FLORIDA DEPARTMENT OF AGRICULTURE

3125 CONNER BOULEVARD, SUITE N
TALLAHASSEE, FLORIDA 32399

PREVENTIVE CONTROLS OF ANIMAL FOOD INSPECTION REPORT

Section 1: General Information

Type of Firm	List the specie(s) the firm prepares feed for:
Number of employees	Annual Gross Income

Section 2: Good Manufacturing Practices

Does the firm have an Environmental Monitoring Program* that provides information on the quality of the manufacturing environment (i.e., pest control)?

*The purpose of the EM Program is to document the state of control of the facility, not to determine the quality of the finished product

◯ YES ◯ NO

Does the import feed or feed ingredients outside of Florida?

◯ YES ◯ NO

Are shipping containers (e.g., totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients examined upon receipt to determine whether contamination or deterioration of animal food has occurred (507.25(b)(1)(i))?

◯ YES ◯ NO

Are raw materials and other ingredients examined to ensure they are suitable for manufacturing and processing into animal food and are handled under conditions that will protect against contamination and minimize deterioration (507.25(b)(1))?

◯ YES ◯ NO

Does the firm manufacture or handle human food?

◯ YES ◯ NO

Does the management ensure the following precautions are taken so that the plant operations do not contribute to contamination (507.25(a)(5))? Select all that apply

☐	Ingredients are stored in containers to protect against contamination
☐	Manufacturing and processing steps (cutting, drying, grindings, mixing, pelleting, etc.) are done in a way to protect against contamination
☐	Filling, assembling, and packaging are done in a way that protects against contamination

When animal food has become adulterated, does management of the firm ensure that it is rejected of, or if appropriate, it is treated or processed to eliminate the adulteration?

*Disposal should be done in a way that protects against the contamination of other animal food (507.25(a)(7))

◯ YES ◯ NO

Are all plant equipment and utensils used in manufacturing, processing, packing, and holding animal food designed, constructed, and used so that they do not adulterate the animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants (507.22(a)(1))?

◯ YES ◯ NO

Are freezer and cold storage compartments used to hold animal food fitted with an accurate temperature measuring device (507.22(c))?

◯ YES ◯ NO ◯ Not applicable

Does management of the establishment ensure that animal food is accurately identified/labeled (507.25(a)(2))?

◯ YES ◯ NO

When the facility is responsible for transporting the animal food itself or arranges with a third-party to transport the animal food, are the shipping containers and bulk vehicles used to distribute animal food examined prior to use (507.27(c))?

◯ YES ◯ NO ◯ Not applicable

Are returned animal food identified as such and segregated until assessed for animal food safety to determine the appropriate disposition (507.27(d))?

◯ YES ◯ NO

Is the plant of suitable size, construction, and design to facilitate cleaning, maintenances, and pest control to reduce the potential for contamination (507.17(b))?

◯ YES ◯ NO

Are the grounds around the plant under control of the management of the establishment kept in a way that will protect against the contamination of the animal food (507.17(a))?

◯ YES ◯ NO

Section 3: Food Safety Plan

Does the firm have a written Food Safety Plan (507.31(a))?

◯ YES ◯ NO

If yes, select the following items the Food Safety Plan includes:

☐	Written hazard analysis (507.33(a)(2))
☐	Written preventive controls (507.34(b))
☐	Written supply-chain program (subpart E)
☐	Written recall plan (507.38(a)(1))
☐	Written procedures for monitoring the implementation of the preventive controls (507.40(a)(1))
☐	Written corrective action procedures (507.42(a)(1))
☐	Written verification procedures (507.49(b))

Does the facility conduct a reanalysis of the Food Safety Plan at least once every 3 years (507.50(a))?

◯ YES ◯ NO ◯ The facility does not have a Food Safety Plan

Are individuals who supervise or perform manufacturing, processing, packing, or holding activities for animal food Qualified Individuals (i.e., have the education, training, or experience necessary) (507.31(b))?

◯ YES ◯ NO

If yes, how many employees are PCQI?

Is the Food Safety Plan signed and dated upon initial completion and upon any modification by the owner, operator, or agent in charge (507.206)?

◯ YES ◯ NO ◯ The facility does not have a Food Safety Plan

Section 4: Hazard Analysis

The following hazards should be considered as a known or reasonably foreseeable hazard at each facility type.
The Inspector should ask questions to see if the hazards were considered and if they are being addressed by a preventive control, a pre-requisite program, or for valid reasons not applicable to that facility.

*The BSE regulation should be cited as a BSE violation and are therefore not included below.

Is the facility a manufacturer of processed dog and cat food?

Dog or cat food, including treats, that have been dehydrated, baked, extruded or other heat processed to be shelf stable.

◯ YES ◯ NO

If yes, select the following hazards that are identified:

	Hazard	Hazard Type	Description
☐	*Salmonella*	Biological	FDA considers pet food to be adulterated under section 402(a)(1) of the FD&C Act when it is contaminated with *Salmonella* (all serotypes) and will not subsequently undergo a commercial heat step or other commercial process that will kill it
☐	Aflatoxins	Chemical	The action level for aflatoxins in dog and cat food is 20ppb
☐	Fumonisin	Chemical	Moisture content above 13%, warm temperatures (80-100°F), and fines (from husks, broken kernels, etc. that reduce airflow during storage) will promote the growth of the fungus during storage
☐	Deoxynivalenol (DON, vomitoxin)	Chemical	Damaged wheat grains may support fungus growth at moisture content at 12% and above. A facility may justify a higher level due to conditions such as storage temperature, storage time, and airflow
☐	Nutrient Deficiencies and Toxicities	Chemical	The recommended minimum thiamine level for growth and reproduction and adult maintenance for cats is 5.6mg/kg food on a dry matter basis. The recommended amount of Vit D in dog food is 500-3,000 IU/KG and signs of Vit D toxicosis appear around 4,000 IU/kg dry matter
☐	Physical Hazards	Physical	Physical hazards in pet food may cause lacerations to the mouth, present a choking hazard, or other internal blockage

Is the facility a manufacturer of Low Acid Canned Food (LACF) of dog and cat food (cans or pouches)?

Dog or cat hermetically sealed in a can or pouch.

These facilities are exempt from the requirements for microbiological hazards covered by part 113.

◯ YES ◯ NO

If yes, select the following hazards that are identified:

	Hazard	Hazard Type	Description
☐	Nutrient Deficiencies and Toxicities	Chemical	The recommended minimum thiamine level for growth and reproduction and adult maintenance for cats is 5.6mg/kg food on a dry matter basis. The recommended amount of Vit D in dog food is 500-3,000 IU/KG and signs of Vit D toxicosis appear around 4,000 IU/kg dry matter
☐	Drug residue	Chemical	Animal drug residues may be introduced into dog and cat food through the use of animal derived ingredients. The exposure risk may be higher in large chunks of meat, fat and animal organs as opposed to finely ground co-mingled ingredients
☐	Physical Hazards	Physical	Physical hazards in pet food may cause lacerations to the mouth, present a choking hazard, or other internal blockage

Is the facility a manufacturer of dog and cat food that as not undergone a heat process?

Dog and cat food intended to be fed in the home that has not been processed with a heat step to control microbiological hazards (e.g. raw pet food). Non-heat commercial processes may include irradiation, high-pressure processing (HPP), and the application of substances to control bacterium.

There are no food additives approved for this use.

◯ YES ◯ NO

If yes, select the following hazards that are identified:

Hazard	Hazard Type	Description

☐	*Listeria monocytogenes (L. monocytogenes)*	Biological	Raw pet food is typically refrigerated or frozen. Since *L. monocytogenes* is capable of growing at refrigeration temperatures, refrigeration is not an adequate control for this biological hazard
☐	*Salmonella*	Biological	FDA considers pet food to be adulterated under section 402(a)(1) of the FD&C Act when it is contaminated with *Salmonella* (all serotypes) and will not subsequently undergo a commercial heat step or other commercial process that will kill it
☐	Pathogenic strains of *Escherichia coli* (*E. coli*)	Biological	The hazard can be introduced through the inclusion of raw materials contaminated with *E. coli* O157:H7. Raw materials, especially raw beef and green leafy vegetable, have been sources of *E. coli* O157:H7 contamination
☐	Animal Drug Residues	Chemical	Animal drug residues may be introduced into dog and cat food through the use of animal derived ingredients. The exposure risk may be higher in large chunks of meat, fat and animal organs as opposed to finely ground co-mingled ingredients
☐	Nutrient Deficiencies and Toxicities	Chemical	The recommended minimum thiamine level for growth and reproduction and adult maintenance for cats is 5.6mg/kg food on a dry matter basis. The recommended amount of Vit D in dog food is 500-3,000 IU/KG and signs of Vit D toxicosis appear around 4,000 IU/kg dry matter
☐	Physical Hazards	Physical	Physical hazards in pet food may cause lacerations to the mouth, present a choking hazard, or other internal blockage

Is the facility a Renderer or Protein Blender?

The rendering industry utilizes packinghouse offal, meat processing waste, restaurant waste, used cooking oils and animal tissues from other sources. Rendered animal food ingredients include the various poultry, meat and marine products which result from the rendering of these animal tissues to salvage protein and fat. Raw materials may include animals that have died otherwise than by slaughter (this usually means animals that died on the farm). Renderers who receive animals that have died otherwise than by slaughter, whether directly from the farm or from someone else in their supply chain who may be processing these animals, should be queried about whether they have a process for evaluating "mass casualty" events.

◯ YES ◯ NO

If yes, select the following hazards that are identified:

	Hazard	**Hazard Type**	**Description**
☐	*Salmonella*	Biological	FDA considers pet food to be adulterated under section 402(a)(1) of the FD&C Act when it is contaminated with *Salmonella* (all serotypes) and will not subsequently undergo a commercial heat step or other commercial process that will kill it
☐	Animal Drug Residues	Chemical	Operations that salvage skeletal muscles, organs, or other tissues for processing should determine whether animals have been euthanized using pentobarbital or other drugs and is so, exclude those animal from use as animal food
☐	Physical Hazards	Physical	Physical hazards in pet food may cause lacerations to the mouth, present a choking hazard, or other internal blockage

Is the facility a Meat Reclaimer (3D/4D Processor)?

3D/4D animal processors harvest animal tissues. Raw materials may include animals that have died otherwise than by slaughter (this usually means animals that died on the farm). Processors who receive animals that have died otherwise than by slaughter, whether directly from the farm or from someone else in their supply chain who may be collecting these animals, should be queried about whether they have a process for evaluating the suitability for use in feed of the raw material they are receiving. Processing is typically limited to deboning with no heat treatment. The products are typically used as food for large carnivores, fur farms, canines, and as an ingredient in canned pet food.

◯ YES ◯ NO

If yes, select the following hazards that are identified:

Hazard	**Hazard Type**	**Description**

☐	*Salmonella*	Biological	FDA considers pet food to be adulterated under section 402(a)(1) of the FD&C Act when it is contaminated with *Salmonella* (all serotypes) and will not subsequently undergo a commercial heat step or other commercial process that will kill it
☐	Animal Drug Residues	Chemical	Animal drug residues may be introduced into dog and cat food through the use of animal derived ingredients. The exposure risk may be higher in large chunks of meat, fat and animal organs as opposed to finely ground co-mingled ingredients
☐	Physical Hazards	Physical	Physical hazards in pet food may cause lacerations to the mouth, present a choking hazard, or other internal blockage

Is the facility a manufacturer of Livestock Feed (Medicated and/or Non-medicated)?

Facilities producing complete or supplemental food rations for livestock species, including poultry, horses and minor species (e.g., aquaculture, sheep, deer). The facility may produce medication and/or non-medicated animal food.

◯ YES ◯ NO

If yes, select the following hazards that are identified:

	Hazard	Hazard Type	Description
☐	Aflatoxins	Chemical	Nuts, grains (corn), and seeds are susceptible.

Action Level	Crops	Species
20ppb	Corn, peanut products, other animal feeds and feed ingredients	Immature animals and lactating animals (chicks, turkey, poults, piglets, calves, dairy cattle, sheep, goats)
300ppb	Corn and peanut products	Finishing beef cattle
300ppb	Cottonseed meal	Beef cattle, swine, or poultry (regardless of age or breeding status)
200ppb	Corn or peanut products	Finishing swine (100lb or greater)
100ppb	Corn and peanut products	Breeding beef cattle, breeding swine, or mature poultry

☐	Fumonisin	Chemical	Moisture content above 13%, warm temperatures (80-100 °F), and fines (from husks, broken kernels, etc. that reduce airflow during storage) will promote the growth of the fungus during storage

Species (lifestage)	Total Fumonisins	Max % of diet (dry weight basis)
Equids (horses) and rabbits	5ppm	20%
Swine and catfish	20ppm	50%
Breeding ruminants, breeding poultry and breeding mink*	30ppm	50%
Ruminants ≥ 3 months old being raised for slaughter and mink being raised for pelt production	60ppm	50%
Poultry being raised for slaughter	100ppm	50%
All other species	10ppm	50%

*Includes lactating dairy cattle and hens laying eggs for human consumption

☐	Deoxynivalenol (DON, vomitoxin)	Chemical	Damaged wheat grains may support fungus growth at moisture content at 12% and above. A facility may justify a higher level due to conditions such as storage temperature, storage time, and airflow

Species (lifestage)	Animal Food	DON	Max % of total ration*
Ruminating beef cattle Feedlot cattle older than 4 months Ruminating dairy cattle older than 4 months	Grains and grain by-products	10ppm (on 88% dry matter basis)	Not specified – see additional total ration limit

			Ruminating beef cattle Feedlot cattle older than 4 months Ruminating dairy cattle older than 4 months	Distillers grains, gluten feeds and gluten meals derived from grains	30ppm (on 88% dry matter basis)	Not specified – see additional total ration limit
			Ruminating beef cattle Feedlot cattle older than 4 months	Total ration	10ppm	100%
			Ruminating dairy cattle older than 4 months	Total ration	5ppm	100%
			Chickens	Grain and grain by-products	10ppm	50%
			Swine	Grain and grain by-products	5ppm	20%
			All other animals	Grain and grain by-products	5ppm	40%
			*The total ration includes grains, all grain by-products including distillers and brewers grains, hay, silage, and roughage			
☐	Nutrient Deficiencies and Toxicities	Chemical	Copper requirements of sheep generally range from 3 to 8 mg Cu/kg diet dry matter, while 15 mg Cu/kg diet or even less can cause toxicosis under certain conditions. Vitamin D is a fat soluble vitamin with elevated levels leading to recalls in fowl (pheasant, poultry, quail), guinea pig, swine, and rabbit foods. Since animals typically consume the same food throughout each lifestage a minor deficiency or toxicity in the food can also result in declining health over time (e.g., calcium deficiency in layer feed)			
☐	Animal Drugs	Chemical	Drug carryover is often the result of incomplete clean-out or flushing of containers and equipment. Errors in batch sequencing may also result in unsafe carryover of a drug to another manufactured animal food for a species or life stage sensitive to an animal drug. For example, if a facility is manufacturing food for equids (e.g., horses) and also uses monensin in the facility, they should identify monensin as a known or reasonably foreseeable hazard			
☐	Physical Hazards	Physical	Physical hazards may cause lacerations to the mouth, present a choking hazard, or other internal blockage			

Is the facility a manufacturer of Vitamins/Minerals and Pre-Mixes?

Facilities producing individual vitamins and minerals, or combinations of vitamins and minerals often referred to as pre-mixes. Technical additive, carriers or diluents may be added (i.e., soybean hulls, dried distillers grains, verxite, silicon dioxide)

◯ YES ◯ NO

If yes, select the following hazards that are identified:

	Hazard	Hazard Type	Description
☐	Nutrient Deficiencies and Toxicities	Chemical	Incorrect batching (the addition or too much or too little) may result in either a vitamin or a mineral toxicity or deficiency. Incorrect labeling of bins, addition of a different ingredient into a dedicated bin, bridging (i.e. compaction does not allow the ingredient to flow out of a bin), and human error have contributed to this manufacturing error in the past. Recalls have been caused by premixes containing: excess urea or other non-protein nitrogen source, high Vitamin D3, premix without Vitamins A, D, and E, high salt, and no salt.
☐	Dioxins	Chemical	Elevated dioxin levels have been found in mineral and mineral premix products dried at temperatures above 500°F. The presence of copper may be an attributing factor
☐	Mycotoxins	Chemical	Technical additives, carriers, or diluents of grain origin may serve as a source of mycotoxin contamination (e.g. rice by-product fractions,

		soybean hulls, dried distillers grains). Due to the low inclusion rate of the pre-mix, the concentration of mycotoxins will have a lower impact on the mycotoxin level in the final animal food. Ingredients should still comply with regulatory levels.
☐ Physical Hazards	Physical	Physical hazards in pet food may cause lacerations to the mouth, present a choking hazard, or other internal blockage

Is the facility a manufacturer of Distillers Products (Fuel Ethanol)?

Facilities producing animal feed co-products from the fuel ethanol industry, including distillers grains and distillers oil.

◯ YES ◯ NO

If yes, select the following hazards that are identified:

Hazard	Hazard Type	Description
☐ Sulfur	Chemical	Cattle consuming distillers grains with excess sulfur may experience toxic effects ranging from less than desired weight gain to fatalities from Polioencephalomalacia (PEM). Sulfur originates in distillers grains from the corn, yeasts, and water used to produce ethanol. It may also be introduced during processing by the use of processing aids used for pH adjustment such as sulfuric acid and sodium bisulfite. Some cleaning agents such as sulfamic acid could add sulfur to the grains if the system is not properly flushed and they become a component of the animal food.
☐ Aflatoxins	Chemical	Nuts, grains (corn), and seeds are susceptible.

Action Level	Crops	Species
20ppb	Corn, peanut products, other animal feeds and feed ingredients	Immature animals and lactating animals (chicks, turkey, poults, piglets, calves, dairy cattle, sheep, goats)
300ppb	Corn and peanut products	Finishing beef cattle
300ppb	Cottonseed meal	Beef cattle, swine, or poultry (regardless of age or breeding status)
200ppb	Corn or peanut products	Finishing swine (100lb or greater)
100ppb	Corn and peanut products	Breeding beef cattle, breeding swine, or mature poultry

☐ Fumonisin	Chemical	Moisture content above 13%, warm temperatures (80-100°F), and fines (from husks, broken kernels, etc. that reduce airflow during storage) will promote the growth of the fungus during storage

Species (lifestage)	Total Fumonisins	Max % of diet (dry weight basis)
Equids (horses) and rabbits	5ppm	20%
Swine and catfish	20ppm	50%
Breeding ruminants, breeding poultry and breeding mink*	30ppm	50%
Ruminants ≥ 3 months old being raised for slaughter and mink being raised for pelt production	60ppm	50%
Poultry being raised for slaughter	100ppm	50%
All other species	10ppm	50%

*Includes lactating dairy cattle and hens laying eggs for human consumption

☐ Deoxynivalenol (DON, vomitoxin)	Chemical	Damaged wheat grains may support fungus growth at moisture content at 12% and above. A facility may justify a higher level due to conditions such as storage temperature, storage time, and airflow

Species (lifestage)	Animal Food	DON	Max % of total ration*

			Ruminating beef cattle Feedlot cattle older than 4 months Ruminating dairy cattle older than 4 months	Grains and grain by-products	10ppm (on 88% dry matter basis)	Not specified – see additional total ration limit
			Ruminating beef cattle Feedlot cattle older than 4 months Ruminating dairy cattle older than 4 months	Distillers grains, gluten feeds and gluten meals derived from grains	30ppm (on 88% dry matter basis)	Not specified – see additional total ration limit
			Ruminating beef cattle Feedlot cattle older than 4 months	Total ration	10ppm	100%
			Ruminating dairy cattle older than 4 months	Total ration	5ppm	100%
			Chickens	Grain and grain by-products	10ppm	50%
			Swine	Grain and grain by-products	5ppm	20%
			All other animals	Grain and grain by-products	5ppm	40%
			*The total ration includes grains, all grain by-products including distillers and brewers grains, hay, silage, and roughage			
☐	Physical Hazards	Physical	Physical hazards may cause lacerations to the mouth, present a choking hazard, or other internal blockage			

Is the facility a manufacturer of Milk Replacer or Colostrum?

Facilities producing milk replacers and/or colostrum intended for young animals (not the same as raw milk for pets)

◯ YES ◯ NO

If yes, select the following hazards that are identified:

	Hazard	Hazard Type	Description
☐	*Salmonella*	Biological	FDA considers an animal feed to be adulterated under section 402(a)(1) of the FD&C Act when it is contaminated with a *Salmonella* serotype that is considered pathogenic to the animal intended to consume the animal feed and the animal feed will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella*. Milk replacer intended for pets is considered adulterated when contaminated with any *Salmonella* serotype
☐	Nutrient Deficiencies and Toxicities	Chemical	Milk replacers and colostrum are generally intended to be the sole source of nutrition for immature animals. Nutrient deficiencies and toxicities may be the result of a processing error at the manufacturing facility. Examples of manufacturing errors include over or under inclusion of an ingredient, use of the wrong ingredient (e.g., vitamin premix), miscalculation when using rework, and nutrient degradation during processing. Facilities should ensure label guarantees are being met
☐	Animal Drugs	Chemical	Drug carryover is often the result of incomplete clean-out or flushing of containers and equipment. Errors in batch sequencing may also result in unsafe carryover of a drug to another manufactured animal food for a species or life stage sensitive to an animal drug. For example, if a facility is manufacturing food for equids (e.g., horses) and also uses monensin in the facility, they should identify monensin as a known or reasonably foreseeable hazard
☐	Physical Hazards	Physical	Physical hazards in pet food may cause lacerations to the mouth, present a choking hazard, or other internal blockage

Section 5: Preventive Controls

Does the facility identify any hazards that require a Preventive Control?

◯ YES ◯ NO

If yes, do the Preventive Controls include the following (507.34)? (Select all that apply)

☐	Process controls
☐	Sanitation controls
☐	Supply-chain controls
☐	Recall Plan
☐	Other (e.g., hygiene training, other good manufacturing practices)

Section 6: Preventive Control Management (answer if Section 5 is "YES")

Does the facility have written procedures established for monitoring the preventive controls (507.40(b))?

◯ YES ◯ NO

Has the facility established written corrective action procedures that are taken if preventive controls are not properly implemented?

◯ YES ◯ NO

Does the facility have documented records of verification and validation that the preventive controls identified and implemented are adequate to control the hazard (507.45 & 507.47)?

◯ YES ◯ NO