NASDA Model
Food Safety Modernization Act Preventive Controls for Animal Food Regulation 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

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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 grateful for the contributions of FDA staff, AAFCO, and state animal food safety professionals for their significant interaction during the development of this framework. The federal/state dialogue improved the overall quality of our efforts.

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Introduction

The National Association of State Departments of Agriculture (NASDA) Model Food Safety Modernization Act Preventive Controls for Animal Food (PCAF) Regulation Implementation Framework contains the fundamental and essential components for the operation of a state animal food safety program that can fully implement Food and Drug Administration (FDA) Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Animal Food regulation (Preventive Controls for Animal Food 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). "NASDA PCAF Framework" is used through this document as shorthand for the name of the framework. "PCAF" is used to encompass all parts of 21 CFR part 507.

The PCAF regulation, as well as this framework, establishes preventive actions to ensure the safety of animal food[1] in an effort to protect animal and human health. The goal of the NASDA PCAF Framework is to provide the foundational knowledge and support to any state considering implementation of a Food Safety Modernization Act (FSMA)-aligned animal food safety program.

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

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	Compliance and Enforcement
Chapter 8	Laboratory Services
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 NASDA PCAF Framework in an extensive collaborative and consensus-building effort through a 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

[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."

members of states with programs of differing size and of 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 NASDA PCAF 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 NASDA PCAF 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 (e.g., education, training, outreach, inspection). The decision on the scope of implementation completed by the state will be made 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. Although the FDA has been involved with the review of this document, this should be viewed as a NASDA document, offering advice to the states (i.e., it is not an FDA document *per se)*. We appreciate the advice, counsel, and recommendations from our FDA colleagues as they measurably improved the NASDA PCAF Framework chapters. This document is considered a living document, one that is destined to be improved over time to allow for improvements that account for advances in technology and experience with implementation. The revision schedule of this document will be decided after its initial release.

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 NASDA PCAF Framework is to provide the foundational knowledge and support to any state considering implementation of such an FSMA-aligned animal food safety program.

Without the commitment from NASDA members and the voluntary involvement of state staff members, this document would not yet be in draft form. Many thanks are extended to 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,

[2] http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm395677.htm

commenters, and reviewers. Your knowledge and passion have made this effort more rewarding. Thank you also to the FDA staff for their contributions. The dialogue improved the overall quality of our efforts.

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Background
Animal Food Regulation, FSMA, and Impact of PCAF

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 100 years. FDA's authority was established in 1906, and some state agencies had regulations in place before 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 animal food is part of the 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 that under United States Department of Agriculture (USDA) jurisdiction—is safe, wholesome, and labeled properly. State agencies are responsible for ensuring that animal food within their jurisdictions is safe and complies 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?

Although the United States has had one of the safest food supplies, there were several significant foodborne illness outbreaks have 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 provided 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 gave FDA important new tools to better ensure the safety of imported human and animal foods and directed 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 industries. 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:

1. 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
2. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (a.k.a. FSVP), 21 CFR part 1, subpart L
3. Sanitary Transportation of Human and Animal Food, 21 CFR part 1, subpart O
4. 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, which is found in 21 CFR part 507. There are six subparts within the regulation:

- Subpart A – General Provisions
- Subpart B – Current Good Manufacturing Practice
- Subpart C – Hazard Analysis and Risk-Based Preventive Controls
- Subpart D – Withdrawal of a Qualified Facility Exemption
- Subpart E – Supply-Chain Program
- Subpart F – Requirements Applying to Records That Must Be Established and Maintained

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 (*cGMP*) 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 that facilities have a food safety plan, conduct a hazard analysis, and implement appropriate preventive controls to ensure control of hazards that can affect both animal and human health.

As regulators, we are obligated to protect the safety of the US 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 affect 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. Whereas 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, often in the kitchen. A pet food contaminated with a pathogen of human health concern 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 US animal food supply has a history of safety, 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 produced by many species of the fungus *Aspergillus* on certain agricultural commodities. Since their discovery in the early 1960s, 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 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 that those companies 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, a mineral premix manufacturer purchased a trace mineral that was a by-product of a metal smelting process. Dioxin contamination is not limited to the US 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 of 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. Although 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 bloodstream and ultimately resulted in accumulation of crystals in the tubules of the 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, it was 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, that food 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 on 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 the FDA before they can be marketed for administration to animals. Although 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 of an animal food resulting from the use of a raw material that contains drug residues. Depending on the chemical property of the drug, residues 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 a 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 and aqueous environments, and it 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 requires, in part, that facilities making medicated feed take steps to ensure adequate clean-out of their equipment in order to maintain proper drug levels and to prevent 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 clean-out 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 who handle that contaminated animal food. Microbial contamination is primarily a concern with pet food because it has the potential to come in direct contact with 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, *Salmonella* 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 food, representing 105 brands. While no illnesses in pets were reported, 79 people in 21 states reported illness 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 of product testing by multiple agencies, along with production codes provided by ill people, 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 United States. As regulatory officials, we 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 Regulation 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, including licensing and registration, label reviews, and inspections and sampling. Inspections are performed 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 versus 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 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 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 CGMPs beyond just medicated feed, redirecting sampling and testing to focus on animal food hazards, training or hiring staff who have the 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 comply with the new regulations.

Chapter 1: Alignment and Consistency

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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—although different from the intent of the NASDA 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 approaches consistent with the funding opportunity announcement guidelines. To aid in harmonization efforts and building toward the future, implementation of the PCAF regulation must be a shared responsibility among 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 their existing 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. Some states will need 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 NASDA PCAF Framework address specific elements that a state animal food safety program will need in order to fully implement the PCAF regulation. This chapter outlines current, ongoing efforts 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 a foundation exists for effectively implementing the PCAF regulation and that 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 is not in its infancy. Most states have well-

established programs that have a deep-rooted 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 NASDA PCAF Framework. As many state programs are currently not identical, state programs can be expected to take different approaches in how they implement 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. Many partners within an IFSS need to work within 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 that they are focusing their resources and attention appropriately and effectively.

As state programs consider implementation of the PCAF regulation, the NASDA PCAF Framework allows flexibility for implementation. However, a systematic approach to development and implementation is needed to build a successful program that protects animal and human health. Even though state programs differ, if each 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 to ensure high rates of compliance with the regulation. Furthermore, the need to develop a systematic inspectional approach to assessing industry compliance with the PCAF regulation will ensure consistency in implementation of PCAF regulatory programs across the country. 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 program's activities with the PCAF regulation supports the shared goal of gaining compliance with the PCAF regulation; in turn, 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 this document. The NASDA 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 NASDA PCAF Framework

The focus of the NASDA PCAF Framework, and 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 NASDA PCAF Framework is to provide foundational knowledge and support to any state implementing an FSMA-aligned animal food safety program. Human and animal health benefits of a PCAF regulation program can be accomplished through multiple approaches; for example, 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 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, both among states and within a state. Elements, structures, processes, and practices must all align with the shared goal to implement an FSMA-aligned animal food safety program.

Much of the PCAF framework calls for self-assessment, identifying questions that programs should ask themselves. The answers are not intended to verify adherence to a specific program standard; rather, 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 (PFP), 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, provides 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

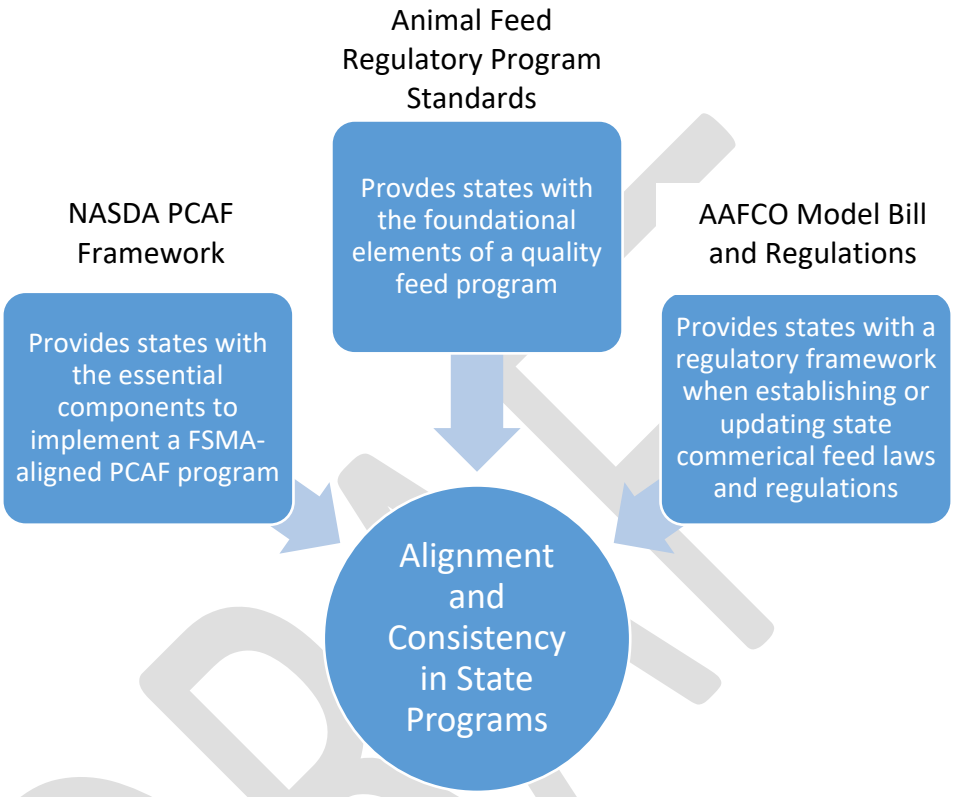
composed of 11 standards that serve as an objective framework to evaluate and improve components of a state program. The standards cover the state program's regulatory foundation, training, inspection program, auditing, feed-related illnesses or death and emergency response, enforcement program, outreach activities, budget and planning, laboratory services, sampling program, and assessment and improvement of standard implementation. Although implementation of the AFRPS is voluntary, state programs that 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 NASDA PCAF Framework.

The development of state 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 when they are administered uniformly and equitably. AAFCO developed, and continues to update, a Model Commercial Feed Bill and Regulations as a regulatory framework to assist states when establishing or updating commercial feed 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, resulting in 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 state feed laws and regulations. Although the AAFCO Model Bill and Regulations have not been passed into law in all states, the subject matter covered within does represent the official policy of the Association. The AAFCO Model Bills and Regulations are supported 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, defining common or unusual ingredient names, and the development of education, training, and outreach.

The focus of these different harmonization documents (NASDA PCAF Framework, AFRPS, and the work of AAFCO) vary in application; however, collectively they are designed to promote uniformity and consistency among state programs. AAFCO, through their Model Bill and

Regulations and other work, provides uniform guidance to individual members when establishing their individual state's laws and regulations. AFRPS ensures a uniform and consistent approach among state animal feed programs, and the NASDA PCAF Framework provides 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. This document provides a uniform and consistent approach to building a PCAF program, but states will 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 second step is 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 third step is to implement these strategies. Implementing these strategies would result in a state having a fully developed PCAF program that includes 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 this document, 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 NASDA 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 on existing harmonization efforts to create uniformity and consistency while developing the individual elements of a PCAF regulation implementation program as outlined in this framework.

Chapter 2: Foundation of Law

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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 or modifying 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 by which to adopt, develop, or amend a state program. If a state intends to implement or align an existing program with a federal regulation, the 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).

2. Background

State programs have historically been involved in animal food safety regulation, including programs with oversight of pet food, medicated feed, and 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 AFRPS Cooperative Agreement is available on FDA's website.[3] If states seek to align existing programs 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.

Statutory authority provides the state agency/program with the legal authority to implement an animal food safety program. This statutory authority may include components such as authorization for the agency to carry out a program, specific legal standards for regulated animal food or animal food firms, the remedies or enforcement actions the agency can take to support the program, or the ability to promulgate rules in support of animal food safety.

3. Purpose and Scope

This chapter addresses the legal and regulatory components that must be in place for a state animal food program to implement, administer, or align a program with the PCAF regulation published in September 2015 (21 CFR part 507). This chapter references other pertinent chapters of the NASDA PCAF Framework, developed through NASDA. This chapter should be considered 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: https://www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/regulatoryprgmstnds/ucm475063.htm#AF2

4. Roles and Responsibilities

State Agency Responsibilities

Regarding existing programs, states fall 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 similar agency
- States considering future authorities and institutional relationships
- States not yet considering future authorities and institutional relationships

Depending on 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, whereas 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 taking 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 Section 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

[4] The FSMA regulations that have been published and are specific to human food are the regulations for Preventive Controls for Human Food (21 CFR part 117), Produce Safety (21 CFR part 112), and the Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR part 121).

needed, the state is responsible for drafting appropriate statutory and/or regulatory language for a program that 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 Chapter 3: Infrastructure and Financial Resources 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 curricula for federal and state personnel implementing the PCAF 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 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 implementation of the PCAF regulation.

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 that plan to implement the PCAF regulation must ensure that four primary components are present. The four crucial components are 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 Legal Foundation for a State Program

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

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. Statutory authority can give a state the legal foundation to promulgate rules, as necessary, and to conduct the work provided for in the authorization. In certain states, statutory authority provides the legal authority to implement the animal food safety program, and rulemaking may not be necessary.

The necessary legal authority may include the need for appropriations, or spending authority, to do the work as well, even when the federal government is providing resources. 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 will 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 a program 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 AAFCO 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

If a state chooses to adopt federal regulations through rulemaking, then that state may need to comply with the state's Administrative Procedures Act (APA). Some states have an APA that establishes procedures and requirements for developing regulations. In addition, states may be able to adopt federal regulations by reference—in whole or in part. Some states permit automatic adoption of critical rule changes, whereas others require specific consideration of each subsequent change. States should consider incorporating language similar to that of the federal FD&C Act and the PCAF regulation for uniformity. Each state should carefully review their ability to adopt the PCAF regulation to ensure a mechanism exists to keep the regulation current with federal changes.

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. 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 already have 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 for Animal Food Safety Authority

Because many states already have a program, most states have the legal authority to enter an 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, nongovernmental organizations (e.g., laboratories, universities), and the federal government, such as FDA. If intrastate memoranda 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 that 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 their ability to protect animal and human health.

State agencies may exchange nonpublic 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 nonpublic 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 nonpublic 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 the state agency must be approved in advance by FDA. A database of state and local agencies that have entered into an ISA is available 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, a 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 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, whereas others 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, whereas other states must adopt the CFR as it exists on a certain date and must make updates when additional provisions are added. 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. Although some states may consider only adopting certain provisions of the PCAF regulation, 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 with 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 as follows:

> **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.

[5] Database of agencies with 20.88 Single Signature Agreements: http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=singlesignaturefood&displayAll=true

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

Because 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 animal food regulatory authority is split between agencies, it is important for these state agencies to coordinate responsibilities. An MOU or other predetermined agreement may be the appropriate mechanism to transfer specific and limited authority or responsibility to another agency when responsibilities are shared among agencies or where the primary food safety agency does not anticipate implementing a program.

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 3, 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 that 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 whether 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.

Chapter 3: Infrastructure and Financial Resources

Table of Contents

1. Executive Summary

This chapter defines and examines the needs for a resource and infrastructure assessment before a state program implements the PCAF regulation. Considering the various types and sizes of state programs throughout the United States, this chapter provides an overview of how an agency would strategize its program to implement the PCAF regulation so the state can develop and implement a program that best fits their needs. This chapter also discusses additional financial support that will be required for states to develop a PCAF program. When applicable, this chapter references topics that have been discussed in other chapters (e.g., 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 the initial overall cost of funding required for states to develop and/or implement a national animal food safety program to be at least $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 this document and include 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 an FSMA animal food safety program.

3. Purpose

This infrastructure assessment is an evaluation conducted by the state program to identify any possible resource 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 annually.

The goal of the proposed funding model is to establish a flexible means by which 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, AFRPS, 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 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: Alignment and Consistency) 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. In the long term, sufficient funding to maintain infrastructure needs for all states is necessary, with consideration of 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 at least 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 other programs are added (e.g., VFDs or other FSMA regulations), additional flexibility to incorporate new program dimensions into a new funding matrix or 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), to accomplish program goals based on volume of inspections, funding constraints, and anticipated demands (time and effort). AFRPS Standard 8 provides a model that a state program can use to calculate their inspection staff needs. The determination should include staff needed in the following areas:

a. Inspections and investigations (including follow-up inspections and surveillance activities)
b. Sampling activities (including sampling conducted by the state program) (see Chapter 5: Education and Outreach and Chapter 6: Inspection Program Planning)
c. Auditing (e.g., financial, inspection, metrics)
d. Outreach
e. Compliance and enforcement
f. Laboratory support

Please refer to the discussions in Chapter 5: Education and Outreach 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 used must be able to address the state's current needs and have the capability to interface with current and future systems or solutions of other programs and agencies, if possible. States may also require a technology system that can expand to encompass future projects and workloads in all program areas that a state agency regulates. For example, the technology system should be expandable as needed because it may also need to function with other program areas such as seed, fertilizer, pesticide, and/or other food safety program areas. A system may also need to

interface with other federal programs such as FDA, USDA, and the Environmental Protection Agency (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. Some state governments must use state information technology (IT) systems, whereas others may be able to participate in other solutions. 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: Technology equipment needs to be compatible with the technology system or solution that a state program uses. The technology system/solution cannot function properly without the appropriate equipment. Technology changes rapidly and a program must be able to adapt. When assessing technology equipment needs, the state program should recognize that the functional and physical lifespan of most electronics is 3 to 4 years. While the technology system or solution mentioned above in Section 5.2 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 security:

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 onsite functions
g. Wi-Fi–enabled smart phones and cameras

State programs should address policy concerns regarding security of the above technology equipment.

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 the following:

a. FDA CGMP Regulator and PC Regulator Training
b. Food Safety Preventive Controls Alliance Course—PCAF Course
c. Other courses required under a state program's training plan

5.5 Inspection Equipment, Materials, and Supplies: Before the start of inspections for compliance with the PCAF regulation, the equipment, materials, and supplies needed to conduct inspections should be evaluated. 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 ensure 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 who 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 (e.g., probes, bags, forms)
c. Personal protective equipment
d. Other inspection equipment, such as the equipment listed in AFRPS Appendix 8.3

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 from a contract laboratory. The infrastructure assessment of laboratory support should include

a. Adequate facilities (e.g., space, utilities, meets safety and security needs)
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. A laboratory information management system compatible with needs

Please refer to the discussions in Chapter 8: Laboratory Services 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 the following:

a. Potential for expansion (through purchase or lease) of existing structures or building facilities. Types of facilities to consider include
    i. Administrative
    ii. Field
    iii. Laboratory facilities
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 over the long term. The infrastructure assessment of program support should include the following:

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.

Please refer to the discussions in Chapter 2: Foundation of Law for a detailed discussion on the legal and regulatory components needed to implement the PCAF regulation.

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 an 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) for 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 will provide assistance as appropriate 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

Chapter 4: Regulator Training

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1. Executive Summary

This chapter outlines the need for state programs to develop a comprehensive training program for 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.

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.

2. Purpose and Scope

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 make sure 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, develop or update a state training plan, 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.

The purpose of a state program's PCAF training plan is twofold:

(1) 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
(2) 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. Competencies important for the success of inspection staff could include development and reinforcement of critical thinking skills and the importance of uniform and consistent standard

operating procedures (SOPs) and other procedures between state and federal animal food safety programs. 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 of a state program. Training can be phased to align short-, mid-, and long-term needs that support capacity development efforts based on the knowledge and experience of a state's inspectional staff.

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

3. Background

Training for animal food regulators has been well established due to the long history of regulation of animal food at both the 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.

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; to develop training to include inspectional approach, regulatory strategies, sampling procedures, and best practices; and to improve upon the system-based approach to an inspection. The section also provides opportunities such as the NASDA PCAF Framework, which 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.

Before performing PCAF inspections, inspectors will need specialized training to ensure comprehension of the new regulation and consistency in inspectional approach. Several training initiatives 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, several training initiatives already underway can be leveraged when developing or updating a state's training program. Some of these initiatives were developed strictly for training on the PCAF regulation, whereas others are not geared directly toward PCAF but are meant to supplement those courses to ensure a well-rounded inspection, compliance, and administrative staff.

PCAF regulation-specific training:

- PCAF regulation-specific FDA training courses
- Food Safety Preventive Controls Alliance (FSPCA) – Preventive Controls for Animal Food Course

Non-PCAF-specific training programs or initiatives that may benefit PCAF regulatory programs:

- Non-PCAF FDA Regulator Courses
- Association of American Feed Control Officials (AAFCO)
- AFRPS Standard 2: Training
- National Curriculum Standards (NCS) and the Partnership for Food Protection (PFP)
- National Certified Investigator and Inspector Training
- International Food Protection Training Institute (IFPTI)

PCAF Regulation-Specific FDA Training Courses

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

- Current Good Manufacturing Practice for Animal Food Regulators
- Preventive Controls for Animal Food Regulators

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 the Office of Training, Education, and Development's (OTED) 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 this course 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, other animal food safety staff with FDA and state programs may find benefit in attending the course. The course is a 3.5-day in-person training.

A Preventive Controls for Animal Food Regulators course has been developed. To attend this course, participants must complete the required prerequisites. The prerequisite courses for attending this course include the CGMP for Animal Food Regulators course, Regulatory Foundations of PCs for Food for Animals (online), and FSPCA Preventive Controls for Animal Food (before 2018: face to face; blended in 2018: online and face to face). A list of these courses can be found in OTED's learning management system (LMS) called Pathlore.[6] The primary audience for this course is inspection staff; however, other animal food safety staff with FDA and state programs may find benefit in attending 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 and Preventive Controls for Animal Food Regulators) will be offered regionally

[6] https://orauportal.fda.gov/stc/ORA/psciis.dll?linkid=720650&mainmenu=ORA&top_frame=1

by an FDA-trained instructor cadre consisting of both state and federal staff who 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 maintained and updated to ensure accuracy and consistency with the PCAF regulation and scientific data.

Current and future training will consist of courses offered through AAFCO, online training courses through FDA's 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.

Food Safety Preventive Controls Alliance (FSPCA)– Preventive Controls for Animal Food Course

FDA partnered with the 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 the primary audience for this course is the regulated industry. For industry, the course is optional, as completion of the course is not specifically required by the regulation and there are other ways to become a PCQI (e.g., other training or on-the-job experience). For regulators, the course is required training for all staff completing PC inspections under an FDA contract or cooperative agreement. FDA encourages regulatory personnel to attend this course and requires the course for FDA investigators and state personnel conducting PCAF contract inspections as a prerequisite for attending FDA's Preventive Controls for Animal Food Regulators course and subsequently performing PC inspections. The FSPCA PCAF course is offered in multiple formats, including a 2.5-day in-person course, a blended learning format with a combination of web-based training and in-person training, and an online-only format. The course covers, through lecture and exercises, both the requirements of the regulation and principles of development and application of risk-based preventive controls. Ideally, both industry and regulatory personnel are included in the same course, which provides greater learning opportunities for both audiences.

FSPCA has also created an online course to help industry, particularly small and very small businesses, implement the CGMP requirements of the PCAF regulation. FDA has not required this course for FDA staff or state personnel conducting inspections under contract. However, this course may be a resource for state programs looking for additional training on CGMPs.

Non-PCAF-Specific Training Programs or Initiatives

FDA Regulator Training

In addition to the PCAF regulation-specific training courses, FDA offers many other courses that could benefit a state program; many of these courses are prerequisites for the PCAF-specific courses. These courses include but are not limited to the following:

- Grain and Feed Mill Inspections
- Bovine spongiform encephalopathy (BSE)

- CGMP for Medicated Feed Inspections
- Regulatory Foundations of Preventive Controls

AAFCO

AAFCO's involvement with 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 new and experienced inspectors 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 represents a collaboration of three associations: AAFCO, the Association of American Plant Food Control Officials (AAPFCO), and the Association of American Seed Control Officials (AASCO). Inspector manuals are distributed by all three associations and included with BITS. The AAFCO Feed Inspector's Manual can be found on the AAFCO website[7] 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.

AFRPS Standard 2: Training

The AFRPS Standard 2: Training[8] 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 (coursework and field training) and continuing education upon completion of basic or advanced training. As states develop their training plans, they may incorporate AAFCO's BITS and AITS courses, college courses, and FDA courses to fulfill the coursework requirements of AFRPS Standard 2.

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 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

[7] http://www.aafco.org

[8] https://www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/regulatoryprgmstnds/ucm475063.htm

efficiencies will be built in, including online and blended learning activities and instructor-led skills courses. While participation in face-to-face courses may require funding for travel, online courses will also be available to minimize travel costs. The NCS can be leveraged, as appropriate, and assist states in saving training time and cost.

The NCS consists of two primary components: (1) Competency Framework, and (2) Curriculum Framework. 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 (e.g., training, courses), 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, 25 courses 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 simultaneously building 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 before implementation. Getting an inspector credentialed could take a considerable amount of time and effort. Once an inspector is credentialed, continuing education will be needed to maintain the credential.

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)[9]. 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 who have attended. This training is held in various locations around the country. The cost to attend the course could be reduced if an event were held near or in your state.

International Food Protection Training Institute

The International Food Protection Training Institute (IFPTI) works in assisting food safety professionals solutions to address issues of concern. States may choose to leverage IFPTI if they decide to develop their own training curriculum. The niche IFPTI often fills is developing curricula and materials that do not exist elsewhere, and it adds value by rounding out the training available. Resources are available through IFPTI[10] that are focused on adult learning and instructor skill training.

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 short-term and longer-term strategies.

Short-term strategies are those that need to be put into place by states—while developing their long-term strategy—to implement training to support the PCAF regulation. Short-term strategies can address the need 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

[9] http://www.clearhq.org
[10] https://ifpti.org/

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. Activities that should be considered in short-term strategies include the following:

- 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 the following:

- 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
- LMS needs to track completion of training
- Assessment of inspectional performance and improvements through FDA/state auditing

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 developing and delivering training. If a state program will develop and deliver the training internally, they need to ensure they have educational experts who are familiar with adult learning concepts, have the necessary subject matter expertise to develop the training, and have skilled instructors to deliver the 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. A sustainable training program could also address the need to develop specific job opportunities and levels for retention of trained staff.

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 levels. To ensure knowledge of the PCAF regulation and uniformity and consistency in inspectional approach, FDA has overseen development of 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 IFSS, these courses were developed with input from state animal food safety regulatory personnel.

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

Chapter 5: Education and Outreach

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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 and education programs, the PCAF regulation will require stronger connections between the state programs and stakeholders. The state program should develop an outreach and education 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, several other groups 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 contact 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. 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. 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, nor does it cover training for staff to be able to conduct outreach, as that topic is covered in Chapter 4: Regulator Training.

3. Background

FSMA, and specifically the PCAF regulation, has fundamentally changed the way the United States 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 was not required to operate under CGMPs before 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 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 resources available 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 regulations, including the PCAF regulation, puts 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, some facilities that were not previously in contact with their state program are now covered by the PCAF regulation. To ensure successful implementation of the PCAF regulation, it will be important for state programs to provide outreach to facilities that had not previously been under state oversight (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 who 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 has traditionally been driven by enforcement actions. But we realize that education can also encourage compliance. An **"educating before and while regulating"** concept incorporates the 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. A state's outreach program will rely on public information to explain the PCAF regulation (and, where appropriate, other FSMA-related regulations).

Although the state program may be the primary outreach contact for animal food facilities, other entities that conduct outreach 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 and other third-party educators.

4. Outreach and Education Plan

Outreach and education should have different activities and goals for a state program. A state program's outreach is defined as an activity of providing knowledge to stakeholders who might not otherwise have access to or awareness of that information or may have access and awareness but need additional information. One goal of an outreach program is to deliver and impart knowledge, especially on technical information or emerging issues. Education should be provided to internal stakeholders, such as state program staff, so they are aware of how their job relates to the PCAF program and have the knowledge required to perform outreach activities to external stakeholders, if needed.

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. This 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; it 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 working to gain industry compliance. After the initial phase, outreach will focus on assisting the industry with gaining and maintaining compliance.

Although 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 and plan. Outreach and education plans should, at a minimum, include the objectives of the plan, the target population, types of activities (including delivery), and objective of a specific activity. States participating in the AFRPS have been working to develop outreach and education plans as outlined in Standard 7: Outreach Activities. Those outreach plans can be modified to include outreach and education on the PCAF regulation. Whereas some state programs may have formal outreach and education programs, others conduct outreach and education in a less formalized manner. Those states should consider developing formalized outreach and education 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 implement a PCAF regulation outreach and education plan. Outreach and education plans should deliver the knowledge needs identified in this document using an appropriate delivery method.

A state program's outreach and education plan will use an action item for delivering educational needs (knowledge) to each audience identified in the plan. The vision is that the majority of industry outreach will be provided one-on-one by state animal food inspectors. Other audiences will be served using other 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. It is also important to establish benchmarks to measure how successful the outreach and education plan is and determine whether revisions to the plan are necessary.

5. Outreach and Education Plan Target Audience

5.1 Overview

The state program's outreach and education 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. Additional industry stakeholders who should be included in the outreach and education plan include livestock producers and pet owners. 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 and Education Needs by Audience

State Agencies

State program staff, both regulatory and nonregulatory (including managers and information officers), who may interact with the animal food industry should have basic knowledge of the PCAF regulation and how to apply it. As a result, a primary **internal audience** for a state program's outreach and education plan should be their own agency and staff. One means for state program to obtain basic knowledge of the PCAF regulation is to attend the FSPCA-PCAF course. State program staff who 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 who 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 **external 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 application of 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 educational material that a state program could provide to facilities might be 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 in 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 has 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's staff 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 assesments. 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.

Some animal food facilities 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, nor have they been inspected by either the state program or FDA. These facilities may have a general lack of understanding of animal food regulations. 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 Additional External 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 should be aware of the animal food supply chain as it affects safety. In addition, as part of supporting an IFSS, farmers purchasing complete feed should be aware of whether their suppliers are complying with current animal food safety regulations. Unsafe animal food can affect their animals and may impact the food supply if the unsafe animal food contaminates meat, milk, or eggs from their animals.

Engagement with livestock producer associations, cooperative extention agents, universities, animal food trade associations, veterinarians, and human food processor trade associations will need to be included in the state program's outreach and education plan. These groups can engage in the development of educational materials, leverage private educational resources, and encourage implementation of the PCAF regulation and state program funding support. These entities will also need to be engaged to reach very small firms as well as mobile

operations manufacturing animal food on farm. Some of these very small firms may need access to the FSPCA-PCAF course or to a state CE program. Other stakeholders who may require specific outreach efforts include consumers and pet owners.

6. Outreach and Education Plan Delivery

6.1 Outreach Delivery Overview

State programs should leverage existing outreach and education plans when considering methods for delivery of outreach. The delivery methods could be a mix of 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 face to face during an inspection. State inspectors have the ability to direct firms to resources that will help them 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 before 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 to their website. 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, whereas others 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 with stakeholders. Opportunities exist for capitalizing on existing meetings already conducted by the state program or on 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., asking questions or responding to questions), and it is recommended that the state program has a means to document who has completed the webinar. AAFCO has an 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 will be necessary to provide knowledge of the PCAF regulation so that these firms can work to gain and maintain compliance. To reach these firms, creation of a new position is recommended: 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 through coordination with academia, industry trade associations, the FSPCA Technical Assistance Network, and the FDA Technical Assistance Network (TAN). Such 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; for example, publications, brochures, websites other than that of a state program, and so on. 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 PC validation). It is recommended that state programs leverage material that is made available for distribution in Feed BIN, FoodSHIELD, or AAFCO's website and consider contributing outreach materials to these existing resources.

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 and education plan. The novel tools include CE requirements, incentive programs, and

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 on 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 United States, 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 have created the most confusion for 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 those 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) but do not need to be elaborate. Some can be as simple as a narrator conducting a webinar and including any needed facts or images. If using webinars as a method for CE, they should be recorded and available for a defined period of time (e.g., several years). Webinars should be approximately 1 hour long for each CE credit. To assess knowledge gain during the webinar, it should include an online quiz and evaluation; additionally, a standard for the required number of correct answers could be developed before awarding CE credits.

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

6.3.3 Optional Incentive Programs

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 frequency 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 the following:

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), or via 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. Conducting 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 a 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 the facility agent as observed.
        b) Educate the 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 generally taps into marketplace demand by informing various animal food customers (e.g., animal food producers or consumers) about the PCAF regulation. We have seen in the human food industry 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 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.

Nontraditional 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

Funding provided to support efforts to develop and deliver industry outreach, education, and technical assistance, as well as to support regulator training, begins in step 2. Some animal food regulatory programs may have a coordinating role in education, whereas in other states, the education function may be completely separate from the state agencies. 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 shared 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 implementation of the PCAF regulation. This section identifies regulatory and other partner entities associated with the PCAF regulation as well as 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, responsibilities include the following:

- Develop an outreach and education plan for the PCAF regulation, either by adding to existing outreach and education plan or developing a new plan, that should at a minimum include the objectives of a plan, the target population, types of outreach activities (including delivery method), and objective of a specific 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 nonregulatory 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 include the following:

- Website page
- Information on activities to engage industry and support compliance (e.g., CE program, incentive program(s), and upstream outreach)
- Publications, handouts, or brochures if identified as a valuable outreach tool in the outreach and education 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 the following:

- Providing timely food safety information within existing security constraints and proprietary information requirements
- Providing technical support to state programs as they develop their outreach and education plan materials
- Supporting FSPCA course content and deployment and supporting state program staff (i.e., not inspectors) who need to attend the course to develop the base knowledge used to support the goals of the outreach and education plan

- Developing outreach materials that will advance both the animal food industry's 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 include

- Guidance documents to industry ahead of implementation of regulatory inspections
- Fact sheets
- Frequently asked questions based on information received through FDA's TAN

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, submit ongoing feedback regarding

the effectiveness of implementation strategies, and accept responsibility for their role in the safe manufacturing and distribution of animal food.

Members of academia are seen as subject matter experts on food safety topics generally and as a resource for identifying best practices for regulators and industry. Thus, academia will play a critical role in outreach, education, and training of both the regulators 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 organizations are also responsible for disseminating information to members and for participating actively and collaboratively in PCAF regulation implementation.

The stakeholders' recommended roles 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.
- Researching information on validation and PC 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 and education 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 and feed labeling guides.
- Providing information to establish a common name for ingredients.

NASDA Responsibilities

- Developing 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, and so on.
- Coordinating efforts with cooperative extension to provide education to the animal food industry.
- Working with associations through their regional network to coordinate with FDA to find synergistic opportunities for implementing the PCAF regulation.

Chapter 6: Inspection Program Planning

Table of Contents

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. The chapter is designed for state programs that take the lead in implementing 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, including routine and for cause inspections. 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 and Outcomes

There should be joint inspectional strategies between the state program and FDA to ensure consistency and uniformity in implementation of the PCAF regulation. Sharing consistent inspectional approaches and data collection strategies will help prevent 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 to 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 IFSS. 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 this 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 NASDA PCAF Framework is intended to assist a state animal food program 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 an 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.

A standardized approach to PCAF inspections should be utilized among all states and FDA to ensure consistency across the country (under future development).

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. Before 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 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 at least annually 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 IFSS. 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 IFSS.

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 allow for efficient use of time and resources when satisfying work plan requirements. A variety of approaches are available 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. 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 NASDA 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

- Feed license and registration information
- Dunn & Bradstreet
- Inspection reports
- FDA inventory lists
- Feed tonnage information
- Trade association member lists
- Field intelligence

Maintaining the inventory is 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 which 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[11,12]) that they submitted to the FDA, which 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 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 inspection frequency based on risk.

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 (perhaps 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

A critical part of the inspection program is conducting routine inspections. The inspection should follow the basic process of conducting an entrance conference, doing the inspection, and conducting an exit conference. A structured inspection will allow the inspectors to be properly prepared to conduct the inspection and allow the company to know what to expect during the inspection and assign personnel to be available, as needed, during the inspection.

Preparing for the inspection before scheduling the event is vital to ensuring success during the inspection. Spending time in advance of the inspection allows the inspector to allot the

[11] https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm

[12] https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsAlphabetically/default.htm

appropriate amount of time and to ensure that proper/necessary resources, including such things as sampling supplies, are available. Reviewing past history, including previous inspection reports, summary reports, laboratory results from samples collected, and other available information pertinent to the production of regulated animal food prior to conducting an inspection, is important to properly preparing to inspect a regulated firm.

The frequency of inspections should be assigned based on risk, including the results of previous inspection history of the firm.

Coordination: The state agency responsible for conducting inspections will work jointly with FDA to determine the workload based on available information and resources; this will include coordination on joint activities, state-specific activities, and FDA-specific activities in the state. 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 before 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 which areas the regulatory efforts need to concentrate on. 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 in compliance with the PCAF regulation. For example:

- Does your state program need to develop inspection protocols/procedures for the PCAF regulation?
- Does your 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 your state program to inspections under PCAF? Will PCAF inspections routinely include sample collections?
- Does your state program need to develop or amend protocols and procedures regarding sample collections under PCAF inspections?
- If collecting samples, does your state program anticipate new types of samples being collected (e.g., samples for environmental monitoring)?
- Will your state program conduct comprehensive (combined) inspections at a single facility (BSE, medicated feed, VFD, PCAF)?
- If conducting comprehensive (combined) inspections, what information needs to be prepared for the inspectors to be able to conduct such inspections?

5.2 Follow-Up Inspections

Follow-up or re-inspections are performed at facilities where noncompliance has been documented. These inspections are to verify that corrective actions have been implemented, as appropriate. Any issues of noncompliance identified should be corrected, either during a routine inspection or before a follow-up inspection. If not immediately corrected, a workable timeline for corrective actions should be established and documented. Before the follow-up inspection, inspectors should evaluate the inspection history. When possible, the same inspector should conduct the initial and follow-up inspection.

Repeat violations or nonconformances may result in additional regulatory actions, as needed to achieve compliance. These actions may include the issuance of an information letter, warning letter, or certified warning letter or other regulatory responses. Other regulatory responses may include voluntary agreement to cease operations, embargo/stop sale of product, an order for product destruction, issuing a recall, or holding a regulatory meeting.

5.3 For Cause Inspection/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 should be taken to protect animal and human health. Conducting a root cause analysis is important in determining the cause of contamination and implementing appropriate mitigation measures. 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. Compliance and enforcement actions should be consistent among state and federal agencies.

5.4 Assignments

It is important for state programs and FDA to work jointly 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 affect 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.

5.5 Disaster/Emergency Response

An established rapid response team (RRT) may play a critical role in responding to man-made emergencies or natural disasters. Establishing these relationships, including roles and responsibilities, will be vital in determining the success of these programs. State feed programs should be an integral part of the food emergency response plan, including the RRT. A state program should have or may need to develop a procedure to evaluate the effectiveness of the program's response.

5.6 Inventory Updates

Inventory updates should be conducted by the state program. Inventory updates should be made when an inspection is conducted or attempted and the firm is found to be "out of business" (OOB), have relocated outside of the agency's geographical jurisdiction, or have a change in business status.

- A state program should expect that there will be numerous inventory updates, especially in the first few years of PCAF regulation implementation. There should be a way to incorporate that into work planning and to 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 the firm on animal food safety and perform other inspections deemed appropriate.

6. Funding

After funding to establish the PCAF program (Step 1 & 2), program funding begins in step 3 to provide support for infrastructure maintenance based on metric goals in each state, to support inspections by state personnel.

- Step 1 – States receive foundational/assessment funding only.
- Step 2 – States receive program development and/or education/outreach and technical assistance funding.
- Step 3 —States receive maintenance funding:
    - Full inspections of large manufacturers at a predetermined 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 by FDA/states.
    - Targeted inspections of higher-risk facilities at a predetermined 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 through 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. Furthermore, the state program will be

responsible for coordinating with laboratories, whether inside or outside their state, to ensure adequate support for their PCAF program. 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 availability of subject matter experts and the 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.

Chapter 7: Compliance and Enforcement

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1. Executive Summary

This chapter details some of the necessary components for state programs to ensure that animal food facilities are in compliance with the PCAF regulation. The NASDA PCAF Framework includes information to ensure an effective compliance and 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 before 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. The success of that enforcement program may be best measured by the level of animal food industry compliance, rather than by 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 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 that the PCAF regulation establishes new CGMP and PC requirements, there should be a period of education before the state program takes 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.

For compliance to be reached, several features should be in place (modified from Lon Fuller, The Morality of Law):

- A law and/or rules exist(s); the lack of it/them leads to *ad hoc* and inconsistent adjudication.
- Stable legislation: Frequent revisions of laws and rules can lead to confusion; however, in order to remain relevant, laws, rules, and guidance must also change as technology, knowledge, or situations change.
- The law or rules must be publicized/made known.
- The legislation or regulation is clear and not obscure; if it is unclear, it is impossible to understand.

- Legislation or regulation is not retrospective; if it has retroactive requirements, the requirement will be perceived as unfair.
- Contradictions in the law or rules lead to confusion.
- Demands that are beyond the power of the regulated industry to accomplish makes compliance impossible.
- Divergence between adjudication/administration and legislation or regulation makes for inconsistent expectations and confusion.
- The public and the regulated industry must have an opportunity to provide input.

To determine what compliance is and how it is done, we should look at several aspects of program development and administration. Several facets of program development and administration are fundamental to a regulatory program. Regulatory programs establish a uniform foundation for the design and management of programs that have the responsibility for regulating. Effective programs define the expectations of a regulatory program. For example, effective regulatory programs involve important elements such as authority, rules, due process, procedures, education, training, inspection, documentation, compliance, enforcement, and appeals. Programs that are effective have administrative procedures in place to make each element functional, uniform, and consistent.

3. Scope

This chapter details some of the necessary components for state programs to ensure a facility's compliance with the PCAF regulation. It is designed to address the components of state programs' enforcement strategies to secure industry compliance with all applicable regulations, ultimately protecting the health of both 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 that 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 an appropriate means to gain compliance before taking enforcement actions due to a violation of the PCAF regulation. Nevertheless, a state program must consider each

violation to determine whether 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 and 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 that 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 results 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 2: AAFCO Enforcement Guidelines Matrix 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 the Center for Veterinary Medicine. The FDA can utilize a variety of enforcement methods to confirm that a noncompliant 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, to utilize the state program's authority in order to achieve compliance, if necessary.

5. Compliance and Enforcement Framing

Importance of Compliance and Enforcement in Developing Uniform and Consistent Regulatory Programs

"Compliance" is defined in many ways, depending upon its use as an action, a program, or a process.[13] Compliance relates to how industry complies with a defined set of standards, rules, or laws. Compliance also relates to how a regulatory program adheres to a preset list of quality principles, SOPs, or other processes to ensure uniformity and consistency in assessing industry compliance with established rules or laws. In addition, compliance can be viewed as the state of adhering to the expected standards by the regulated industry.

Outreach and education can facilitate industry's compliance with ever-changing regulations. This is accomplished through trainings, workshops, or guidance documents.

Inspections are intended to assess industry's compliance. When industry fails to comply, regulatory programs take enforcement actions as necessary to protect public health and encourage compliance. The focus of this chapter is on compliance as it relates to industry complying with a set of regulations and a regulatory program complying with internal processes and procedures designed to ensure uniformity and consistency in enforcement strategies.

In many regulatory programs, inspection functions are conducted independent from compliance functions. Separating inspection and compliance functions should ensure consistency across a regulatory program by incorporating a system of checks and balances. Compliance staff should evaluate inspection reports to assure the appropriate application of laws and regulations, to assure accuracy in assessing industry compliance, and to ensure that inspectional documentation is complete to support findings in accordance with program policies and procedures. Objective evaluation by a separate compliance staff looking across a program will ensure fairness and objectivity in evaluating industry compliance.

Components of a Compliance and Enforcement Program:

There are several necessary principles to establishing a uniform compliance and enforcement program. A regulatory program should develop processes and procedures such as those below:

- Systematically assessing industry compliance with appropriate laws and regulations;

[13] https://searchdatamanagement.techtarget.com/definition/compliance

- Establishing a risk-based inspectional process that follows the work plan;
- Documenting inspection observations or findings;
- Distinguishing between observations that should be documented on an inspection report versus additional items that the inspector will discuss with management;
- Writing observations or findings in a manner that is legally defensible;
- Organizing observations in order of significance;
- Assembling an inspection report that includes inspection observations, and supporting documentation (e.g., maps, floor plans, process flow diagrams, photographs, sample collections);
- Reviewing inspection reports and inspectional findings;
- Developing a timeline for submission of inspection reports and review of the reports, and making compliance decisions;
- Developing a process for scheduling and tracking follow-up and re-inspections related to enforcement activities; and,
- Ensuring documentation and enforcement activities are consistent across the entire program.

Progressive Enforcement Strategies:

a. Regulatory programs should identify a clear progression of enforcement actions to be taken to gain industry compliance. Additional enforcement actions should be taken when continued noncompliance is found in a subsequent inspection. These enforcement actions should be structured, while still allowing for flexibility to address situations with severe public health impact, and should be scaled to match the severity of the situation. This allows for appropriate resource allocation on the part of regulatory staff and industry to address situations of noncompliance.
b. The state program should identify key factors to assess when determining options for enforcement actions. These factors can include the inspection type, the severity of the condition observed, the compliance history of the facility, and other factors.
c. The purpose of an enforcement action must be clear.
d. Enforcement tools are used to attain industry compliance when other strategies are unsuccessful. Enforcement tools can include
    - Advisory or informational letter
    - Warning letters with or without a required response
    - Withdrawal from distribution orders
    - Informal hearings/meetings
    - Mediation
    - Civil penalty
    - Cancellation, probation, or conditional status
    - Administrative hearing

- Condemnation and confiscation
- Injunction
- Criminal prosecution

e. Outcome-Based Categories:

The overall purpose of enforcement can be summarized into four outcome-based categories, based on public health risk. These outcome-based categories may or may not run sequentially, based on the severity of the public health concern:

1. **Voluntary compliance** where the industry/firm elects to make changes to achieve compliance on his/her own after verbal or written notification from the agency. Tools to achieve this may include verbal notification, letter of information, or educational sessions.
2. **Structured enforcement** to ensure that industry follows through on noncompliance issues to prevent public hazards. Tools to achieve this may include letter of information, notice of corrective actions, notice of potential compliance or enforcement actions, monetary penalties, and court-compelled or negotiated agreements.
3. **Elevated enforcement** to prevent or limit a firm's operation to protect public health due to the presence of a significant public health issue that has not been corrected. Tools to achieve this may include stop sales, embargoes, injunctions, monetary penalties, court-compelled actions, or negotiated agreements. The scope of action should be related to the nature of the violation and impact on the animal food; for example, action may be limited to the animal food being manufactured at that time if corrective actions are put in place, so future products won't be affected by the non-compliance.
4. **Immediate enforcement** actions, such as seizure or stop sale, are generally associated with an egregious condition and their purpose is to protect public health by preventing contaminated product from entering the marketplace. This would be considered the most severe level of action and the purpose would be to prevent continued activities until the egregious condition is corrected, and if product is in commerce, it is no longer available in the marketplace.

f. Enforcement Decisions:

The Program should develop a process to assess the severity of the conditions observed and the compliance history of the facility to determine the enforcement actions or range of actions that could be considered. The state program should develop a range of enforcement actions they may take based on the factors presented here.

1. History of the firm
2. Attitude
3. Scope
4. Nature of the violation

5. Impact of the violation
6. Resources

Further explanation of each factor listed above can be found in Appendix 2: AAFCO Enforcement Guidelines Matrix.

6. 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 whether a new inspection is warranted or whether 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 that have chosen to implement the AFRPS, the AFRPS provide steps not only to review the authority (Standard 1: Regulatory Foundation) but also 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 whether 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 consider 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.

7. Resources

A large resource need 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.

IT is another resource that is not readily available to all state programs and could affect their enforcement capabilities or timeliness. Having access to IT (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 whether 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 to determine whether additional sampling is necessary. Because the PCAF regulation is intended to reduce hazards, receiving information on available laboratory data in a timely manner could prevent contaminated animal food from being distributed.

State laboratories may also be at a hindrance due to lack of resources available for analytical testing. Chapter 8: Laboratory Services outlines the importance of laboratory services for a state program and the steps to prepare laboratories for implementation of the PCAF regulation. Laboratories serve a critical role in enforcement. If a state laboratory is delayed in analyzing an adulterated animal food sampled due to lack of resources, the state program may be unable to take 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.

Chapter 8: Laboratory Services

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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 PC and may also be used by both industry and regulators to ensure a PC 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[14] standards, or the *2014 AAFCO Quality Assurance Quality Control Guidelines*[15]). This chapter provides a checklist to determine the laboratory resources needed to facilitate implementation of the PCAF regulation in support of animal food quality and safety, and to assess the gap between current laboratory resources and additional resources needed to support the implementation.

2. Background

For over a century, regulatory decisions in state programs have been supported by results of laboratory testing. The role that laboratories play was critical before 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) toward contamination issues that pose risk for both human and animal health (e.g., mycotoxins, microbial pathogens, nutrient deficiencies and toxicities, drug residues, dioxins, melamine). Although 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 PC and may also be used by both industry and regulators to ensure that a PC is working. To that end, one of the primary goals of a laboratory is to provide defensible or 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[16] (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 17025:2005. The 2014 document provides a valuable resource to animal food laboratories supporting state programs and is designed to serve as a supplement to ISO/IEC 17025 for animal food laboratories seeking accreditation.

3. Purpose and 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

[14] The most recent version of ISO 17025 should be complied with (2017 at time of this writing) if sufficient time/resources have been provided to allow implementation of the new standard. Standards available from http://webstore.ansi.org/default.aspx

[15] https://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories

[16] https://www.aafco.org/Laboratory/Proficiency-Testing-Program

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 third-party[17] accreditation to ISO/IEC 17025 or to implement and comply with the *2014 AAFCO Quality Assurance/Quality Control Guidelines*; and (3) the 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 laboratory resources are 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

Identifying, planning, and coordinating of laboratory services to implement the PCAF regulation consists of two phases: (1) **defining program needs**, and (2) a **gap analysis** of current resources against the needs defined in the first phase.

4.2 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.

[17] Laboratories should select an accreditation body that is a full signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), which is a formal recognition of the technical competence of inspection bodies to perform specific types of inspection. Accreditation bodies that are full members of ILAC can be found at the ILAC website: http://ilac.org/signatory-search/.

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 and determine the statistical requirements (e.g., replicates).
i. Identify the quality requirements to meet program objectives: quality management system, accreditation to ISO 17025 standards, quality control needs, and other.
j. Determine the physical sample 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 whether data meet the checklist published in the data acceptance white paper by APHL[18] (*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 versus subcontracting if capacity needs are low or fluctuate, noting that subcontractors 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.
    ii. Determine whether facility has adequate biological, radiological, and/or chemical safety infrastructure to meet the needs.

[18] https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/Accreditation-Resources.aspx or https://www.aphl.org/aboutAPHL/publications/Documents/FS-2017Jun-Best-Practices-Food-Feed-Data.pdf (Contact your feed administrator or laboratory lead for access).

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 and format and accessibility of training. A model competency framework is under development.[19]

c. Equipment requirements
   i. Assess whether current equipment inventory meets requirements and whether 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 (LIMS)
   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.

f. Assess whether data, quality system, and reporting requirements meet the checklist published in the Data Acceptance White Paper (*Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories)*.

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 4.1 to successfully support a state program implementing the PCAF regulation, and actively participate in the **"Gap analysis"** (see details in Section 4.2 of this chapter). Once the gap is defined, the state agency needs to facilitate by providing laboratory resources to meet the gap. For example:

[19] https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/Accreditation-Resources.aspx or https://www.aphl.org/programs/food_safety/laboratory-accreditation/Documents/Lab%20Framework%20May%2017%202018.pdf

- 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 by 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 laboratory infrastructure.
- Seeking and providing additional resources to support laboratory services (e.g., instrumentation, training, service contracts, LIMS).
- 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[20], 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 because 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 have developed resources to assist laboratories with ISO 17025 accreditation, including the development of critical best practices manuals. These laboratory resources include the following:

[20] https://www.aafco.org/Regulatory/Committees/Proficiency-Testing-Program

- *PFP Food/Feed Laboratory Testing Best Practices Manual*[21]
- *2014 Quality Assurance/Quality Control for Feed Laboratories*[22]
- *Guidelines on Obtaining Defensible Samples*[23]
- *Guidelines on Obtaining Defensible Test Portions*[24]
- Development of a website of accreditation resources[25]
- Work toward a curriculum framework for governmental regulatory laboratories[26]
- Expansion of the scope of the AAFCO Proficiency Testing Programs[27]
- Provision of 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[28] works to develop or improve analytical methods, document laboratory best practices, publish quality assurance guidelines, publish laboratory sampling guidance, provide training resources, coordinate with other AAFCO committees and lab associations, and provide 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. Supporting Documents

AAFCO (Association of American Feed Control Officials). (2014). *AAFCO Quality Assurance Quality Control Guidelines for Feed Laboratories*. AAFCO, Champaign, IL.

AAFCO (Association of American Feed Control Officials). (2015). *Guidance on Obtaining Defensible Samples: GOODSamples*. AAFCO, Champaign, IL.

AAFCO (Association of American Feed Control Officials). (2018). *Guidance on Obtaining Defensible Test Portions: GOOD Test Portions*. AAFCO, Champaign, IL.

APHL (Association of Public Health Laboratories). (2017). *APHL Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories*. APHL, Silver Spring, MD.

[21] https://www.pfp-ifss.org/ifss-resources/human-and-animal-food-testing-laboratories-best-practices-manual-december-2018/
[22] https://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories
[23] https://www.aafco.org/Publications/GOODSamples
[24] https://www.aafco.org/Publications/GOODTestPortions
[25] https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/Accreditation-Resources.aspx
[26] https://www.aphl.org/programs/food_safety/laboratory-
[27] https://www.aafco.org/Laboratory/Proficiency-Testing-Program
[28] https://www.aafco.org/Regulatory/Committees/Laboratory-Methods-and-Services

ISO (International Organization for Standardization). (2005). General requirements for the competence of testing and calibration laboratories. Standard no. 17025. ISO, Geneva, Switzerland.

ISO (International Organization for Standardization). (2017). General requirements for the competence of testing and calibration laboratories. Standard no. 17025. ISO, Geneva, Switzerland.

Chapter 9: Dispute Resolution

[Text under Development]

Appendix 1: Fundamental Steps to Building Future State PCAF Programs

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 implementing the program. For each of the fundamental steps, a number of activities are 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. Although state programs may be able to conduct some of these activities using current resources, additional resources are needed to ensure that 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 and complexity, begin process of identifying industries, and develop an inventory and establishing priorities.
- Assess current infrastructure including 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, and 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

- Continue 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 have begun or completed 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.
- Participate in pilot programs.

Step 3: Implementation

- Continue 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 affected stakeholders as appropriate to the industry.
- Collaborate with affected stakeholders regarding FSMA implementation.
- Initiate inspection program including, as appropriate, laboratory support, compliance, and enforcement.

Appendix 2: AAFCO Enforcement Guidelines Matrix

These enforcement guidelines are provided with the intent to encourage uniformity of enforcement by feed control officials; however, it is important for all to recognize that these are *guidelines*, not a specific recipe to be blindly followed. It is clear that application of guidelines may vary in different environments, and 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 selecting an enforcement tool or tools and applying same for the purpose of achieving compliance. Some violations are minor whereas 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 viewing a violation in perspective.

(1) What is the nature or gravity of the violation? To what risk or potential risk has a violation exposed humans, animals, or the environment? What level or potential level of harm or damage is associated with the violation?
(2) What is the violator's culpability? Is the violation an accident, mistake, or omission or is it a result of intent, negligence, defiance, indifference, fraud, etc.?
(3) Has the violator shown good faith efforts to comply, be cooperative, and correct errors or deficiencies?
(4) What is the history of prior violations, including willingness and effort to achieve compliance?
(5) 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?
(6) 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 a more serious 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-repeated 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 typically outlines 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 presented 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 bring 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 is 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 that 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. 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 before 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 noncompliant 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 relabel 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 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 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 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 ranges of factor values but the chart could be modified to include more or fewer 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, and requirements for their operation? Do they have QA 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 QA/training programs; corrections are promised and made promptly; when appropriate, they 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 and the scope of the violation can be important factors 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, or 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? Does the violation involve a single product and/or is it specific to a single lot, or is it a multi-product or 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 affected is relatively small; noncritical process violation
3: 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 affects 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

recordkeeping/control issues or include product defects or contaminations; whether they are the result of human error; whether they are the result of lack of knowledge and understanding of the firm/individual's responsibility or its legal requirements; and whether the violations were done knowingly or deliberately. When determining whether the violation is significant or less 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 recordkeeping 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 Good Manufacturing Practices (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 affect 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, immunocompromised, 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 whether 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

Violation Category	Factor Value Range			
	4 to 8	9 to 12	13 to 19	20 to 29
Labeling	No Action	Warning Letter	Condemnation/ Seizure	Prosecution
			Informal Hearing/ Meeting	Formal Hearing
		Stop Sale	Injunction	Injunction
			Refer to Other Agency	Refer to Other Agency
	Information Letter	Informal Hearing/ Mediation	Civil Money Penalty	Civil Money Penalty
GMPs				
Sample Results				
Contaminations				
Administrative				

Appendix 3: Human Food By-Products for Use as Animal Food

The PCAF regulation includes streamlined regulatory provisions for human food facilities that manufacture, process, pack, or hold human food, and pack and hold 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.

Currently, the streamlined regulatory requirements are divided into three different options based on the activities that the human food facility is performing on the human food by-products for use as animal food after those by-products have been separated from the human food.

Activities performed on human food by-products	**Regulatory requirements**
No further manufacturing/processing; just packing and holding (meet criteria in 21 CFR 507.12)	Subject to the limited holding and distribution requirements in 21 CFR 507.28 (also co-located in 21 CFR 117.95).
Performing only certain manufacturing/processing activities as described in Section D of Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry	Subject to the CGMP requirements and have the option to follow the CGMP requirements in 21 CFR part 507, or part 117 (21 CFR 507.1(d)). Have enforcement discretion from following the PC requirements
Performing manufacturing/processing activities beyond the scope of the enforcement discretion guidance	Subject to the CGMP and PC requirements (unless other exemptions apply. Have the option to follow the requirements in 21 CFR part 507, or part 117 (21 CFR 507.1(d)).

How human food and state animal food regulatory programs are organized within the state agency structure varies. Some human and animal food regulatory programs are within the same program area, whereas others are in different program areas but within the same state department. In some states, the human and animal food regulatory programs are not 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 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 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, 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 human food facilities that would be subject to the human food by-products for use as animal food requirements in the PCAF regulation. 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 PCAF regulation is applicable to a human food facility that distributes 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 PCAF requirements. This may affect the number of firms in a state's animal food safety program's firm inventory.

Human food facilities that further manufacture/process their human food by-products for use as animal food have the choice under the PCAF regulation to follow the CGMP and hazard analysis and risk-based preventive control requirements in the Preventive Controls for Human Food regulation (part 117) or the PCAF regulation (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 an 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 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 facilities 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 applies to 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 human food facilities by human food safety staff or may need to make animal food safety staff available for human food education and outreach events.

Appendix 4: Information Sharing

[Text under Development]

Appendix 5: 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; includes pet food, animal feed, and raw materials and ingredients.

Audit: 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 nonformal 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 spore-forming bacteria.

Facility: A domestic facility or a foreign facility that is required to register under section 415 of the Federal FD&C 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 FD&C 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" include 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/

Full-Time Equivalent Employee (FTE): 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 FTEs 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 (PC) 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 PC and its role in the facility's food safety system.

Holding: Storage of animal food; holding 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 FD&C 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; and GOOD Test Portions: http://www.aafco.org/Publications/GOODTestPortions)

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): An essential part of laboratory policy, which ensures that the feed laboratory consistently provides reliable and defensible analytical services. QA is designed to ensure that 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)

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)

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)

Laboratory Standard Operating Procedures (SOPs): Written procedures that 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 (e.g., replicates, blanks,

spikes, control samples). (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, 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; 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 activities that are exempt from registration under section 415 of the Federal FD&C 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, nonprofit 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 US agriculture. 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 FD&C 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 (PC): 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 use to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive Controls Qualified Individual (PCQI): 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 food

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 21 CFR 507 part 1, subpart M.

Qualified End-User: With respect to food, a qualified end-user is 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 21 CFR Chapter 1, Subchapter A, Part 1, Subpart H 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: A 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) 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: 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: As given in section 201(r) of the Federal FD&C Act.

Receiving Facility: A facility that is subject to subparts C and E of 21 CFR 507.3 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 the 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; and GOOD Test Portions: http://www.aafco.org/Publications/GOODTestPortions)

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; and GOOD Test Portions: http://www.aafco.org/Publications/GOODTestPortions)

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 FTEs.

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

Subsidiary: Any company that 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; and GOOD Test Portions: http://www.aafco.org/Publications/GOODTestPortions)

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; it is the quotient of the water vapor pressure of a 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.

Appendix 6: Acronyms

AALA	American Association for Laboratory Accreditation
AAFCO	Association of American Feed Control Officials
AAPFCO	Association of American Plant Food Control Officials
AAFCO OP	Association of American Feed Control Officials Official Publication
AASCO	Association of American Seed Control Officials
ACLASS	Assured Calibration and Laboratory Accreditation Select Services
AFDO	Association of Food and Drug Officials
AFIA	American Feed Industry Association
AFRPS	Animal Feed Regulatory Program Standards
AFSIG	Animal Food Safety Implementation Group
AIHA	American Industrial Hygiene Association
AITS	AAFCO Advanced Inspector Training Seminar
ANAB	ANSI-ASQ National Accreditation Board
ANSI	American National Standards Institute
APA	Administrative Procedures Act
APHL	Association of Public Health Laboratories
ASQ	American Society for Quality
ASTHO	Association of State and Territorial Health Organizations
BITS	AAFCO Basic Inspector Training Seminar
BSE	Bovine spongiform encephalopathy
CE	Continuing education
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practices
CII	Critical Infrastructure Information
CLEAR	Council on Licensure, Enforcement and Regulation
CSG	Council of State Government
EPA	Environmental Protection Agency
FD&C Act	Federal Food, Drug and Cosmetic Act
FDA	Food and Drug Administration
FOIA	Freedom of Information Acts
FOIL	Freedom of Information Laws
FQS	Forensic Quality Services
FSMA	Food Safety Modernization Act
FSPCA	Food Safety Preventive Controls Alliance
FSVP	Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
FTE	Full-time employees

GMP	Good Manufacturing Practices
GOODSamples	Guidance on Obtaining Defensible Samples
GOOD Test Portions	Guidance on Obtaining Defensible Test Portions
GRAS	Generally recognized as safe
HAACP	Hazard analysis and critical control points
IAS	International Accreditation Service
IEC	International Electrotechnical Commission
IFPTI	International Food Protection Training Institute
IFSS	Integrated Food Safety System
ISA	Single Signature 20.88 Long-Term Food Information Sharing Agreement
ISO	International Organization for Standardization
IT	Information technology
LIMS	Laboratory information management system
LMS	Learning management system
MOU	Memorandum of understanding
NASDA	National Association of State Departments of Agriculture
NCS	National Curriculum Standards
NCSL	National Conference on State Legislatures
NGFA	National Grain and Feed Association
NVALP	National Voluntary Laboratory Accreditation Program
OOB	Out of business
OP	AAFCO Official Publication
ORA	Office of Regulatory Affairs
OTED	FDA Office of Training, Education and Development
PC	Preventive controls
PCAF	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) found in 21 CFR part 507
PCQI	Preventive controls qualified individual
PFI	Pet Food Institute
PFP	Partnership for Food Protection
PJLA	Perry Johnson Laboratory Accreditation
QA	Quality assurance
QC	Quality control
RRT	Rapid response team
SOP	Standard operating procedures
TWG	Technical Working Group
USDA	United States Department of Agriculture
VFD	Veterinary Feed Directives

Appendix 7: Resources

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/