

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

6751 Steger Drive  
Cincinnati, OH 45237  
(513) 679 2700

DATE(S) OF INSPECTION

05/21-23,26,29,30/2009

FEI NUMBER

1021417

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

To: Richard M. Barton, General Manager

FIRM NAME

Bi-County Farm Bureau Coop Association Inc.

STREET ADDRESS

8300 Dixie Highway

CITY, STATE AND ZIP CODE

Florence, KY 41042

TYPE OF ESTABLISHMENT INSPECTED

Animal feed manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

**OBSERVATION 1**

Effective measures are not being taken to exclude pests from the processing areas or to protect against the contamination of food on the premises by pests.

**a. Specifically, on 05/21/2009:**

1. Approximately twelve live rodents were observed in the feed mill. Approximately four rodents were observed traveling between a ceiling support rail and an opening in the ceiling caused from a sagging board approximately two feet from the south wall of the first floor. A live rodent was observed crawling under a pallet of feed oats approximately fifteen feet from the NW corner of the first floor. A live rodent was observed eating product spilled on the floor between pallets of alfalfa cubes and feed oats approximately fifteen feet from the NW corner of the first floor. Two live rodents were observed moving around near the bottom of the stairs in the basement of the mill. Approximately four live rodents were observed on the corn pile in the basement.
2. Approximately nine dead rodents were observed on the first floor of the feed mill in close proximity to various pallets of animal feeds. Two dead rodents were observed within a foot of a pallet of goat feed located approximately 10 feet from the SW corner. One dead rodent was within three inches of a pallet of trace mineral salt located along the west wall. Approximately seven dead rodents were observed on a shovel an employee was carrying after he swept them up from the floor; the three rodents described above were included in the count. Two dead rodents were observed on the floor, one within two inches and one within seven inches of a pallet of bagged Layena Sunfresh Recipe Pellet chicken feed located on the south wall.
3. Four live birds were observed flying inside the first floor of the feed mill and resting on a ceiling support brace near a bird's nest located approximately fifteen feet west of the loading dock.

**b. Specifically, on 05/22/2009:**

1. Approximately 17 live rodents were observed in the feed mill. A live rodent was observed running along west wall into a bait box. Another live rodent was observed on north wall approximately five feet to the east of Legends Show & Pleasure Textured Horse Feed. A live rodent was observed in the northwest corner of the facility going under pallets and jumping on bags of product. Two live rodents were observed approximately 15 ft. from the northwest corner of the building behind and under product. A live rodent was observed running along the west wall. Approximately 11 live rodents were observed running in the basement.
2. Three dead rodents were observed in the feed mill. A dead rodent was observed in the crack between the floor and the west wall, approximately 15 ft from northwest corner and approximately six inches from a pallet of Agri-Flex Bentonite. Two dead rodents were observed on the basement floor.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Michael E. Campbell Brigitte K. Hofmann Cynthia T. Cain	Michael E. Campbell, Investigator Brigitte K. Hofmann, Investigator CYNTHIA T. CAIN, INVESTIGATOR	05/30/2009 05/30/2009 5/30/2009

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3. Approximately three live birds were observed in the feed mill. The birds were flying above product all over the facility and sitting on the beams around a bird's nest that was in a wood crevice located approximately six beams from the east entrance along the south side of the building.

4. One lot containing 35/50 lb. paper bags of Legends Show & Pleasure Textured Horse Feed were found with evidence typical of rodent activity. The lot consisted of four pallets. The pallets were numbered and counted as followed: Pallet 4 had 10 bags; it was leaning against two overlapping pieces of cardboard which were leaning against the north wall. Pallet 3 had 10 bags; it was leaning against pallet 4. Pallet 2 had 8 bags; it was leaning against pallet 3. Pallet 1 had 7 bags; it was leaning against pallet 2. Eight of 35 of the bags in the lot were examined. These eight bags exhibited evidence of apparent rodent gnawing, apparent rodent excreta pellets, and/or fluorescing stains. This included five bags with one or more apparent rodent excreta pellets on the exterior of the bags, five bags with fluorescing stains varying from 1 1/2 to 5 inches in length on the exterior of the bags. Two bags exhibited apparent rodent gnaw holes, one to the product. This apparent gnaw hole was observed 05/21/2009 but was taped over when investigators returned on 05/22/2009. There were a total of 44 apparent rodent excreta pellets, five fluorescing stains and two apparent gnaw holes observed on the 8 bags examined of 35 bags in the lot. All 35 bags of Legends Show & Pleasure Textured Horse Feed were marked with lot # W9118. The bags were received on or about 04/30/2009 and had been in the feed mill for approximately 22 days. This product was stored approximately 25 feet from the northwest corner of the feed mill.

5. Three pallets containing 28/50 lb. bags of Feed Grade Sodium Bicarbonate were found with evidence typical of rodent activity. The sodium bicarbonate consisted of 28 bags on three pallets. Pallet 3 contained 10 white bags; it was leaning against the west wall. Pallet 2 contained 9 white bags and one brown bags; it was leaning against pallet 3. Pallet 1 contained 8 brown bags; it was leaning against pallet 2. On 05/21/2009, three apparent rodent excreta pellets were observed touching product under a hole in the white paper bag on pallet 2. When investigators returned on 5/22/09, the hole on this bag had been taped over. The bags were counted; this bag is bag 10 on pallet 2. When the tape was peeled back, the same three apparent rodent excreta pellets were observed in the product. There were also several apparent rodent excreta pellets stuck to the tape. The white bags were not marked with a lot number. This product was stored approximately 25 feet from the southwest corner of the feed mill.

c. Specifically, on 05/23/2009:

1. Approximately 13 live rodents were observed in the feed mill. Three live rodents were observed on the north wall, approximately 10 feet from the northwest corner of the building. Three rodents were observed directly under and on products Reliance Horse Feed, Bio-Cube Alfalfa Cubes, and feed oats which are located on the north wall, approximately 10-15 feet from northwest corner of the facility. A live rodent was observed approximately 22 feet from the southwest corner of the facility and approximately three feet to the east of Home Grown Game Bird & Poultry product. Four live rodents were observed under Layena Sunfresh Recipe Pellet chicken feed along the south wall, approximately five feet to the east of Home Grown Game Bird & Poultry. Two live rodents were observed on the east wall of the second floor of the feed mill.

2. Three dead rodents were observed in the feed mill. A dead rodent was observed approximately one inch below a pallet of Home Grown Game Bird & Poultry product along the south wall, approximately 19 ft from southwest corner. Two dead rodents were observed in an overflow of product near the northeast corner of the facility and underneath the auger, which has an approximately one foot square opening in the housing, which transports product from the outside dump pit to the hopper inside the building.

3. A dead bird was observed covered by dirt and dust on the second floor of the feed mill near the blender.

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d. Specifically, on 05/26/2009:

1. Approximately 10 live rodents were observed in the feed mill. Two live rodents were observed crawling in and out of the ingredient dump and then into the auger housing of the mixer, which contained ingredients used in mixing feed, located on the bottom of the mixer closest to the northeast corner of the feed mill. A live rodent and a live bird were observed in the scale buggy resting on top of product throughout the day; the scale buggy is used to weigh ingredients before dumping into the ingredient dump directly under the bottom of the mixers.

2. Spilled product on the manufacturing floor, where apparent REP was sampled, was observed being swept into the bottom of the mixer by an employee using a broom. The spillage was caused by dumping ingredients into the bottom of the mixers from the scale buggy.

3. A lot containing 18 bags of Layena Sunfresh Recipe Pellet chicken feed was found with evidence typical of rodent activity. The lot consisted of 18 bags on two pallets. Pallet 2 contained 10 bags; it was leaning against two overlapping pieces of cardboard which were leaning against the south wall. Pallet 2 contained 10 bags; it was leaning against the south wall. Pallet 1 contained 8 bags; it was leaning against pallet 2. All bags in the lot were examined. 12 bags exhibited evidence of apparent rodent activity. This included eleven bags with one or more apparent rodent excreta pellets on the exterior of the bags and two bags which exhibited apparent rodent gnaw holes, one to the product. There were a total of 19 apparent rodent excreta pellets and three apparent gnaw holes on the bags. Apparent rodent excreta pellets too numerous to count were observed under and around each pallet. A dead rodent was observed approximately three feet northeast of the lot. All 18 bags of Layena Sunfresh Recipe Pellet chicken feed were marked with lot # 3APR28FRF. The bags were received on or about 05/12/2009 and had been in the feed mill for approximately 11 days. This product was stored approximately 20 feet from the southwest corner of the feed mill.

4. A lot containing 10 bags of Bio-Cubes Alfalfa Cubes was found with evidence typical of rodent activity. The lot consisted of 10 bags on two pallets. Pallet 2 contained 7 bags; it was leaning against north wall. Pallet 1 contained 3 bags; it was leaning against pallet 2. All bags in the lot were examined. Nine bags exhibited evidence typical of rodent activity. This included eight bags with one or more apparent rodent excreta pellets on the exterior of the bags and two bags which exhibited apparent rodent gnaw holes, both to the product. There were a total of 184 apparent rodent excreta pellets and two apparent gnaw holes on the bags. Apparent rodent excreta pellets too numerous to count were observed under and around each pallet. All bags were marked lot 892. The bags were received on or about 02/16/2009 and had been in the feed mill for approximately three months. This product was stored approximately 15 feet east from the northwest corner of the feed mill. During the examination of this lot, two live rodents were running over, around and under the bags and the pallets, and running into and out of holes where the floor meets the north wall about three feet west of the lot and three feet east of the lot. Live rodents were also observed eating product spilled from an adjacent lot of oats around and under the lot of alfalfa.

5. During the examination of Layena Sunfresh Recipe Pellet chicken feed, at least eight birds were observed flying in and out of the west window about 25 feet away, eating spilled product from the floor about 15 feet east of the lot, and/or visiting an active nest.

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**OBSERVATION 2**

Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.

Specifically,

- a. The first floor of the feed mill contained apparent rodent excreta pellets (REP) too numerous to count in the manufacturing area, as well as all four corners, around the inside perimeter of the floor, and directly under and around numerous pallets of feed. Approximately 69 apparent REP were observed within one to 18 inches of an open grate on the first floor with the open top corn grinder directly below in the basement. Numerous apparent REP was also observed on top of bags of feed that were not mentioned in observation 1. Numerous areas of the floor directly under and around pallets of bagged feed were littered with piles of feed that contained apparent REP, live rodents, and dead rodents.
- b. Product was observed on the floor during every day of the inspection that Investigators were in the feed mill. In particular, feed oats were observed on the ground spilled under the Alfalfa cubes from 05/21/2009 until 05/26/2009. Many other products were also broken open and on the floor such as Layena Sunfresh Recipe Pellet chicken feed and Reliance Horse Feed.
- c. The auger that entered the building from the north, directly from the silos, had approximately a five feet section of the auger housing that was open on the top of the auger. The open section of the auger had approximately six spots of apparent bird droppings along the inside section of the auger, as well as the shaft of the auger. The corn was in direct contact with the bird droppings on the side of the auger in at least one location.
- d. The basement floor of the feed mill also contained apparent REP too numerous to count. The room in the NE corner of the basement that contains the corn grinder, contained a pyramid shaped pile of corn up to approximately three feet high with apparent REP too numerous to count in it, as well as live rodents. The basement also had piles of corn approximately three feet long by two feet wide along the perimeter of the basement. Plant life could be seen growing in at least one pile of corn.
- e. Product overflow was not disposed of in a sufficient time frame. A large pile of oats was outside in a pit near the northeast corner of the building. The oats overflow was within five to 15 feet from both open augers and the open window under the steps on the north side of the building.
- f. On 05/22/2009-05/26/2009, a scale buggy was covered with approximately a 1/2 inch thick layer of dirt around the upper perimeter of the buggy. The scale buggy is used to weigh ingredients before they are dumped into the mixer.
- g. There was water in the basement up to four inches deep in places caused from groundwater leaking into the basement. Pallets were placed on the floor to walk across so employees could reach the boiler room and room with the corn grinder.
- h. On the floor in the basement, there was a pile of black debris that was approximately six inches high and one foot wide in diameter and contained apparent REP. The pile was also covered with apparent maggots too numerous to count.
- i. The second floor of the feed mill, above the mixers, contained a grayish dust and dirt build up on the entire floor and equipment that was there. The build up was approximately 1/2 inch to 6 inches deep in different areas of the second floor. The walls were also coated in the dusty and dirty substance in many areas. An apparent dead bird covered in approximately 1/2 in. of dust and dirt was observed near the center of the second floor.
- j. Cob webs, dirt, and rotting wood were observed throughout the entire firm. Particles ranging in size from a 1/2 inch or less were observed falling from the ceiling in every area of the firm on the first floor and basement.

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**OBSERVATION 3**

Failure to maintain buildings in repair sufficient to prevent food from becoming adulterated.

Specifically, there were numerous deficiencies in the feed mill that allow ingress and egress of pests.

- a. On the inside of the feed mill: A hole in the floor along the wall in the northwest corner of the facility was observed with rodent activity. Another hole in the floor along the west wall, approximately four feet from the northwest corner was observed with rodent activity. A hole in the floor in the southeast corner of the firm approximately 10 feet from the loading dock was observed. The bottom right side of a door in the basement of the feed mill on the north wall was observed with an approximately three inch by four inch hole leading directly outside. Also, a gap approximately 9 feet long and 2 inches high leading directly outside was observed under the door near the southeast corner of the basement.
- b. On the north side of the building: A window was missing leading into the basement located on the north side of the building under the steps and approximately eight inches from the open top corn grinder. The roof of the boiler room had holes around the edges. A window located on the north side of the building, directly above the boiler room roof, had a window panel missing. On the north side of the building, approximately 20 feet from the northwest corner of the firm, a door that leads to the basement has an opening approximately one inch to two inches wide almost completely down the center of it.
- c. On the west side of the building: The window closest to the southwest corner of the facility had a missing pane.
- d. On the south side of the building: The westernmost window on the south wall was broken with approximately half of a pane missing.

**OBSERVATION 4**

Use of rodenticides without observing necessary precautions and restrictions to protect against contamination of food.

Specifically;

- a. On 05/22/2009, (b) (4) a pelleted rodenticide, was observed in four different locations in the feed mill. The label on (b) (4) indicates "KEEP AWAY FROM FOODSTUFFS". However, an open bag of (b) (4) with approximately 11 pellets that had fallen out of the bag, was observed on the floor approximately two inches to the east of a pallet of Legends Show & Pleasure Textured Horse Feed. Another open bag of (b) (4) was observed in the northeast corner of the feed mill approximately eight feet from the Legends Show & Pleasure Textured Horse Feed. An open bag of (b) (4) was observed in the center of the west wall, approximately two inches from product. A bag of (b) (4) was observed in the center of the south wall, within approximately four inches of product.
- b. On 05/26/2009, two more open bags of (b) (4) were observed under the wooden divider located on the first floor in the center of the feed mill. The two open bags of (b) (4) were approximately three feet from each other and both bags were approximately three feet from product to the north and south sides of the (b) (4) bags.

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**OBSERVATION 5**

Failure to cut weeds or grass that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures.

Specifically,

a. On 05/22/2009, weeds, grass, and plant life were observed across the driveway between the south outer wall of the feed mill and the shed to the south of the feed mill. The weeds, grass, and plant life were directly adjacent to the outer north wall of the shed. The weeds, grass, and plant life were between three feet and seven feet tall. The weeds, grass, and plant life were approximately 30 feet to 40 feet from the feed mill.

b. There is a plant growing to the side and above the boiler room attached to the feed mill. The plant has branches directly above the roof of the boiler room. The roof of the boiler room has 2 holes approximately 1 foot long by 2 feet wide. One branch is approximately 6 inches from the opening in the boiler room's roof.

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*Michael E. Campbell*  
*Brigitte K. Hofmann*  
*Cynthia T. Cain*

**EMPLOYEE(S) NAME AND TITLE (Print or Type)**

Michael E. Campbell, Investigator  
Brigitte K. Hofmann, Investigator  
CYNTHIA T. CAIN, INVESTIGATOR

**DATE ISSUED**

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5/30/09