry through the requirements of the PCAF regulation. The website should provide a central location to obtain information such as frequently asked questions, notices to industry, copies of the PCAF regulation, guidance documents for industry and regulators, template forms, procedures, training notices, policies, and links to hygiene training. Some state programs may want to develop their own content for the PCAF regulation, while some may consider leveraging information from FDA’s website on the PCAF regulation to help populate the PCAF regulation content on the state program’s website. In addition to information on the PCAF regulation, the state program’s website should consider providing information on the AAFCO OP, Labeling Guides, and CE course information.

6.2.3 Meetings: Face-to-face meetings are an excellent opportunity to conduct outreach to stakeholders. Opportunities exist for capitalizing on existing meetings already conducted by the state program or of meetings held by associations or stakeholders to present PCAF information. A state program can rely on these existing meetings or invest in holding additional meetings with stakeholders.

6.2.4 Workshops: Workshops also provide a chance for face-to-face interaction between the state program and animal food industry stakeholders. State programs can host workshops or partner with other entities, such as universities or Cooperative Extension Animal Food Safety Specialists (see section 6.2.6) to deliver outreach and education. Workshops require advanced planning and should consider factors such as intended audience, agenda, speakers, location, duration, and desired outcomes. One type of workshop that a state program can sponsor is the FSPCA-PCAF course.

6.2.5 Webinars: Webinar technology can be used as an outreach delivery mechanism that provides for interaction with stakeholders but does not require the logistics necessary for meetings and workshops. Webinars provide for outreach and education to be delivered in multiple locations simultaneously. Webinars also can be recorded and made available for future use and updated as needed. Webinars should provide an opportunity for audience participation (e.g., such as asking questions or responding to questions), and it is recommended that there be a way for the state program to document who has completed the webinar. AAFCO has an already established training tracking system that state programs can utilize for tracking webinar completion.

6.2.6 Cooperative Extension Animal Food Safety Specialist
Outreach to very small firms is going to be a necessity to provide knowledge of the PCAF regulation so that the firm can work to gain and maintain compliance. To reach these firms, the creation of a new position is recommended titled a Cooperative Extension Animal Food Safety
Specialist. States can utilize grant funds to allow Cooperative Extension to help with education and outreach. They can also address industry technical needs to implement the PCAF regulation. Issues such as control-step validations and hazard identification can be handled by coordination with academia, industry trade associations, the FSPCA Technical Assistance Network, and the FDA Technical Assistance Network (TAN). The specialists may also perform voluntary auditing for any incentive programs and help with CE courses.

6.2.7 Additional resources
There are other ways to deliver outreach such as through publications, brochures, websites other than that of a state program, or other mechanisms. The state program should identify additional federal, state, and university resources to make, store, and deliver public information to animal food firms. These resources could be used as a repository for the state program to disseminate regulatory, scientific, and technical information (e.g., information on preventive control validation). It is recommended that state programs leverage material, and consider contributing outreach material, that is made available for distribution in Feed BIN, FoodSHIELD, or AAFCO’s Website.

6.3 Activities to Engage Industry and Support Compliance

6.3.1 Overview
A state program should consider novel tools to engage the animal food industry and increase compliance with the PCAF regulation. These novel tools can be added to a state program’s outreach plan. The novel tools include CE requirements, incentive program, and conducting upstream outreach. While most of these novel tools can be implemented and maintained by the state program, some will need support at a national level to be effective.

6.3.2 Continuing Education
The state program can develop and propose administrative rules requiring an animal food firm’s PCQI to obtain at least one CE credit each year. One of the CE courses must include a refresher course about some aspect of the PCAF regulation. Requiring CE by a PCQI will facilitate interaction with the firm on food safety topics.

State agencies are encouraged to pattern their CE program after any similar existing program. For example, many states already run a pesticide applicator program with similar interaction with industry.

A state program may select topics for their CE program to address local educational needs. However, to ensure consistency across the US, it is recommended that CE topics be considered annually by AAFCO’s Board of Directors. AAFCO would select topics that focus on specific FSMA animal food safety topics, particularly topics that have generated the most questions for AAFCO
or that created the most confusion with animal food firms. Some potential topics for CE credits could be hazard assessment training for very small firms and recordkeeping requirements for small and very small firms. The primary focus for selecting CE topics should be ones that have significance for animal food safety and animal and human health.

CE courses should fit the needs of the intended audience (i.e., PCQI). CE courses do not have to be elaborate. Some can be as simple as a narrator conducting a webinar and include any needed facts or images. If using webinars as method for CE, webinars should be recorded and be available for a defined period of time (e.g., several years). Webinars should be approximately an hour long for each CE credit. To assess knowledge gain during the webinar, the webinar should include an online quiz and evaluation, and a standard for the required number of correct answers could also be developed prior to awarding CE credits.

AAFCO can support the state by maintaining transcripts accessible to all states and a CE training catalog.

6.3.3 Incentive Program(s)
Implementing an incentive program can promote (1) earlier understanding and acceptance of the PCAF regulation’s requirements and (2) more effective compliance. Incentive programs can contain both educational and regulatory incentives. A process to identify potential incentives and engage with the regulatory community can be developed by the state program. Once regulatory inspections for the PCAF regulation begin, regulators can implement a well-defined incentive program designed to reduce inspection frequencies or inspection length. This program will be risk-based taking into consideration an animal food facility’s known and reasonably foreseeable hazards and compliance history. Examples of incentives include:

a) Public scoring of PCAF inspections (CGMP, PC, or both) and/or sample pass/fail rates which can be shared on the state program’s website, door stickers (e.g., similar to a restaurant grading system), and social media (e.g., Facebook and Twitter).
b) Animal food facility of the year contests: State or national, based on compliance with the PCAF regulation.
c) CE credit scholarships awarded to firms exceeding set benchmarks.
d) Conduct PCAF “mock” inspections for compliance with CGMP or PC (or both) requirements, including these provisions:
   i. Best performed by the Cooperative Extension Animal Food Safety Specialist, but could be done by the state animal food inspector.
   ii. Include an introductory meeting to explain the process and have the facility’s contact participate in the PCAF “mock” inspection.
      a) Discuss with the facility’s agent that an egregious violation will result in immediate corrective action or possible stoppage of activities (e.g.,
observation of immediate food safety risk in operation that has not been appropriately corrected).

iii. Perform “mock” inspection

iv. Identify areas of improvement in operations from receiving to loadout using regulatory tools such as guidance documents (from either the state program or FDA). For consistency, it is important that the reviews use the same tools as the regulatory inspection(s).

v. Observations orally communicated to facility as they are observed.
   a) Identify deficiencies to facility agent as observed.
   b) Educate manufacturer on how they might mitigate deficiencies.
   c) The line between regulatory inspection and voluntary “mock” inspections must be observed.
   d) Immediately address deficiencies that would pose an imminent animal and human health threat.

6.3.4 Upstream Outreach:
Effective compliance is best obtained when there is a marketplace demand for it. A new outreach tool to implement the PCAF regulations and increase their relevance for animal food firms or distributors will be “upstream outreach.” This type of outreach tends to tap into the marketplace demand by informing various animal food customers (e.g., animal food producers or consumers) about the PCAF regulation. We have seen in human food that distribution systems quickly demand safe food as new food safety regulations are implemented. By the state program conducting upstream outreach, customers will generate demand for safe animal food that will reach upstream to the animal food manufacturer.

If animal food is not safe, customers are not likely to buy the food. Demands for safe animal food should translate into marketplace requirements for animal food firms to learn as much as possible about safe animal food. Livestock producer groups can raise awareness of the regulations, while state animal food inspectors and extension staff will have to deliver tools to assist the animal food industry with PCAF regulation implementation. The goal of upstream outreach is to inform the consumers, animal producers, and their trade groups about the PCAF regulation and the regulation’s benefits to them, which will create a market demand for safe animal food produced under the PCAF regulation.

Non-traditional ingredient manufacturers, such as those making multipurpose industrial products or human foods, will also provide unique outreach challenges for the PCAF regulation. The state program will need to determine their customer base and use upstream outreach.
7. Funding
Begins in Step 2 of funding, provided to support efforts to develop and deliver industry outreach, education and technical assistance as well as to support regulator training. Some animal food regulatory programs may have a coordinating role in education, while the education function may be completely separate from the state agencies in other states. As a general rule, funding for education should be available for all states.

a) Step 1 – States receive foundational/assessment funding only.
b) Step 2 – Education, Outreach and Technical Assistance funding is at its highest point, to allow support for program development activities. A portion of the Education, Outreach and Technical Assistance funding could be awarded, using a subcontract, to Land Grant Universities, cooperative extension programs or other entities as appropriate to support collaborative efforts.
c) Step 3 – Education, Outreach and Technical Assistance funding settles to a level that allows program sustainability. A portion of the Education, Outreach and Technical Assistance funding could be awarded, using a subcontract, to Land Grant Universities, cooperative extension programs or other entities as appropriate to support collaborative efforts.

8. Responsibilities
Responsibilities for outreach on the PCAF regulation are a shared responsibility between state and federal regulators, regulatory associations, and the animal food industry. The type of outreach a state program can conduct varies greatly based on the legal authority an entity has to participate in the implementation of the PCAF regulation. This section identifies regulatory and other partner-entities associated with the PCAF regulation and identifies some of the outreach responsibilities they may assume during implementation of this rule.

State Agency Responsibilities
Each state should determine the degree to which they adopt the PCAF regulation requirements and participate in outreach efforts for implementation.

For outreach, the responsibilities include these:
• Developing an outreach plan for the PCAF regulation, either by adding to existing outreach plan or developing a new plan, that should at a minimum include the objectives of an outreach plan, the target population, types of outreach activities (including delivery), and objective of a specific outreach activity.
• Identify gaps in a regulated facility’s knowledge of the PCAF regulation.
• Identify gaps in compliance with the PCAF regulation and seek educational materials needed to correct the gap(s).
• Facilitate activities that support compliance (e.g. CE program, incentive program, upstream outreach).
• Set up a website to disseminate educational materials and training schedules.
• Share public information with non-regulatory partners, including educational outreach and research information.
• Share public information on enforcement of egregious violations, status of industry compliance, and other information.

Educational materials the state program could develop:
• Website page
• Information on activities to engage industry and support compliance (e.g., CE program, incentive program(s), and upstream outreach)
• Publications, hand-outs, or brochures if identified as a valuable outreach tool in the outreach plan.

FDA Responsibilities
FDA is responsible for developing support for the PCAF regulation with outreach and educational materials. Additionally, FDA works closely with all regulatory partners to establish the food safety culture and vision, set priorities, and develop processes for inspections, training, and outreach and education for regulators and regulated facilities.

FDA’s outreach and education responsibilities include:
• Providing timely food safety information within existing security constraints and proprietary information requirements.
• Providing technical support to state programs as they develop their outreach plan materials
• Supporting FSPCA course content and deployment and supporting state program staff (i.e. not inspectors) that need to attend the course to develop the base knowledge used to support the goals of the outreach plan.
• Developing outreach materials that will advance both the animal food industry and regulatory partners knowledge of PCAF regulation related matters (e.g., policy interpretations, information on emerging hazards, information on validation)
• Developing PCAF regulation subject matter experts for regulatory interface

Educational Materials for FDA to develop or provide to state programs:
• Guidance documents to industry ahead of implementation of regulatory inspections.
• Fact sheets
• Frequently asked questions based on information received through FDA’s Technical Assistance Network
Stakeholder (industry, academia, Cooperative Extension, commodity groups, Farm Bureau, and other feed organizations) responsibilities in outreach

Industry should participate in available outreach and training activities, submission of ongoing feedback regarding the effectiveness of implementation strategies, and accepting responsibility for their role in the safe manufacturing and distribution of animal food.

Academia is seen as Subject Matter Experts on food safety topics generally and as a resource for identifying best practices for regulators and industry. Academia will play a critical role in outreach, education, and training of both the regulators and industry, and will provide ongoing support in a multitude of roles.

The animal food industry, academia, livestock groups, and regulatory associations will be points of contact for communications regarding the PCAF regulation. These associations are also responsible for disseminating information to members and for participating actively and collaboratively in PCAF regulation implementation.

The stakeholders’ recommended role in information sharing would include:

- Disseminating public information provided by regulatory partners to enhance compliance with the PCAF regulation.
- Developing and providing personal hygiene training relevant to animal food safety.
- Sharing research on validation and preventive control steps to improve animal food safety.
- Providing information from Cooperative Extension, farm industry, and other animal food groups to regulated communities that do not have access to Web-based electronic media.
- Developing national information and education sharing networks and processes on animal food manufacturer audits and inspections, recalls, import alerts, laboratory findings or methods, and other food safety procedures. We recommend a database approach that allows information to be rapidly shared. Alternative methods of information sharing will need to be considered as part of the recommendation.
- Collaborating in the development of animal food safety capabilities, including training, joint inspections, meetings and conferences, risk communication, assessment and risk management, and emergency preparedness and response plans.
- Coordinating effective communication among state agriculture departments, state health departments, universities, and other state officials.
- Research information on validation and preventive control methods.

AAFCO Responsibilities

- Providing workshops on topics supporting state regulator needs such as proper labeling.
• Providing national meetings to build consistency in understanding and interpreting the PCAF regulation.
• Participating in FDA and NASDA implementation outreach planning and the development of educational materials.
• Supporting and coordinating a CE program run by the states, including identifying topics and developing educational materials.
• Supporting state needs for tracking training or outreach activities.
• Providing Model regulations, feed labeling guides.
• Providing information to establish a common name for ingredients.

**NASDA Responsibilities**

• Develop a national website to house educational materials as they are developed by state programs. It should provide a central location to obtain information such as written interpretations, guidance documents for industry and regulators, template forms, procedures, policies, etc.
• Coordinating efforts with Cooperative Extension to provide education to the animal food industry.
• Work with associations through their regional network to coordinate with FDA to find synergistic opportunities for implementing the PCAF regulation.
## Table of Contents

1. Executive Summary .................................................................................................................. 68
2. Purpose / Outcomes .................................................................................................................. 68
3. Background ................................................................................................................................. 69
4. Firm Inventory Subject to PCAF Regulation .............................................................................. 69
5. Inspection Program Activities under PCAF Regulation ............................................................ 72
6. Funding ......................................................................................................................................... 74
7. Responsibilities ............................................................................................................................ 74
1. Executive Summary
This chapter outlines plans to establish procedures for work planning related to inspection program areas related to implementation of the PCAF regulation. This chapter is designed for state programs that take the lead for implementation of the regulation. Some items in this framework may need to be modified from state to state based on the state agency’s involvement in implementation.

Implementation of the PCAF regulation requires continued partnership through work planning procedures and processes for future state-federal collaborations. Under the current procedures, state agencies leverage existing workloads to conduct contract inspections for the FDA. The FDA relies on an existing inventory of facilities to determine contract lists for the states, which help the FDA meet established priorities and performance goals.

Future collaborations will include the aspects of work planning with the FDA along with inventory and information sharing. This will provide a solid base for required inspections like, routine and for-cause. The final projected outcome of this chapter will include a guide for state, federal, and other agencies responsibilities under this regulation.

The process outlined in this chapter reflects the priorities of state programs in collaboration with the FDA to ensure successful implementation of the PCAF regulation and establish a primary role of state agencies in enforcement of the regulation.

2. Purpose / Outcomes
There should be joint inspectional strategies between the state program and the FDA to ensure consistency and uniformity in implementation of the PCAF regulation. Sharing consistent inspectional approaches and data collection strategies will help to avoid duplication of efforts and maximize use of regulatory resources.

Implementation of the PCAF regulation will require significant planning and resources. One of the primary activities a state program must conduct is to identify the work plan that must be completed to conduct regulatory inspection activities. A method to identify firms subject to the PCAF regulation must be established to develop and maintain an inventory of animal food firms. For a list of required resources see section 4.1. An assessment must be done to categorize facilities based on risk to prioritize inspections. AFRPS Standard 3: Inspection Program provides elements to assist a state program in these activities. FDA and state programs should share information to help facilitate informed risk matrices that will form the basis for a national approach that can be utilized to prioritize inspectional objectives. Annual work plans should be established based on factors such as risk, mandated inspection frequency, and most efficient use of resources. Targets for the number of inspections to be completed should be established based on available resources and determination of which firms will be inspected from year to year.
Communication between state agencies and the FDA should be maintained to facilitate better informed strategies for inspectional priorities. Inspection results, information regarding animal food safety incidents, and investigations should be shared among the agencies. Planning of inspections are included in this section as well as for cause/investigations and disaster/emergency response. Target completion goals should be set during the work planning process.

3. **Background**

A state program has a primary role in the implementation of the PCAF regulation in that state and as a part of an integrated food safety system. There will be a need for some states to have a transitional period between the compliance date of the PCAF regulation and the date the state agency conducts inspections under their own authority and becomes a joint partner with FDA as the regulatory authority. The purpose of the inspection program planning chapter is to create a baseline for all stakeholders to use to assess resource needs and plan work activities to ensure successful implementation of the PCAF regulation using a risk-based approach. Under the current procedures, state programs can either leverage existing workloads to conduct contract inspections for the FDA or conduct inspections under state authority. Currently, the FDA relies on an existing inventory of firms to determine contract lists for the states, which help the FDA meet established priorities and performance goals. While states can conduct inspections for the PCAF regulation under contract, the PCAF Framework is intended to assist a state animal food program to plan and conduct inspections under the state program’s authority. A data strategy to develop, maintain, and share an animal food firm inventory must be created, so the state can adequately plan for conducting PCAF inspections. For state programs implementing the AFRPS, AFRPS Standard 8: Planning and Resources provides elements for a state program to document and evaluate the state program’s work plan and conduct evaluation of resources needed to implement the work plan.

Consistency among state agencies engaged in animal food safety inspection programs will enhance the national goal of increasing animal and human health protection. Accurate assessments of inspection program inventory will improve coordination with the FDA (and other state programs) through data sharing, work planning, and resource allocation. This inspection program planning will improve the consistency and uniformity needed to successfully implement the PCAF regulation.

4. **Firm Inventory Subject to PCAF Regulation**

Because of their historical inspection programs, most state programs already have an existing inventory of animal food firms within their state. Current state inventories are compiled per regulatory requirements under state law that includes inspections for facilities that must comply with state licensing requirements, as well as certain federal regulations. Prior to starting inspections under the PCAF regulation, the state program will need an accurate
inventory that reflects facilities that will be subject to the PCAF regulation. Few states are expected to see expanded inventories to include animal food facilities subject to the PCAF regulation as; most states will already have an established inventory.

Reviewing inventories is a relatively simple line item in the work planning process. Input will be needed from the inspection staff to ensure the current inventory is accurate. The most difficult firms to identify and track in the inventory are very small businesses, such as on farm manufacturers and in home pet treat suppliers that may not be subject to the PCAF regulation under FDA’s authority. Reviewing the firm list on at least an annual basis should be included as part of work planning to dedicate needed resources to this effort.

Sharing data on inventory between state program and federal partners is vital to working in an integrated food safety system. Inventory sharing allows for more efficient and effective planning and minimizes duplication of inspections to ensure inspectional coverage of domestic animal food facilities. Inventory information sharing improves coordination and communication between state and federal partners moving closer to mutual reliance and an integrated food safety system.

4.1 Inventory Resources
Gathering and updating firm inventories is necessary in fulfilling work plan requirements (see chapter 6, section 5). Accurate firm inventory data allows for efficient use of time and resources when satisfying work plan requirements. There are a variety of approaches for gathering and updating a state’s animal food firm inventory. Each approach will require resources for the state program to maintain the information and work with regulatory partners. Some of these resources include, but are not limited to: staff time, technological systems or solutions, and equipment. For more information on resources, see Chapter 3: Infrastructure in the PCAF Framework. The partners will also require resources for any efforts they contribute. These resources must be factored in when determining work planning.

Information currently available that could be utilized to supplement the inventory of firms includes but not limited to:

4.1.1 Feed License and Registration Information
4.1.2 Dunn & Bradstreet
4.1.3 Inspection Reports
4.1.4 FDA Inventory Lists
4.1.5 Feed Tonnage Information
4.1.6 Trade Association Member Lists
4.1.7 Field Intelligence

Maintaining the inventory will be another task that will require resources as the inventory is very dynamic and subject to change. Maintaining an inventory of covered firms should not impede the process of establishing an inspection program. Determining which firms are subject
to the PCAF regulation and what firms are exempt will be another significant task in maintaining the PCAF regulation inventory. For example, states will need a method to identify which firms are considered “qualified facilities.” One method to determine whether a facility is a “qualified facility” is to ask the facility to show a copy of the attestation (e.g. Form FDA 3942(b): Qualified Facility Attestation for Animal Food Facility\footnote{https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm} \footnote{https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsAlphabetically/default.htm}) that they submitted to the FDA that attests they meet the financial limitations to be a qualified facility.

4.2 Work Planning

Work planning is a critical component of an inspection program. State programs work plan to conduct inspections under their own authority. States may have already established an inventory based on risk and account for that in the work plan developed through implementation of AFRPS standards 3 (Inspection Program), 8 (Planning and Resources), and 11 (Sample Collection). Many states also work with FDA when developing a work plan because under the current contract procedures, state agencies leverage existing assignments to conduct contract inspections for the FDA. For more information on assignments, see section 5.3 in this chapter.

Work plans should be developed based on risk. FSMA section 201 requires that FDA utilize six factors when identifying high risk facilities. Some states have developed risk-based work plans. AFRPS Standard 3: Inspection Program requires that states categorize their facilities based on a minimum of three risk factors. Some states have already implemented those factors into their risk-based work planning and some have incorporated additional factors. For states that currently do not use risk-based work planning, they should consider incorporating risk into the work plan.

As states begin to work plan to conduct PCAF regulation inspections, work planning needs to be updated to move from base work currently conducted by the state program (e.g., sampling, BSE, medicated feed, education) to account for new work to inspect under the PCAF regulation. These inspections take longer (maybe up to 5-7 days) and need to be conducted at a minimum frequency. FSMA section 201 requires FDA to conduct inspections at a minimum inspection frequency. At a minimum, high risk facilities should be inspected every three years, and non-high risk facilities should be inspected at least once every five years. When developing the work plan, states should consider the inspection frequency for both high risk and non-high risk facilities. Some states may already exceed the frequency required by FDA under FSMA.
5. Inspection Program Activities under PCAF Regulation

5.1 Routine Regulatory Inspections:

Coordination: The state agency responsible for conducting inspections will work jointly with FDA to determine the workload based on available information and resources. A risk-based approach will be used to determine the number of inspections to be completed for the year. The firms that will be inspected should be determined prior to the start of the inspection year. Joint inspections between the State agency and FDA may be conducted as appropriate. Information from various agencies (state or federal) on animal food manufacturing from across the nation may be utilized to determine what areas the regulatory efforts need to concentrate on to provide FDA with meaningful inspectional data. This coordination and open communication between state programs and FDA will provide focus for work planning of inspection activities based on relative risk of the facility.

Inspection: State programs should evaluate their current inspection protocols or procedures to determine whether any modifications are needed to perform inspections for compliance with the PCAF regulation. For example:

- Does the state program need to develop inspection protocols/procedures for the PCAF regulation?
- Does the state program want to amend existing inspection protocols/procedures or have a separate protocol/procedure for the PCAF regulation?
- What activities would need to change from the routine types of inspections currently performed by the state program to inspections under PCAF?
- Will PCAF inspections routinely include sample collections?
- If collecting samples, do you anticipate new types of samples being collect (e.g., samples for environmental monitoring)?
- Will the state program “stack” “stacking” multiple types of inspections at a single facility (BSE, medicated feed, VFD, PCAF)?
- If “stacking” multiple types of inspections, what information needs to be prepared for the inspectors to be able to conduct such inspections?

5.2 Inspection for cause (Investigation)

When an animal food safety incident is suspected, inspections are used as part of a state program’s overall investigation. During an investigation, proactive measures will be taken to protect animal and human health. Prior to the investigation a conference call or in person meeting should be scheduled with inspectors and directors (or a designee) from all participating agencies, including any appropriate compliance personnel. During this meeting, the reasons for the investigation should be discussed as well as recommendations for the focus of the investigation. Laboratory personnel should be included if there is a need for samples to be taken during the investigation. Multiple inspectors may be assigned to maximize efficiency of an investigation so that an inspection, record review, and sampling can be done in a timely
manner. All administrative compliance and enforcement actions needed to correct problems that put consumers at risk should be done with a joint State and Federal Strategy. This will allow for the designation of the leading authority for the investigation.

5.3 Assignments:
The state program will work jointly with the FDA to make decisions on yearly inspections and assignments. The state must be made aware of or involved in all assignments initiated outside the state program that impact firms covered under the state inspection program. This includes in-depth environmental sampling assessments, for cause investigations, and regulatory surveillance samples. Also, states need to be aware that they can perform inspections under their own state’s statutory authority. For more guidance on assignments based on state authority, see Chapter 2: Foundation of Law of the PCAF Framework.

5.4 Disaster/Emergency Response:
In the event of an emergency or natural disaster, the state emergency response network, including a Rapid Response Team (RRT) if available in that state, should be notified. The RRT has the resources and established relationships to be able to quickly respond to a variety of emergency situations. If an emergency response is needed within a state, dedicating resources to the emergency would be deemed high priority and could impact the ability of the state program to complete its inspection work plan. A state program may need to develop a procedure to evaluate the work plan and determine if changes are needed following an emergency or natural disaster.

5.5 Inventory Updates:
Inventory updates should be conducted by the state program. Inventory updates should be made when an inspection is attempted and the firm is found to be: “Out of Business” (OOB), not subject to coverage due to closing, relocated outside of the agency’s geographical jurisdiction, or when a complete inspection cannot be accomplished.

- A state program should expect that there will be a lot of Inventory Updates, especially in the first few years of PCAF regulation implementation. There should be a way to incorporate that into work planning and the target goals to ensure these visits do not prevent a state program from reaching the inspection goals.
- When an inspector visits a firm and determines the firm is “exempt” from the PCAF regulation, the inspector should use the opportunity to educate on animal food safety and perform other inspections deemed appropriate.
6. Funding
Begin in Step 3 of funding, provided to support State personnel conducting regulatory inspections of animal food manufacturing facilities.

- Step 1 – States receive foundational/assessment funding only.
- Step 2 – States receive program development and/or Education/Outreach and Technical Assistance funding.
- Step 3 – Per inspection funding and infrastructure maintenance based on metric goals in each State, to support inspections by State personnel:
  - Full inspections of large manufacturers at a pre-determined maximum percentage of facilities (to be determined by available funding and metrics, and FDA/State goals and priorities) subject to the Animal Food PC Rule, at a per inspection rate to be determined by FDA/States.
  - Targeted inspections of higher risk facilities at a pre-determined maximum percentage of facilities (to be determined by available funding and metrics, and FDA/State goals and priorities) subject to the PCAF regulation, at a per inspection rate to be determined FDA/States.
  - Re-inspections, up to 25% of total full and targeted inspections at a per inspection rate to be determined by FDA/States.
  - Sample collection and analysis as needed

7. Responsibilities

State Agency Responsibilities
Responsibility for providing inspectors, qualified thru education, experience and training, to conduct animal food safety inspections under the PCAF regulations lies with the State Program. Likewise, the State Program will provide these inspectors with technology systems and equipment sufficient to identify and track firm inventory, capture and maintain inspection reports and allow for inspector time management. Additionally, the State Program will work in partnership with FDA to create effective risk based work plans to eliminate duplicative inspections as well as share inventory and inspection data to ensure animal feed safety.

FDA Responsibilities
FDA will be responsible for providing the required training and education to inspectors, as well as providing both scientific and technical support through the availability to subject matter experts and the technical assistance network (TAN). Additionally, FDA will work in partnership with the state program to create effective risk based work plans to eliminate duplicative inspections as well as share inventory and inspection data to ensure animal feed safety.

Other Responsibilities
AAFCO has a responsibility for providing State Programs with access to the advanced proficiency training and continuing education needed by State Program inspectors to complete Part 507 inspections. AAFCO will also provide laboratory support in the regards to methodology and analytical development.
NASDA will be responsible for working with FDA on behalf of State Programs to ensure that adequate funding, needed to conduct Part 507 inspections, is available.
## Table of Contents

1. Executive Summary .............................................................................................................................. 77  
2. Background .......................................................................................................................................... 77  
3. Purpose/Scope ....................................................................................................................................... 78  
4. Laboratory Resource “Checklist” to prepare for PCAF implementation .................................................. 78  
5. Responsibilities ...................................................................................................................................... 80  
6. Related Documents and Other Resources ............................................................................................ 82
1. Executive Summary

Laboratory services are a critical component of any state program implementing the PCAF regulation. Laboratory results may be used by industry to verify or validate a preventive control and may also be used by both industry and regulators to ensure a preventive control is working. To that end, one of the primary goals of a laboratory is to provide defensible/actionable and fit-for-decision data to regulatory agencies. For a state program to have the greatest impact on animal food safety, the laboratory services should encompass the capability and capacity for critical methods and operate under a recognized quality system (ISO/IEC 17025 standards, or the 2014 AAFCO Quality Assurance Quality Control Guidelines\(^\text{14}\)). This chapter provides a “checklist” to determine the laboratory resources needed to support implementation of the PCAF regulation in support of animal food quality and safety, and assess the gap between current laboratory resources and additional resources needed to support the implementation.

2. Background

Regulatory decisions in state programs have been supported by results of laboratory testing for over a century. The role that laboratories play was critical prior to and will remain a critical component of a state program as it implements the PCAF regulation. The PCAF regulation will influence the scope and direction of animal food testing and influence a shift from economic and misbranding issues (e.g., crude protein, crude fat, minerals, vitamins) towards contamination issues that pose risk for both human and animal health (e.g., mycotoxins, microbial pathogens, nutrient deficiencies and toxicities, drug residues, dioxins, melamine). While the PCAF regulation does not require environmental or product sampling for all hazards, laboratory results may be used by industry to verify or validate a preventive control and may also be used by both industry and regulators to ensure a preventive control is working. To that end, one of the primary goals of a laboratory is to provide defensible/actionable and fit-for-decision data to regulatory agencies.

Quality assurance (QA) has historically been a priority in animal food regulatory laboratories. AAFCO has sponsored a Laboratory Proficiency Testing Program\(^\text{15}\) (formally Check Sample Program) that has been in operation since 1930. QA guidance was formalized with the publication of the AAFCO Quality Assurance Quality Control Guidelines for Feed Laboratories in 1998 (original) and in 2007 (revision). The AAFCO Quality Assurance Quality Control Guidelines were revised and reorganized in 2014 to track the sections of ISO/IEC 17025:2017. The 2014 document provides a valuable resource to

---

\(^{13}\) The most recent version of ISO 17025 should be complied with; laboratories should comply with the 2017 version until the next version is available and sufficient (time/resources) has been provided to comply with the updated version.

\(^{14}\) [https://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories](https://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories)

\(^{15}\) [https://www.aafco.org/Laboratory/Proficiency-Testing-Program](https://www.aafco.org/Laboratory/Proficiency-Testing-Program)
animal food laboratories supporting state programs, and is designed to serve as a supplement to ISO/IEC 17025:2017 for animal food laboratories seeking accreditation.

3. Purpose/Scope
While most states have a program, the PCAF regulation shifts the focus of animal food safety from responsive to preventive. Although the shift from a responsive to a preventive food safety system does not drastically change the role of the laboratory, strategic changes must be addressed to ensure the laboratory can support the PCAF regulation for product testing and environmental monitoring. For a state program to have the greatest impact on animal food safety, the laboratory services should encompass the capability and capacity for critical methods and operate under a recognized quality system (ISO/IEC 17025 or the 2014 AAFCO Quality Assurance Quality Control Guidelines).

This chapter outlines the laboratory resources needed to support animal food quality and safety, including: (1) the capability and capacity to perform relevant methods; (2) sufficient quality management and technical systems to achieve and maintain ISO/IEC 17025:2017 accreditation (or implement and comply with the AAFCO Quality Assurance/Quality Control guidelines,); and (3) resources for data assessment and handling. A “checklist” is provided to determine the laboratory resources needed to support implementation of the PCAF regulation and assess the gap between current laboratory resources and additional resources needed to support the implementation. The resources are grouped by: facility needs, personnel and training, equipment requirements, quality system requirements, data capture and storage, and requirements for acceptance of data shared among agencies. The goal is to ensure reliable, defensible, fit-for-use test results acceptable to all stakeholders. It is important that there are laboratory resources available to the state program to support and maintain the economic viability of the local agricultural food producing industry.

4. Laboratory Resource “Checklist” to prepare for PCAF implementation
Planning and coordination of laboratory services to implement the PCAF regulation consists of two phases: first, defining program needs, and second, a gap analysis of current resources against the needs defined in the first phase.

4.1 Defining program needs: Agency administration, program, inspection, and laboratory staff must be involved in outlining and communicating program objectives and how laboratory services will facilitate meeting the objectives. The elements to consider for initial assessment are as follows:
   a. Identify the regulations (including the PCAF regulation) or food safety objectives.
   b. Identify products that will be collected
c. Identify analyte(s) of concern, and the concentration of concern for each analyte.

d. Establish the required confidence level (maximum tolerable measurement error) to make a regulatory decision.

e. Identify tests/methods that are fit-for-purpose at the concentration of concern (achieves performance criteria within error tolerance). Methods that must be identified include both laboratory sampling and analytical methods. List options for facility, equipment, and training requirements for each test/method.

f. Determine set up costs for each method, including ongoing costs for each method.

g. Determine the projected capacity requirements (e.g., projected numbers of samples per time period, monitoring capacity, and surge capacity).

h. Establish how inference will be made; determine the statistical requirements (replicates, etc.).

i. Identify the quality requirements to meet program objectives: Quality Management System, ISO 17025: 2017 Accreditation, quality control needs, or other.

j. Determine the physical and data storage requirements (legal mandates or QA needs).

k. Define data capture and reporting requirements for generating reports. Consider data fields (e.g., quality data, final results, test methods, limit of detection, limit of quantitation, error or uncertainty, chain of custody). Evaluate the mechanism necessary for communicating and archiving data and results.

l. Determine whether data will be shared with another agency. If so, determine if data meets the checklist published in the Data Acceptance White Paper by APHL16 (Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories).

4.2 Gap analysis: Evaluation and assessment of projected needs against current infrastructure and personnel resources. If the gap is insurmountable, consider cost analysis of setting up vs. subcontracting if capacity needs are low or fluctuate, noting that sub-contractors must meet the same quality and proficiency requirements as an agency laboratory. Or consider using a laboratory network to share laboratory resources if capacity needs are low or fluctuate.

a. Laboratory facility assessment
   i. Determine whether facility has adequate laboratory space and utilities to meet the needs.

---

(Contact your feed administrator or laboratory lead for access)
ii. Determine whether facility has adequate biological, radiological and/or chemical safety infrastructure to meet the needs.

iii. Determine whether facility has adequate building security to meet the needs.

b. Personnel and training
   i. Determine whether organization has sufficient staff without hiring additional positions. If additional position(s) are needed, determine the required competencies.
   ii. Assess training needs for staff (competency framework link) and format and accessibility of training.

c. Equipment requirements
   i. Assess if current equipment inventory meets requirements and if there is need for acquisition of new equipment.
   ii. Assess equipment maintenance needs (e.g., service contracts) and replacement cycle.

d. Quality requirements
   i. Assess whether the laboratory’s Quality Management System meets the quality requirements identified by the program objectives.

e. Data capture, reporting, and archiving requirements (Laboratory Information Management System)
   i. Assess current reporting capability against projected program needs under consideration.
   ii. Evaluate the compatibility of database with program and other agency databases.
   iii. Assess security requirements, electronic communications, and storage


5. Responsibilities

State Agency
The State Agency includes upper management, the state program staff (including inspection staff), and laboratory staff. These representatives may be located in multiple state agencies. The State Agency must actively participate in “Defining program needs” listed in Section 4 to successfully support a state program implementing the PCAF regulation, and actively participate in the “Gap analysis” (see details in Section 4.0 b. of this chapter). Once the gap is defined, the state agency needs to facilitate by providing laboratory resources to meet the gap. For example:

- Provide the structure for communication among all agency stakeholders
- Provide for training
• Provide resources for quality management systems
• Determine enforcement strategies and capabilities for the program
• Determine resource for sustainability of the sampling plan
• Work with state laboratory to ensure staff, supplies, equipment and other resources are available to address sampling plan.

Additionally, the State Agency should recognize the importance of and encourage participation of state laboratory personnel of their respective states in AAFCO laboratory related committees and in attendance at AAFCO meetings. Involvement of laboratory personnel in AAFCO serves the agency as attendees engage in education and training activities provided by AAFCO and through resource sharing by cooperating on analytical methods and other needs, and by networking to facilitate harmonization among states and FDA.

**Federal Agencies**
State and Federal Agencies are partners in implementing the PCAF regulation and other FSMA related regulations. To that end and pending funding, the Federal Agencies are responsible for:

- Seeking and providing resources, such as ISO accreditation as is currently being provided through the current FDA AFRPS Cooperative Agreement.
- Seeking and providing additional resources to support laboratory services (e.g., instrumentation, training, service contracts, LIMS, etc.)
- Promoting and participating in the sharing of data in support of compliance and enforcement actions.
- Providing technical guidance for the standardization of enforcement approaches to include use of state laboratory data and the implementation of regulatory methods.
- Participating actively in the AAFCO Laboratory Methods and Services and Proficiency Testing Program Committees\(^\text{17}\), and associated working groups.

**Associations**

a. NASDA will recognize the importance of and encourage participation of state laboratory personnel of their respective states in AAFCO laboratory related committees and in attendance at AAFCO meetings. Involvement of laboratory personnel in AAFCO serves the local agency as attendees engage in education and training activities provided by AAFCO and through resource sharing by cooperating on analytical methods and other needs, and by networking to facilitate harmonization among states and FDA.

b. APHL, AFDO and AAFCO through cooperative agreement with FDA have developed resources to assist laboratories with ISO 17025 accreditation, including the development of critical best practices manuals. These laboratory resources include the following:
   - *PFP Food/Feed Laboratory Testing Best Practices Manual*\(^\text{18}\)

\(^{17}\) [https://www.aafco.org/Regulatory/Committees/Proficiency-Testing-Program](https://www.aafco.org/Regulatory/Committees/Proficiency-Testing-Program)
• 2014 Quality Assurance/Quality Control for Feed Laboratories
• Guidelines on Obtaining Defensible Samples
• Guidelines on Obtaining Defensible Test Portions
• Hosting a website of accreditation resources
• Work toward a curriculum framework for governmental regulatory laboratories.
• Expansion of the scope of the AAFCO Proficiency Testing Programs
• Providing resources to facilitate accreditation to ISO 17043:2010 for the AAFCO Proficiency Testing Program.

c. AAFCO provides support for the laboratories through its Laboratory Methods and Services and Proficiency Testing Program Committees.
   • The AAFCO Laboratory Services Committee works to develop or improve analytical methods, document laboratory best practices, document quality assurance guidelines, document laboratory sampling guidance, provide training resources, coordinate with other AAFCO committees, and provide other resources to laboratories.
   • The proficiency testing programs administered by the AAFCO Proficiency Testing Program Committee are utilized by federal, state, local, industry and private laboratories around the world. The schemes in the program are accredited by ANSI-ASQ National Accreditation Board (ANAB) to ISO 17043:2010.

6. Related Documents and Other Resources
   a. Accrediting Bodies
      i. ANSI-ASQ National Accreditation Board (ANAB)- http://anab.org/ and their associated brands ACLASS, FQS, and ANAB
      ii. American Association for Laboratory Accreditation (A2LA) https://www.a2la.org/
      iii. Perry Johnson Laboratory Accreditation (PJLA) http://www.pjlabs.com/
      v. International Accreditation Service http://iaisonline.org/
      vi. National Voluntary Laboratory Accreditation Program (NVLAP) - http://www.nist.gov/nvlap/ - technically part of the US government and only accredits a few narrow disciplines.

https://www.fda.gov/ForFederalStateandLocalOfficials/ProgramsInitiatives/PartnershipforFoodProtectionPFP/ucm404633.htm
19 https://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories
20 https://www.aafco.org/Publications/GOODSamples
21 https://www.aafco.org/Publications/GOODTestPortions
22 https://www.aafco.org/Laboratory/Proficiency-Testing-Program
23 https://www.aafco.org/Regulatory/Committees/Laboratory-Methods-and-Services
NASDA Model Animal Food Safety Implementation Framework
Chapter 8: Enforcement

Table of Contents

1. Executive Summary ............................................................................................................. 84
2. Background ......................................................................................................................... 84
3. Scope ................................................................................................................................... 84
4. Responsibilities .................................................................................................................... 85
5. Enforcement Program Implementation Challenges and Potential Solutions ......................... 86
6. Resources .............................................................................................................................. 87
1. Executive Summary
This chapter details some of the necessary components for state programs to ensure animal food facilities compliance with the PCAF regulation. The PCAF Framework includes information to ensure an effective enforcement program strategy.

With the size, diversity and complexity of the animal food industry, it would be difficult, if not impossible, to maintain a reasonable level of compliance without the acceptance and cooperation of the individual facilities in the regulated community. Much of the success of state programs is due to the cooperation received from industry in relation to their desire to ensure the safety, integrity, and quality of the animal food they manufacture and distribute. Seeking voluntary compliance by an animal food facility should be given strong emphasis. Education should be included as a valid option in gaining compliance with the PCAF regulation prior to taking enforcement actions due to a violation.

A state program may develop an enforcement strategy based on the rules and regulations that govern the animal food regulated by that program and the success of that enforcement program may be best measured by the level of animal food industry compliance, rather than the number of citations issued.

2. Background
State programs have been enforcing animal food regulations for many years in efforts to ensure a safe animal food supply. Much of the success of state programs is due to the existence of enforcement programs, coordination of resources with other regulatory agencies when problems are detected, and the cooperation received from industry in relation to their desire to ensure the safety, integrity and quality of the animal food they manufacture and distribute.

Considering the PCAF regulation establishes new CGMP and PC requirements, there should be a period of education prior to the state program taking enforcement actions to gain compliance as the industry establishes the necessary steps to implement these new requirements. This allowance however should not prevent a state program from developing a plan of enforcement that can be utilized should it be necessary to prevent an animal food safety issue.

3. Scope
The Enforcement Chapter details some of the necessary components for state programs to ensure a facility’s compliance with the PCAF regulation. This chapter is designed to address the components of state program’s enforcement strategies to secure industry compliance with all applicable regulations, ultimately protecting both the health of animals and humans by limiting residue exposures to food producing animals as well as microbial contamination of animal food handled in the home (i.e. pet food). Sustainable compliance will be gained through education and training; however, a state program must have an established enforcement strategy to compel compliance, when necessary.

This chapter will address the potential enforcement actions that a state program may utilize in order to achieve industry compliance with the PCAF regulation. Additionally this chapter will outline potential challenges and solutions regarding state program enforcement capabilities.
The desired outcome of an enforcement program provides for a regulated industry that participates and complies with animal food regulations (including the PCAF regulation), fully incorporating its principles in efforts to provide safe animal food. Additionally, the outcome supports the development of a uniform enforcement strategy which can be utilized by state programs to ensure compliance is achieved.

4. Responsibilities

Seeking voluntary compliance by an animal food firm should be given strong emphasis. Education is appropriate means to gain compliance prior to taking enforcement actions due to a violation of the PCAF regulation. Nevertheless, a state program must consider each violation to determine if there is a potential safety issue that could arise from a facility’s failure to implement the regulations correctly.

State Program
A majority of state programs perform animal food facility inspections both under their own authority as well as under contract with FDA. State programs are expected to have adequately trained staff who can determine compliance for each inspected facility and document any observations, with supporting evidence, that demonstrate a facility’s failure to comply with established regulations. The state program is expected to complete the required components of each inspection in a timely manner to confirm regulatory authority has been established and determine the level of enforcement action necessary to ensure that the facility produces safe unadulterated animal food.

The State Program is expected to utilize established procedures and enforcement tools to determine that any observation discovered during an inspection is effectively corrected. Additionally, the State Program will be responsible for confirming that a facility’s corrective actions have been implemented.

If the observed violation resulted in adulterated animal food being distributed into interstate commerce, the State Program will collaborate with FDA and all necessary jurisdictions.

AAFCO has established model enforcement guidelines that can be utilized by state programs. These enforcement guidelines are provided with the intention of encouraging uniformity of enforcement tools selected. These guidelines are published in the Official Publication of AAFCO as approved by the Board of Directors and membership and can be utilized by state programs. However, the state program must review the applicable rules and regulations, with the assistance of legal counsel if necessary, to determine the exact authority provided under the state’s statute.

A state program may develop an enforcement strategy based on the rules and regulations that govern the products regulated by that program and the success of that enforcement program may be best measured by the level of industry compliance. Various factors, such as facility history of compliance and response, the nature and egregiousness of the violation and the resources available to the state program should be considered when developing a matrix.
**See Appendix 1 For the AAFCO Enforcement Guidelines.**

**FDA Responsibilities**

The FDA is likewise expected to complete animal food facility inspections in a timely manner, under their own authority, utilizing adequately trained staff to determine violations, record observations, collect evidence and determine a risk appropriate response. Cases against an animal food facility, should enforcement action be necessary, are expected to be assessed in a timely manner by the FDA ORA Human and Animal Food Division (formerly FDA District Offices) and Center for Veterinary Medicine. The FDA can utilize a variety of enforcement methods to confirm that a non-compliant facility does not distribute adulterated animal food into commerce as well. Based on the animal and human health risk presented by the facility and its products, FDA, could initiate a mandatory recall or administratively detain the violative animal food. FDA may also suspend the food facility registration of the noncompliant facility. In addition, FDA could seek judicial relief, either seizing violative product or enjoining the firm from specific action.

Additionally, the FDA is expected to reach out to the corresponding state program to provide any information regarding a facility in their area, in order to utilize the state program’s authority in order to achieve compliance, if necessary.

5. **Enforcement Program Implementation Challenges and Potential Solutions**

**New Regulations Have Not Been Incorporated or Adopted by State Programs**

Many state programs have yet to incorporate the PCAF regulation into their law and subsequent regulations. While this does not hinder inspections performed under contract with FDA, as they can be performed under Federal authority, it does deter the state program’s ability to achieve immediate compliance by enforcing regulations under state authority.

Historically, state programs gained almost immediate compliance within an animal food facility by enforcing state regulatory authority. This method is utilized during inspections conducted under state authority or immediately after closing out a federally contracted inspection performed under federal authority.

State programs that have yet to incorporate the PCAF regulation into their governing regulations or adopted the regulation by reference may not be able to gain compliance in a timely fashion. Without the authority to influence an animal food facility to comply with a specific citation in the PCAF regulation, the state program may have to document the observations, collect evidence, and submit an enforcement recommendation to FDA. The FDA will then have to assess the situation and determine if a new inspection is warranted or if the state program submitted all the required documentation to pursue an action under the authority of the FD&C Act. In order to navigate this challenge, the state program will have to determine if they wish to align their regulatory authority with the PCAF regulation as discussed in Chapter 2: Foundation of Law in this document.

If a product is deemed adulterated, the state program has the authority to take enforcement action to verify that the product is secure under a regulatory order, such as a Stop Sale.
However, this is a reactive action and the premise of the PCAF regulation is to prevent food from becoming adulterated.

**Enforcement Capabilities and Matrix Development**

In order to implement a structured enforcement program, a state program must review their available authority to develop a practical matrix. For those state programs whom have chosen to implement the AFRPS, the AFRPS provide steps not only to review the authority (Standard 1: Regulatory Foundation), but to establish an enforcement matrix based on the resources available to the state program (Standard 6: Enforcement Program). State programs with a developed matrix should consider whether the matrix supports enforcement of the PCAF regulation or if changes need to be made to accommodate enforcement of the regulation. Non-AFRPS states will have to establish their authority and develop a matrix without the guidance of the AFRPS. The matrix should take into account the state program’s overall animal food regulations in addition to the PCAF regulation. AFRPS states are available to provide guidance to those state programs that are considering developing the proper steps to review and enforce regulations.

**6. Resources**

One of the biggest resource needs for a state program to enforce the PCAF regulation is for training. Training must be accessible to the state program, to ensure the field staff is adequately trained to perform these new inspections and subsequently enforce the PCAF regulations. (See Chapter 4: Regulator Training for a discussion of training needs). Additionally, the state program may not have staff with the proper educational background to perform the field and administrative duties needed to consistently enforce the regulation.

Information Technology (IT) is another resource that is not readily available to all state programs and could impact their enforcement capabilities or timeliness. Having access to information technology (systems and solutions) benefits the entire state program, not just for its implementation of the PCAF regulation. Unfortunately, both the software programs and equipment needed to access the programs remotely are expensive and without resources allocated for improving IT for the field staff, enforcement actions may be delayed due to inaccessibility. By providing current mobile technology to the field staff that allows access to real time data, the communication between the field staff and the state program would provide for quicker action to gain compliance from a firm. Field staff can also view registration details to establish if a facility has failed to register itself or a product with the state program, which will ultimately assist with risk assessment of that location. If the state program utilizes software programs that can be accessed remotely, the field staff can view laboratory results in order to determine if additional sampling is necessary. Because the PCAF regulation is intended to reduce hazards, information to laboratory data in a timely manner could prevent contaminated animal food from being distributed.

State laboratories may also be at a disadvantage due to lack of resources available for analytical testing. Chapter 7: Laboratory Services outlines the importance of laboratory services for a state program and the steps to prepare laboratories for implementation of the PCAF regulation. The laboratories serve a critical role in enforcement. If a state laboratory is delayed analyzing an adulterated animal food sampled due to lack of resources, the state program may be unable
to take an effective enforcement action on the violative sample to adequately protect the public from the misbranded or adulterated animal food.

The AFRPS provides the State Program with the tools necessary to determine any resource needs (Standard 8: Planning and Resource) in order to have an effective inspection and enforcement program (Standard 3: Inspection and Standard 6: Enforcement Program). Once any resource needs are identified, there is a greater chance of resolving the challenge by working to reduce these needs.

State programs need to perform reviews, such as those in the AFRPS, to determine the resource needs for their specific program. By assessing the resources available to the State Program, each State Program can determine what a successful enforcement program will look like based on their capabilities.
[Text under Development]
To ensure a harmonized approach to building PCAF programs, state programs should take a step-wise approach to address three fundamental steps. These three fundamental steps include assessing current capacity and capabilities, developing the program, and implementation of the program. For each of the fundamental steps, there are a number of activities recommended for state programs to consider so they can build their PCAF programs in a harmonized way that promotes alignment and consistency across state programs. While state programs may be able to conduct some of these activities using current resources, additional resources are needed to ensure state programs have sufficient resources to successfully build their PCAF programs.

Step 1: Assessment of Current Demands, Capacity, and Capabilities to Identify Gaps and Develop Strategic Plans:

- Assess industry volume & complexity, begin process of identifying industry, developing an inventory and establishing priorities;
- Assess current infrastructure including Information Technology (IT) needs to support development and implementation of an animal food safety program;
- Assess programmatic capacity and capability to implement an animal food safety program that includes (as determined by program goals):
  - Education
  - Outreach
  - Inspection
  - Compliance and Enforcement
  - Laboratory (notably increased method proficiency/network)
- Assess program goals (education, outreach, inspection, enforcement, and laboratory) and determine gaps in current capacity, capability and infrastructure to meet goals;
- For each assessment area and identified gaps, develop a strategic implementation plan with specific tasks, objectives, timelines and milestones for short and long term programmatic development;
- Ensure regulatory authority, credentialing, MOUs are in place or at least are included in the program development plan;
- Develop strategies and administer industry outreach and educational programs to build an awareness of and encourage compliance with the PCAF regulation with an eye on continuing education and the inspection/education feedback loop;
- Establish information sharing processes with local, state and federal partners.

Step 2: State Program Development
• Continued development of Step 1 deliverables;
• Develop strategies for administrative support programs to support IT development, outreach, education, inspection, compliance and enforcement programs;
• Obtain training for inspection, compliance and management personnel, and plan for implementation of these functions (some states have jumpstarted their efforts and may already have begun or accomplished these program elements);
• Participate in educational sessions and meetings with industry and other regulators;
• Develop strategies to implement a comprehensive uniform and consistent nationwide inspection program that includes provisions for significant outreach and education prior to and during compliance and enforcement;
• Develop strategies for product sampling and analysis protocols, to be employed as necessary during inspections or investigations, or, as an alternative, establish a relationship with a servicing laboratory to meet analytical needs;
• Establish/formalize partnerships with academic institutions, industry experts and associations as appropriate;
• Develop and begin to deliver outreach and education programs for industry;
• Initiate IT development for data sharing, etc.; and
• Participate in pilot programs.

Step 3: Implementation
• Continued development and implementation of Step 1 and 2 deliverables;
• Conduct extensive industry outreach and education programs;
• Identify best management practices and mitigation strategies to facilitate industry compliance activities;
• Facilitate information sharing among impacted stakeholders as appropriate to the industry;
• Collaborate with impacted stakeholders regarding FSMA implementation; and
• Initiate inspection program including, as appropriate, laboratory support, compliance and enforcement.
These enforcement guidelines are provided with the intention of encouraging uniformity of enforcement by feed control officials, however, it is most important for all to recognize these are indeed guidelines, not a specific recipe to be blindly followed. It is clear that application of guidelines may vary somewhat in different environments, while guideline interpretations may be influenced or colored by local political realities.

Selection of Enforcement Tools

When voluntary compliance is unsuccessful the state program must determine the steps necessary to achieve compliance. However, due to the complexity and variety of the regulated industry, no two cases or sets of circumstances are quite identical. There are almost always several factors to consider before selection of an enforcement tool or tools and application of same for the purpose of achieving compliance. Some violations are only minor while others may be serious or very serious. Violation can be largely administrative or technical in nature.

The following list of factors is provided as a guide for putting a violation into perspective.

- What is the nature or gravity of the violation? To what risks or potential risk has a violation exposed humans, animals or the environment? What level or potential level of harm/damage is associated with the violation?
- What is the violator’s culpability? Is the violation an accident, mistake or omission or the result of intent, negligence, defiance, indifference, fraud, etc.?
- Has the violator shown good faith efforts to comply, be cooperative, correct errors or deficiencies?
- What is the history of prior violations including willingness and efforts to achieve compliance?
- If an economic penalty is available, what is appropriate for the current violation and business and would it provide the right economic deterrent to future violations?
- Can the state and the violator afford the resources to achieve compliance and are the resources in proportion to the violation and benefits of compliance?

Enforcement Options

The selection of an appropriate enforcement tool should normally allow opportunity for a more stringent action for a repeat violation or more grave violation of the same nature. Thus the following tools are generally arranged in progressive order.

Advisory or Informational Letter

This can be a form of both compliance assistance and education and would usually apply to non-repetitive violations of no risk to health, safety or the environment. Administrative violations involving licensing, product registration and payment of fees are examples.
Warning Letters with or without a Required Response
This tool would usually clearly outline the violation and require corrective action(s). The letter might or might not request a written response upon correction. This tool would be appropriate for violations that have or could present risk to health, safety or the environment. Further, it could be appropriate for repetitive administrative violations.

Withdrawal from Distribution Orders
This tool is appropriate when health, safety or the environment would be put at risk from distribution of a feed. It might also be used when other tools have failed to achieve compliance for serious administrative violations or gross labeling violations.

Informal Hearings/Meetings
This tool is appropriate for providing an opportunity to bringing together parties to discuss and understand the nature of a violation. It may lead to an agreed order or consent decree. Use of this tool would be appropriate for many violations including those that may be chronic; threats to health, safety or the environment; civil penalties and license denials/revocation or other serious administrative actions. This tool may be used in conjunction with others to facilitate compliance.

Mediation
A meeting of all parties which produces a consent decree or compliance agreement.

Civil Penalty
A civil penalty is a monetary penalty assessed for a violation. Civil penalty fines are based on a numeric point matrix determined by the severity of the violation and the repeat nature of the offense. A notice shall be given and an opportunity for an administrative (formal) hearing must be provided. This tool should be used in addition to other tools to prevent chronic violations or to address illegal acts when other tools are not available. Where appropriate, an informational letter, warning letter, informal hearing/meeting and/or administrative hearing should precede the use of civil penalties.

Cancellation, Probation or Conditional Status
These actions are usually taken against a license, permit or registration due to repeat violations, including reporting of distributions and payment of fees or chronic analytical deficiencies.

Administrative Hearing
An opportunity for an administrative (formal) hearing is provided to the regulated establishment prior to the issuance of a civil penalty, license denial or license revocation. An administrative hearing may result in a consent decree with the regulated establishment. This tool should be used in chronic violations or when threats to health or safety exist.

Condemnation and Confiscation
This tool may be applied to a lot of non-compliant feed and may involve a court in the
local area. A feed found violative by the court may be subject to condemnation and disposition after first allowing the claimant/manufacturer opportunity to seek release of the feed or request opportunity to reprocess or re-label the feed for compliance. This tool would be appropriate for use when a practice or product presents a risk to health, safety or the environment. It may also be applicable in other cases such as chronic violations.

**Injunction**

This tool may be used to restrain a firm from any or all violations. The tool would be used in case of a serious threat of immediate or irreparable harm. Use may also be appropriate to restrain a firm from operation in wanton violation of a chronic nature involving administrative aspects of the law.

**Criminal Prosecution**

Prosecution in a court may be pursued against a firm or person that impedes, obstructs, hinders, or otherwise prevents or attempts to prevent enforcement of commercial feed regulation. This tool can be used for any violation, but other tools may be appropriate.

Many of these enforcement tools can be used together or in conjunction with one another, especially letters and stop sales. Use of tools in combination depends on the violation, response, compliance history and corrective actions required.

**AAFCO Enforcement Guidelines Factor Application**

Below is a listing and description of six (6) factors to consider when selecting an appropriate enforcement tool to deal with the finding of a violation in a product or product labeling, or in the manufacturing, holding/storage, and/or distribution process. Each factor description includes a numerical weight assigned to a relative condition of each factor.

To use this guideline, select the most appropriate relative condition for each factor and note the numerical value. The total numerical value combined for all of the factors could then be used to help select the appropriate enforcement tool from the Violation Chart.

A sample Violation Chart follows this discussion of Factors. That chart suggests five (5) major categories of violations but could be modified to include additional violation categories or to break the larger category into more than one. The sample chart includes four (4) ranges of factor values but the chart could be modified to include more or less numbers of value ranges, or the values within a range could be modified. The modifications are suggested to meet the needs of any particular state.

**Factor 1—History of the Firm**

The history of regulatory contact with a firm or individual can be indicative of their commitment to assuring they are operating in compliance. History can include inspections, sample analysis, label reviews, and previous enforcement actions. It should include consideration of whether corrections were promised and completed, whether corrections were made promptly, and whether the same or similar problems occur repeatedly. The following relative weights can be
used in assessing the history of the firm:

1. Firm has extensive history and is always found in compliance
2. No history on file for this firm
3. Firm’s history shows only minor violations, always corrected
4. Firm’s history shows instances of significant violations and/or repeated minor violations
5. Firm’s history shows instances of significant violations and promised corrections are rarely made

**Factor 2—Attitude**
The attitude of the firm or individual can also be used to help assess their commitment to assuring they are operating in compliance, and the level of enforcement action needed to encourage commitment. Does the firm or individual promise correction and follow through? Are they aware of laws/regulations/ requirements for their operation? Do they have Quality Assurance and/or training programs? Do they accept responsibility for problems that are uncovered? Are corrections made promptly? Do they make corrections while you are there but do not maintain the correction? When appropriate, do they examine similar systems/products to make overall correction? The following relative weights can be used in assessing the attitude of the firm:

1. Accept responsibility for assuring compliance; aware of the requirements and/or have Quality Assurance/training programs; corrections are promised and made promptly; when appropriate, extend corrections to similar products/systems
2. Accept responsibility for assuring compliance; aware of the requirements; corrections promised but not made in a timely manner or corrections are not sustained
3. Do not accept responsibility for assuring compliance; not aware of the requirements; no promise of correction; no correction

**Factor 3—Scope**
Scope of the firm’s business as well as the scope of the violation can be an important factor in choosing an appropriate enforcement action. Consider the distribution of the violative products is it limited to local distribution; multi county; statewide; multiple state; nationwide; worldwide? What is the quantity of violative product involved? How many animals are affected? Are the violative products intended for a limited or unique population, or are they for a broader population? Is the violation involving a single product and/or is it single lot specific, or is it multi product or a process violation? Is this an industry practice? The following relative weights can be used in assessing the scope of the violation:

1. Very limited distribution, quantity, or limited purchaser; violation is limited to a single lot
2. Distribution is limited to statewide and/or bordering states; violation is limited to one or two products, quantity of product distributed is relatively small and/or the number of animals effected is relatively small; non critical process violation
distribution is unlimited and may involve large quantities of product and/or affect a large number of animals; violation involves critical processes and/or multiple products

Factor 4—Nature of the Violation
The nature of the violation has an impact on the type of enforcement action and may influence whether the action focuses on the product/process or on individuals. Consider whether the violations are minor or significant; whether they are sporadic or continuous; whether they involve only record keeping/control issues or they include product defects or contaminations; whether they are the result of human error; whether they were the result of lack of knowledge and understanding of the firm/individual’s responsibility or the legal requirements; whether the violations were done knowingly or deliberately. When determining whether the violation is significant or not as significant, or whether it would be a major or minor violation, available and current science and policy should be considered. The following relative weights can be used in assessing the nature of the violation:

(1) minor labeling violations and/or minor, sporadic record keeping violations
(2) violations are not minor but they are isolated incidents, the result of human error, or the result of lack of knowledge about requirements
(3) significant GMP (asterisked items on FDA Form 2481) and/or labeling violations; contaminations; fraud
(4) deliberate, knowing violations that result in hazard to animal and human health

Factor 5—Impact of the Violation
Selecting the most appropriate enforcement tool is strongly tied to the impact the violation has on the user of the product (economic impact, fraud), the safety of the animal, and human health safety. You should consider whether the violations effect food producing or non-food producing animals. Are they violations that are economic or fraudulent in nature? Do they compromise animal safety? Do they pose a risk to human health safety? Is there a particular population at risk (children, immuno-compromised, elderly)? The following relative weights can be used in assessing the impact of the violation:

(1) minor economic or fraud violations
(2) animal safety concerns
(3) human health safety concern but limited population
(4) human health safety concern with a risk to all populations

Factor 6—Resources
Consider what resources your agency has to devote to the violative findings. Has your agency established overall compliance goals and objectives? Has your agency prioritized their enforcement efforts? Are they devoted in part to special initiatives? Have you established communication networks to determine if the violations have been encountered elsewhere? If so, are they pursuing enforcement? Are there other agencies that may be able to pursue action consistent with your compliance goals?

(1) no resources are available
(2) limited resources are available
(3) ample resources are available
## Example Violation Chart

<table>
<thead>
<tr>
<th>Factor Value Range</th>
<th>4 to 8</th>
<th>9 to 12</th>
<th>13 to 19</th>
<th>20 to 29</th>
</tr>
</thead>
<tbody>
<tr>
<td>Violation Category</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information Letter</td>
<td>No Action</td>
<td>Stop Sale</td>
<td></td>
<td>Informal Hearing/Meeting</td>
</tr>
<tr>
<td></td>
<td>Warning Letter</td>
<td></td>
<td>Informal Hearing/Meeting</td>
<td>Injunction</td>
</tr>
<tr>
<td></td>
<td>Informal Hearing/Mediation</td>
<td></td>
<td>Injunction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refer to Other Agency</td>
<td></td>
<td>Refer to Other Agency</td>
<td>Civil Money</td>
</tr>
<tr>
<td>GMPs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample Results</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contaminations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administrative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Preventive Controls for Animal Food rule includes streamlined regulatory provisions for human food facilities that manufacture, process, pack, or hold human food by-products for use as animal food. Many human food facilities send by-product of human food production, or human food that does not meet quality specifications for use as animal food. The streamlined provisions do not apply to by-products of non-food manufacturing and processing such as dried distillers grains from ethanol production or for human food or human food by-products from potentially contaminated or adulterated human food.

There is variability in how human food and state animal food regulatory programs are organized within the state agency structure. Some human and animal food regulatory programs are within the same program area. Others are in different program areas, but within the same state department. In some states, the human and animal food regulatory programs are not even in the same department. As a result, implementing streamlined requirements in food facilities subject to both the human and animal food requirements may require careful planning and collaboration between the animal and human food regulatory program areas within the state. This appendix is intended to identify some of the key considerations that a state should consider as they implement the animal food safety requirements at a human food facility with human food by-products for use as animal food.

The primary consideration is whether the human or animal food safety program, or a combination, will implement the animal food requirements in a human food facility that has human food by-products for use as animal food. Each state should consider their unique human and animal food regulatory programs and structure when doing so. In addition, the state may consider factors such as inspectional efficiencies, training and education needs, knowledge sharing between program areas, and regulatory authority limitations when deciding how these requirements will be implemented.

In addition, the state will need to consider what human food facilities with human food by-products for use as animal food are subject to the animal food safety requirements, and whether the animal food safety program currently registers, or licenses, or otherwise includes those facilities in their animal food inspectional inventory. States have different registration, licensure, or other mechanisms that identify facilities as an animal food facility. These mechanisms may or may not capture all the human food facilities that would be subject to the human food by-products for use as animal food requirements in the Preventive Controls for Animal Food rule. For example, some states base licensure on whether a facility makes sales of animal food and would not include a human food facility that gives away by-products for use as animal food directly to a farmer in their animal food inventory. The Preventive Controls for Animal Food rule is applicable to a human food facility that manufactures, processes, packs, or holds human food by-products for use as animal food regardless of whether it is given away or sold. The state will need to take into consideration the scope of the human food facilities with human food by-products for use as animal food that will be included in the inventory that will be
inspected to the Preventive Controls for Animal Food requirements. This may impact the number of firms in a state’s animal food safety program’s firm inventory.

Human food facilities that further manufacture/process their human by-products for use as animal food have the choice under the Preventive Controls for Animal Food rule to follow the CGMP and hazard analysis and risk-based preventive control requirements in the Preventive Controls for Human Food rule (part 117) or the Preventive Controls for Animal Food rule (part 507). FDA has made the decision to use the regulatory citations in part 507 for any issues noted during an inspection with respect to human food by-products for use as animal food because the part 507 requirements provide more flexibility. FDA expects that states performing inspections on behalf of FDA will utilize this approach for those inspections. However, states will need to consider whether they will also implement this approach for their state inspections, or whether they will conduct their inspection to the regulatory requirements the firm has chosen to comply with.

If a state determines that the human food safety program is best suited to perform inspections of human food by-products for use as animal food, there may still be a need for expertise from the animal food safety program to support those inspection efforts. In general, the human food and animal food requirements in the Preventive Controls for Human Food and Preventive Controls for Animal Food regulations are the same. There are some differences in the types of hazards that need to be considered for human food and animal food. Animal food safety plans are not required to consider allergens as a hazard, but are required to consider nutrient toxicities and deficiencies as a hazard. In addition, there is more flexibility for compliance with the requirements in animal food facilities because of the wide variability in different types of firms manufacturing animal food for different species. For example, what may be acceptable for compliance with the human food by-products requirements for animal food going to a livestock species may be different than for animal food going to a pet species. As a result, there may be a need for the animal food safety program to provide information and training to the human food safety staff. There may also be a need for the animal food safety staff to be available for consultation when human food safety staff is reviewing a hazard analysis for human food by-products for use as animal food.

Another consideration is how the state regulatory agency will perform education and outreach to human food facilities with human food by-products for use as animal food. Some human food facility with human food by-products for use as animal food may not recognize themselves as animal food facilities subject to animal food regulatory requirements. Irrespective of which food safety program implements the requirements, it may be beneficial to consider leveraging the interactions a human food safety program area has with human food facilities to bridge any knowledge gaps in whether and how the animal food safety requirement apply to a human food by-products for use as animal food. The animal food safety program may need to develop and provide educational and outreach materials to be shared with the human food facilities by the human food safety staff, or may need to make animal food safety staff available for human food education and outreach events.
Appendix 3: Information Sharing

[Text under Development]
NASDA Model Animal Food Safety Implementation Framework
Appendix 4: Definitions

AAFCO OP: The association of American Feed Control Officials prints an annual Official Publication (OP) that contains a globally recognized positive list of animal food ingredient definitions and common names. It also contains model Bills and rules that governments can adopt to enable the consistent regulation of animal feed manufacturing and distribution. Membership is restricted to agencies that regulate animal food but meetings engage industry, consumers and regulators.

Adequate: that which is needed to accomplish the intended purpose in keeping with good public (human and animal) health practice.

Affiliate: any facility that controls, is controlled by, or is under common control with another facility.

AFIA: The American Feed Industry Association is the voice for the animal feed manufacturing industry. http://www.afia.org/

Animal Food: food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

Audit: means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Calendar Day: every day shown on the calendar.

Cooperative Extension: a non-formal educational program implemented in the United States designed to help people use research-based knowledge to improve their lives. The service is provided by the state's designated land-grant universities.

Correction: an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).

Critical Control Point: a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Education: the act or process of imparting or acquiring general knowledge

Environmental Pathogen: a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be
contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

**Facility:** a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

**Feed:** Material consumed or intended to be consumed by animals other than humans that contributes nutrition, taste, or aroma or has a technical effect on the consumed material. This includes raw material, ingredients, and finished products.

**Firm:** anyone who manufactures animal food

**Food:** food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

**Food-Contact Surfaces:** surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the animal food or onto surfaces that contact the animal food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and animal food-contact surfaces of equipment.

**FoodSHIELD:** a web-based system for communication, coordination, education, and training among the nation's food and agriculture sectors. This secure system allows animal and human health and food regulatory officials at the local, state, and federal levels across the nation to work together. It also helps communicate food safety information among other government agencies. [https://www.foodshield.org/](https://www.foodshield.org/)

**Full-Time Equivalent Employee:** term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours * 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

**Hazard:** any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.

**Hazard Requiring a Preventive Control:** a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and
components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

**Holding:** storage of animal food and also includes activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that animal food, such as fumigating animal food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that animal food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks.

**Inference:** The process of estimating a concentration or characteristic of a larger amount of material from data derived from a smaller amount of material. (Sources: GOODSamples: [http://www.aafco.org/Publications/GOODSamples](http://www.aafco.org/Publications/GOODSamples); and GOOD Test Portions: [http://www.aafco.org/Publications/GOODTest Portions](http://www.aafco.org/Publications/GOODTest Portions))

**Known or Reasonably Foreseeable Hazard:** a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food.

**Laboratory Quality Assurance (QA)** is an essential part of laboratory policy, which ensures that the feed laboratory consistently provides reliable and defensible analytical services. QA is designed to ensure appropriate laboratory quality control and quality assessment procedures are practiced and documented in an efficient and economic manner. The establishment of QA is the responsibility of the laboratory management. (Source: AAFCO Quality Assurance Quality Control Guidelines: [http://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories](http://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories))

**Laboratory Quality Control (QC):** The specific laboratory activities whose purpose is to measure and control the quality of the analytical data so it meets the needs of the feed program. (Source: AAFCO Quality Assurance Quality Control Guidelines: [http://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories](http://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories))

**Laboratory Quality Management:** The overall system of laboratory activities whose purpose is to provide assurance that the overall quality control activities are being done effectively. It involves a continuing evaluation of the laboratory procedures and results and performance of individual methods. (Source: AAFCO Quality Assurance Quality Control Guidelines: [http://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories](http://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories))
Laboratory Standard Operating Procedures (SOPs): Written procedures which describe routine laboratory activities in detail. SOPs are prepared for any routine activities that affect the overall quality and defensibility of analytical data. For Feed Laboratories, these activities include, but are not limited to, sample receiving and handling, analytical methods, standards preparation and calibration, instrument maintenance and calibration, laboratory safety, personnel training and analytical quality control (replicates, blanks, spikes, control samples, etc.). (Source: AAFCO Quality Assurance Quality Control Guidelines: http://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories)

Laboratory Sampling: All manipulations performed on the laboratory sample after receipt and acceptance through selection of the test portion. (Source: GOOD Test Portions: http://www.aafco.org/Publications/GOODTestPortions)

Laboratory Sampling Protocol: A detailed procedure for obtaining a test portion from a laboratory sample. The protocol includes appropriate mass, number of increments, sample correctness, quality control, and procedures for maintaining evidentiary integrity necessary to meet sample quality criteria. (Source: GOOD Test Portions: http://www.aafco.org/Publications/GOODTestPortions)

Livestock: includes cattle, sheep, horses, goats, and other domestic animals ordinarily raised or used on the farm. Turkeys or domesticated fowl are considered poultry and not livestock. Fish raised for human food are not considered livestock.

Lot: the animal food produced during a period of time and identified by an establishment's specific code.

Manufacturing/Processing: making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms: yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject animal food to decomposition, that indicate
that animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated.

**Mixed-Type Facility**: an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

**Monitor**: to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

**NGFA**: The National Grain and Feed Association, founded in 1896, is a broad-based, non-profit trade association that represents and provides services for grain, feed and related commercial businesses. Its activities focus on enhancing the growth and economic performance of U.S. agriculture. [https://www.ngfa.org/](https://www.ngfa.org/)

**Outreach**: an activity of providing services to any populations who might not otherwise have access to those services. Outreach has an educational role.

**Packing**: placing animal food into a container other than packaging the animal food and also includes repacking and activities performed incidental to packing or repacking an animal food (e.g., activities performed for the safe or effective packing or repacking of that animal food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

**Pathogen**: a microorganism of public (human or animal) health significance.

**Pest**: any objectionable animals or insects including birds, rodents, flies, and larvae.

**Plant**: the building or structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

**Preventive controls**: those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

**Preventive controls qualified individual**: a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

**Program**: An operational unit(s) in a regulatory agency that is responsible for the regulatory oversight of ANIMAL FEED
**Qualified Auditor:** a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

**Qualified End-User:** with respect to food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in 1.227 of this chapter) that:

(1) Is located:
   (i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or retail food establishment; or
   (ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

**Qualified Facility:** (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

**Qualified Facility Exemption:** an exemption applicable to a qualified facility under 507.5(d).

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

**Raw Agricultural Commodity:** has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

**Receiving Facility:** a facility that is subject to subparts C and E of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.
**Retail Food Establishment**: an establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

**Retail Feed Store**: A firm whose majority of animal food sales are to farm businesses. Animal Food sales to consumers are less than those to farmers or other businesses. These firms are subject to FDA food facility registration.

**Retailer**: See Retail Food Establishment

**Rework**: clean, unadulterated animal food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

**Sample**: A mass/volume of a material selected from a larger mass/volume of material using principles of Theory of Sampling. The word sample should only be used with a modifier as follows:

- **Primary sample**: The material taken from a decision.
- **Laboratory sample**: The material received by the laboratory.
- **Analytical sample**: The material from which test portions are removed.

(Sources: GOODSamples: [http://www.aafco.org/Publications/GOODSamples](http://www.aafco.org/Publications/GOODSamples); and GOOD Test Portions: [http://www.aafco.org/Publications/GOODTest Portions](http://www.aafco.org/Publications/GOODTest Portions))

**Sampling Protocol**: A sampling protocol is a detailed procedure for obtaining a representative sample from a specific decision unit that meets the sample quality criteria. The protocol includes appropriate mass, number of increments, sample correctness, quality control, and procedures for maintaining evidentiary integrity. (Sources: GOODSamples: [http://www.aafco.org/Publications/GOODSamples](http://www.aafco.org/Publications/GOODSamples); and GOOD Test Portions: [http://www.aafco.org/Publications/GOODTest Portions](http://www.aafco.org/Publications/GOODTest Portions))

**Sanitize**: to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable
microorganisms, but without adversely affecting the product or its safety for animals or humans.

Significantly Minimize: to reduce to an acceptable level, including to eliminate.

Small Business: a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

State Regulatory Personnel: State agency staff in direct contact with the regulated industry.

Subsidiary: any company which is owned or controlled directly or indirectly by another company.

Supplier: the establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Supply-Chain-Applied Control: a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Test portion: The quantity of material taken from the analytical sample (Sources: GOODSamples: [http://www.aafco.org/Publications/GOODSamples](http://www.aafco.org/Publications/GOODSamples); and GOOD Test Portions: [http://www.aafco.org/Publications/GOODTest Portions](http://www.aafco.org/Publications/GOODTest Portions))

Training: the action of teaching a person a particular skill

Unexposed Packaged Animal Food: packaged animal food that is not exposed to the environment.

Validation: obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification: the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Very Small Business: a business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).

Water Activity (wa): a measure of the free moisture in an animal food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.
**Written Procedures for Receiving Raw Materials and other Ingredients**: written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

**You**: the owner, operator, or agent in charge of a facility.
## NASDA Model Animal Food Safety Implementation Framework
### Appendix 5: Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AALA</td>
<td>American Association for Laboratory Accreditation</td>
</tr>
<tr>
<td>AAFCO</td>
<td>Association of American Feed Control Officials</td>
</tr>
<tr>
<td>AAPFCO</td>
<td>Association of American Plant Food Control Officials</td>
</tr>
<tr>
<td>AAFCO OP</td>
<td>Association of American Feed Control Officials Official Publication</td>
</tr>
<tr>
<td>AASCO</td>
<td>Association of American Seed Control Officials</td>
</tr>
<tr>
<td>ACLASS</td>
<td>Assured Calibration and Laboratory Accreditation Select Services</td>
</tr>
<tr>
<td>AFDO</td>
<td>Association of Food and Drug Officials</td>
</tr>
<tr>
<td>AFIA</td>
<td>American Feed Industry Association</td>
</tr>
<tr>
<td>AFRPS</td>
<td>Animal Feed Regulatory Program Standards</td>
</tr>
<tr>
<td>AFSIG</td>
<td>Animal Food Safety Implementation Group</td>
</tr>
<tr>
<td>AIHA</td>
<td>American Industrial Hygiene Association</td>
</tr>
<tr>
<td>AITS</td>
<td>AAFCO Advanced Inspector Training Seminar</td>
</tr>
<tr>
<td>ANAB</td>
<td>ANSI-ASQ National Accreditation Board</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>APA</td>
<td>Administrative Procedures Act</td>
</tr>
<tr>
<td>APHL</td>
<td>Association of Public Health Laboratories</td>
</tr>
<tr>
<td>ASQ</td>
<td>American Society for Quality</td>
</tr>
<tr>
<td>ASTHO</td>
<td>Association of State and Territorial Health Organizations</td>
</tr>
<tr>
<td>BITS</td>
<td>AAFCO Basic Inspector Training Seminar</td>
</tr>
<tr>
<td>BSE</td>
<td>Bovine Spongiform Encephalopathy</td>
</tr>
<tr>
<td>CE</td>
<td>Continuing Education</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>CGMP</td>
<td>Current Good Manufacturing Practices</td>
</tr>
<tr>
<td>CII</td>
<td>Critical Infrastructure Information</td>
</tr>
<tr>
<td>CLEAR</td>
<td>Council on Licensure, Enforcement and Regulation</td>
</tr>
<tr>
<td>CSG</td>
<td>Council of State Government</td>
</tr>
<tr>
<td>EPA</td>
<td>Environmental Protection Agency</td>
</tr>
<tr>
<td>FD&amp;C Act</td>
<td>Federal Food, Drug and Cosmetic Act</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FOIA</td>
<td>Freedom on Information Acts</td>
</tr>
<tr>
<td>FOIL</td>
<td>Freedom on Information Laws</td>
</tr>
<tr>
<td>FQS</td>
<td>Forensic Quality Services</td>
</tr>
<tr>
<td>FSMA</td>
<td>Food Association of Animal Feed Safety Modernization Act</td>
</tr>
<tr>
<td>FSPCA</td>
<td>Food Safety Preventive Controls Alliance</td>
</tr>
<tr>
<td>FSVP</td>
<td>Foreign Supplier Verification Programs for Importers of Food for Humans and Animals</td>
</tr>
<tr>
<td>FTE</td>
<td>Full Time Employees</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>GOODSamples</td>
<td>Guidance on Obtaining Defensible Samples</td>
</tr>
<tr>
<td>GOOD Test Portions</td>
<td>Guidance on Obtaining Defensible Test Portions</td>
</tr>
<tr>
<td>GRAS</td>
<td>Generally Recognized as Safe</td>
</tr>
<tr>
<td>HAACP</td>
<td>Hazard Analysis and Critical Control Points</td>
</tr>
<tr>
<td>IAS</td>
<td>International Accreditation Service</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>IFPTI</td>
<td>International Food Protection Training Institute</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>IFSS</td>
<td>Integrated Food Safety System</td>
</tr>
<tr>
<td>ISA</td>
<td>Single Signature 20.88 Long-Term Food Information Sharing Agreement</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>LIMS</td>
<td>Laboratory Information Management System</td>
</tr>
<tr>
<td>LMS</td>
<td>Learning Management System</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>NASDA</td>
<td>National Association of State Departments of Agriculture</td>
</tr>
<tr>
<td>NCS</td>
<td>National Curriculum Standards</td>
</tr>
<tr>
<td>NCSL</td>
<td>National Conference on State Legislatures</td>
</tr>
<tr>
<td>NGFA</td>
<td>National Grain and Feed Association</td>
</tr>
<tr>
<td>NVALP</td>
<td>National Voluntary Laboratory Accreditation Program</td>
</tr>
<tr>
<td>OOB</td>
<td>Out of Business</td>
</tr>
<tr>
<td>OP</td>
<td>AAFCO Official Publication</td>
</tr>
<tr>
<td>ORA</td>
<td>Office of Regulatory Affairs</td>
</tr>
<tr>
<td>OTED</td>
<td>FDA Office of Training, Education and Development</td>
</tr>
<tr>
<td>PC</td>
<td>Preventive Controls</td>
</tr>
<tr>
<td>PCAF</td>
<td>Preventive Controls for Animal Food (i.e. the regulation known as FDA’s Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Animal Food)</td>
</tr>
<tr>
<td>PCQI</td>
<td>Preventive Controls Qualified Individual</td>
</tr>
<tr>
<td>PFI</td>
<td>Pet Food Institute</td>
</tr>
<tr>
<td>PFP</td>
<td>Partnership for Food Protection</td>
</tr>
<tr>
<td>PJLA</td>
<td>Perry Johnson Laboratory Accreditation</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
</tr>
<tr>
<td>---------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control</td>
</tr>
<tr>
<td>RRT</td>
<td>Rapid Response Team</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>TWG</td>
<td>Technical Working Group</td>
</tr>
<tr>
<td>USDA</td>
<td>United States Department of Agriculture</td>
</tr>
<tr>
<td>VFD</td>
<td>Veterinary Feed Directives</td>
</tr>
<tr>
<td>VM</td>
<td>Veterinary Medicine</td>
</tr>
</tbody>
</table>
American Feed Industry Association (AFIA)
http://www.afia.org/

Animal Feed Regulatory Program Standards (AFRPS)
https://www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/regulatoryprgmstnds/ucm475063.htm#AF2

Association of American Feed Control Officials (AAFCO)
https://www.aafco.org/

FDA Animal & Veterinary Website
https://www.fda.gov/AnimalVeterinary/default.htm

Food Safety Modernization Act (FSMA) website
https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

National Grain and Feed Association (NGFA)
https://www.ngfa.org/

NC State University Feed Science Program and Feed Mill Education Unit
https://projects.ncsu.edu/project/feedmill/feedmill.html

Pet Food Institute (PFI)
https://www.petfoodinstitute.org/