FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

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FLORIDA FEED PROGRAM
PRODUCTION, DISTRIBUTION, AND REGULATION
OF COMMERCIAL FEED AND FEEDSTUFF

FISCAL YEAR 2023-2024

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1.0 SUMMARY

This report represents Fiscal Year 2023-2024 activities. The Department's Feed Regulatory Program in the Division of Agricultural Environmental Services is directly responsible for assuring the safety and wholesomeness of animal food sold in Florida. This is accomplished through registration and inspection of manufacturers; evaluation of feed products in the marketplace; and administration of a privatized laboratory program which analyzes and evaluates registrant-submitted samples for guaranteed nutritive values and potential contaminants.

The division administers and enforces the provisions of Chapter 580, Florida Statutes (F.S.) and Rule 5E-3, Florida Administrative Code (F.A.C.), supports the enforcement of federal feed regulations, and investigates consumer complaints related to animal food. Regulatory oversight is further enhanced through the performance of targeted analytical testing on feed products sold in the state.

2.0 BACKGROUND

In 1994, the Florida Legislature passed Senate Bill 2704, containing several significant changes to Chapter 580 F.S., Commercial Feed and Feedstuff. The amended law went into effect on January 1, 1995, and contained the following substantive modifications:

The bill consolidated the powers and duties of the Department into one section in the current law, modified the fees for master registration, removed the requirement for issuing a warning letter prior to imposing a fine, authorized probation, and required that any penalty imposed be commensurate with the severity of the violation. Additionally, inspection fees were eliminated and the requirement to maintain Feed Dealer's Bonds and Certificates of Deposit was repealed. Registrants were made responsible for submission of regulatory samples and payment for associated certified laboratory analyses. The bill also adopted language from the Association of American Feed Control Officials Model Feed Regulations regarding guaranteed analysis and labeling requirements, adulteration, misbranding, and condemnation of feed and feedstuffs.

Senate Bill 2704 further amended Chapter 580 F.S. by replacing the feed regulatory inspection program with a certification program for private laboratory testing of commercial feed. The bill required anyone who distributed commercial feed in the state to obtain a master registration from the Department before initiating distribution. Under this program, commercial feed registrants (including ingredient suppliers) assumed responsibility for having their feed sampled and tested at prescribed frequencies to protect consumers who purchase feed for their animals.

The bill identified five areas of testing in which the Department developed standards and established certification: (1) nutrients; (2) mycotoxins; (3) microbiological organisms; (4) pesticide residues; and (5) drugs. Any qualified laboratory may apply for certification in one or more of these five areas. The costs to apply for certification consist of a $100 application fee and $300 for each category. Registrants must send their samples to certified laboratories, who in turn must report results to the Department on a quarterly basis. Samples that are determined to be violative must be reported to the Department immediately. A registrant may apply for an exemption from the certified laboratory testing requirement by submitting its quality assurance/quality control plans, including laboratory testing protocols, to the Department for review and approval/disapproval. The Department charges a fee for any evaluation to cover direct and indirect costs. Such exempt businesses must: 1) maintain the results of all laboratory tests performed on feed and feed ingredients for three years or as required by federal regulations, whichever is longer; 2) make records available for inspection by Department officials; and 3) provide the results of any check-sample programs.

The Department developed a testing matrix to establish the type and frequency of feed sampling and analyses that must be performed by registrants. The quantity and type of samples required is based on the annual volume of animal feed distributed and the species for which the products are intended. However, if there is evidence of a hazard to animal or public health, the Department is authorized to require additional sampling and testing. Although the implementation of the private laboratory product compliance assessment program shifted primary responsibility for product compliance evaluations from the Department to feed program registrants, the Department retained the authority to inspect, sample, and test any feed or feedstuffs in the state and to take appropriate action to prohibit the distribution of violative feed or feedstuffs.

In 2001, the Florida Legislature made additional fundamental changes to Chapter 580 F.S. These changes include reinstating regulation of pet food, mandating that all feed labels bear all information required by the U.S. Federal Food and Drug Administration, and eliminating the requirement of annual, on-site audits of certified feed laboratories, thus permitting better utilization of personnel for field regulatory activities.

The Department implemented modifications to Rule 5E-3.003 F.A.C. in 2006 in order to revise definitions to coincide with those listed in the Association of American Feed Control Officials (AAFCO) official publication and categorize new products developed within the feed industry; to redefine an explicit sampling period; to modify sampling requirements for mixed feeds and ingredients to correspond with revised definitions; and to implement a more focused, risk-based approach to regulatory enforcement.

During the 2008 Florida legislative session, Senate Bill No. 1702 amended Chapter 580.041 F.S., by increasing the master registration fees imposed on commercial feed distributors. The 2008 bill implemented the most recent fee increase. Current Feed registration fees are as follows:

SALES IN TONS	FEE
Zero, up to and including 25	$40
More than 25, up to and including 50	$75
More than 50, up to and including 100	$150
More than 100, up to and including 300	$375
More than 300, up to and including 600	$600
More than 600, up to and including 1,000	$900
More than 1,000, up to and including 2,000	$1,250
More than 2,000, up to and including 5,000	$2,000
More than 5,000	$3,500

During the 2012 Legislative Session, additional changes to Chapter 580 F.S. were adopted by the Legislature and became effective July 1, 2012. The Commercial Feed Technical Council was eliminated, and a new Agricultural Feed, Seed, and Fertilizer Advisory Council was created under Section 570.451 F.S. The council consists of 15 members, including 2 from the feed industry, and serves an advisory role to the Department on feed, seed, and fertilizer enforcement issues. Language was also added to clarify the appropriate action to be taken after analysis of any feed or feedstuff deems a sample in violation of Chapter 580 F.S. or rules adopted there-under; to provide that penalties are payable to the consumer or, if no consumer is identified, to the Department. In addition, Chapter 580 F.S. was modified to require the submission of quarterly tonnage reports by feed registrants and subsequently Rule 5E-3.020 F.A.C., implementing the reporting requirement, became effective on April 18, 2013.

During the 2014 Legislative Session, several changes were made to Chapter 580 F.S. and became effective July 1, 2014. Section 580.036 F.S. was modified to provide reference to the Agricultural Feed, Seed, and Fertilizer Advisory Council, Section 580.041 F.S. was revised to provide a reference to the Department's website option for managing Feed Master Registrations, and Section 580.071 F.S. expanded the definition of adulterated feed to establish consistency with national standards. In addition, Section 580.121 F.S. was modified to reflect administrative fine classifications pursuant to Section 570.971 F.S. and specify Class I, as the authorized category for feed penalties. Class I administrative fines are not to exceed $1,000 per violation.

During the 2019 Legislative Session, Section 581.217 F.S. was created which directs the Department of Agriculture and Consumer Services to adopt rules to regulate cultivation of hemp in this state. The subsequent rulemaking aligned 5E-3 F.A.C. with the provisions of Section 581.217 F.S. to regulate the distribution and retail sale of pet and specialty pet food, and pet and specialty pet treat products containing hemp extract.

The changes to 5E-3 F.A.C. established necessary product definitions and testing requirements, addressed hemp-derived products intended for use as feed ingredients, established tolerances relating to hemp derivatives in animal feed and delineated labeling requirements specific to hemp-based ingredients and feeds containing hemp-derived products.

3.0 CURRENT PROGRAM STATUS

During the 2023 Florida legislative session, House Bill No. 959 amended Chapter 580.031 F.S. by creating a definition, and 580.051 F.S. by providing an exception from guaranteed analysis requirements, for products sold solely as dosage form animal products; providing labeling requirements for dosage form animal products; and providing an effective date.

3.1 FEED SAFETY INSPECTIONS - BOVINE SPONGIFORM ENCEPHALOPATHY (BSE), GOOD MANUFACTURING PRACTICES (GMP), VETERINARY FEED DIRECTIVE (VFD) AND PREVENTIVE CONTROLS (PC)

While the United States has traditionally maintained one of the safest food and feed supplies, there were a number of significant foodborne illness outbreaks that resulted in human and animal illness and deaths between roughly 2000 and 2010, that helped prompt the passage of the FDA Food Safety Modernization Act (FSMA). On January 4, 2011, FSMA was signed into law with broad support from the food industry and consumer groups. FSMA shifted the focus from primarily reacting to food/feed safety problems to preventing them and authorized the FDA to build an integrated national food safety system in partnership with state, tribal, and local authorities. FSMA created new and modified existing regulatory requirements to achieve and maintain compliance with the following animal feed regulatory focus areas:

Title 21, Part 507 of the Code of Federal Regulations (CFR), Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, also known as the Preventive Controls for Animal Food or PCAF rule, established both current good manufacturing practice (CGMP) and

hazard analysis and risk based preventive controls (PC) requirements for animal food. The CGMP requirements are baseline safety and sanitation requirements for the manufacturing, processing, packing and holding of animal food. Under the PC requirements, animal food facilities are required to have a food safety plan that includes an analysis of hazards to determine which ones need risk-based preventive controls to significantly minimize or prevent the hazards, and a process to verify appropriate implementation of these controls.

Additional feed-related regulations developed under 21 CFR, Part 558.6, Veterinary feed directive drugs, require a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that authorizes the use of a VFD drug (a drug intended for use in or on animal feed, which is limited to use under the professional supervision of a licensed veterinarian) or combination VFD drug, in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client's animals only in accordance with the approved conditions for use.

21 CFR, Part 589.2000, Animal proteins prohibited in ruminant feed, and 589.2001 Cattle materials prohibited in animal food or feed to prevent the transmission of Bovine Spongiform Encephalopathy (BSE), were enacted to address this progressively degenerative and fatal neurological disease in cattle (and other ruminant animals) caused by infectious protein agents called prions and characterized by long incubation periods of up to several years prior to manifestation of symptoms. During the late 1980s and early 1990s, the disease was spread within the United Kingdom and ultimately to other countries through the practice of using rendered (ruminant) proteins as an ingredient in cattle and other livestock feed. Subsequent animal feed restrictions and compliance inspection programs put in place to prevent the spread of this disease through contaminated feed have been highly effective in reducing the number of BSE cases worldwide.

Since 2002, the Department has maintained a partnership with the U.S. Food and Drug Administration (FDA) to perform compliance inspections to ensure compliance with the aforementioned federal feed regulations. As the exigency of BSE has diminished, compliance inspection activities have been redirected increasingly toward more comprehensive evaluations of feed manufacturing processes, recognition and mitigation of risks, and preventive controls to address identified hazards. Accordingly, seven (7) BSE, two (2) VFD Trace-back/Trace-forward inspections, five (5) Part 507 Current Good Manufacturing Practices (cGMP) Inspections, one (1) Preventive Controls for Animal Feed (PCAF) Part 507 CGMP + Preventive Controls Inspection, two (2) Inspection Oversight Audits, and five (5) standalone Veterinary Feed Distributor Inspections are planned for the

2024-2025 fiscal year.

As an integral component of FSMA implementation, FDA established the Animal Feed Regulatory Program Standards (AFRPS) to facilitate the development of an integrated safety system for animal feed. The AFRPS contain 11 standards that are intended to provide a uniform foundation for the design and management of State programs responsible for the regulation of animal feed. In September 2015, the Division of Agricultural Environmental Services (AES) was awarded a 5-year grant from the US Food and Drug Administration (FDA) to implement the AFRPS. The funding was utilized to enhance existing program infrastructure and develop a more comprehensive feed safety monitoring and enforcement program in Florida. The laboratory component of the grant provided resources for expanded surveillance sampling and the development of enhanced analytical capabilities for contaminants. Most importantly, the grant enabled the laboratory to obtain ISO17025 accreditation in August 2019, and to maintain accreditation as a mechanism to satisfy all relevant and required quality system competencies.

AES was approved in 2020 for continued funding under a new AFRPS Maintenance/ Preventive Controls 5-year grant and continues to receive positive feedback from the FDA on overall progress toward completion of grant objectives. The AES Interval 4 AFRPS Assessment was conducted in April 2024 and AES received a passing report. FDA determined that full implementation has been maintained for all 11 standards. Although general implementation of AFRPS has been completed, the program and associated standards require continual monitoring and evaluation to ensure that any relevant legislative or programmatic changes are incorporated into the current regulatory framework.

Since its procurement in 2015, the grant has enabled the Department to conduct directed sampling and testing of animal feed and feed ingredients for the presence of contaminants including mycotoxins, heavy metals, ionophores and pesticides. In FY 2023-2024, one hundred forty-three sample assays (143) were performed for the mycotoxins: aflatoxin, fumonisin and vomitoxin. Eighty-seven (87) surveillance samples were tested for heavy metals including arsenic, lead, cadmium, chromium, thallium, beryllium, copper, barium, antimony, nickel, iron, cobalt, and molybdenum; ionophore testing was completed on nineteen (19) samples; cannabinoid testing was completed on twenty-five (25) samples; and ten (10) samples were tested for pesticides. Results of all mycotoxin, heavy metal, and pesticide analyses were determined to be below FDA action, guidance, and advisory levels.

3.2 LABORATORIES CERTIFIED/EXEMPTED BY THE DEPARTMENT

Five independent laboratories retained their certification status with the Department, and two registrant laboratories maintained certified laboratory testing exemptions. All laboratories participate in check sample program, and proficiency results from each of the certified laboratories are reviewed as necessary.

3.3 RESULTS OF ANALYSES REPORTED BY CERTIFIED LABORATORIES

In accordance with the Department's sampling matrices for ingredients and mixed feeds, a total of **1,428** samples were submitted and analyzed in fiscal year 2023-2024 and **84** were found to be violative in one or more categories. This represents an overall violation rate of **5.9** percent. Penalties for violative samples are paid to the consumer, if identified. Penalties for violative samples that do not have an associated consumer are payable to the Department.

3.4 NUMBER AND SUBJECT MATTER OF CONSUMER COMPLAINTS

In fiscal year 2023-2024, the Department received and investigated twelve (12) animal feed complaints. Seven (7) complaints involved unregistered companies distributing pet food and dairy products; two (2) of the complaints involved reportedly contaminated or otherwise deleterious, pet food products; one (1) complaint involved a reportedly contaminated or otherwise deleterious chicken feed product; and two (2) complaints involved reportedly contaminated or deleterious, livestock feed. Investigations conducted in response to animal health complaints were unable to substantiate allegations that reported adverse effects were related to consumption of the suspect products. However, inspectional documentation and determinations supported enforcement responses in the seven (7) complaint investigations involving unregistered companies distributing animal feed products.

3.5 TOTAL AMOUNT OF FEES AND PENALTIES BY TYPE COLLECTED BY THE DEPARTMENT

The total amount of fees and penalties collected was $715,051.23 for fiscal year 2023-2024. They are listed below by type:

Master Registration	$554,790.00
Deficiency Penalties	$16,932.23
Administrative Fines	$139,829.00
Laboratory Certification Fees	$3,500.00

Projected registration fees for next fiscal year are $554,790.00.

Appendix
Florida Feed Program Overview

FDACS - FY	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24
# of Certified Laboratories	5	6	7	4	4	5	6	**5**
# of Samples Submitted	1,918	2,310	1,750	1,455	1,228	1,892	1,506	**1,428**
Sample Violation Rate	6.0%	6.5%	5.0%	5.2%	7.8%	4.1%	12%	**5.9%**
Consumer Complaints	8	10	14	9	8	10	11	**12**
Master Registration Fees Collected	$554,105	$577,020	$575,945	$573,670	$569,900	$553,105	$561,770	**$554,790**
Deficiency Penalties Collected	$6,244	$41,159	$29,870	$4,852	$17,956	$9,048	$43,004	**$16,932**
Administrative Fines Collected	$55,036	$154,142	$1,273	$64,878	$114,770	$125,896	$62,250	**$139,829**
Laboratory Certification Fees Collected	$3,200	$4,050	$4,100	$2,800	$3,100	$3,500	$3,100	**$3,500**
Total Fees and Penalties Collected	$618,585	$776,371	$611,188	$646,200	$705,726	$691,549	$670,124	**$715,051**