

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

DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 09/19/2012 - 09/28/2012*
	FEI NUMBER 1000373073

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Raymond J. Kasel, Owner

FIRM NAME Kasel Associates Industries, Inc.	STREET ADDRESS 3315 Walnut St
CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80205-2429	TYPE ESTABLISHMENT INSPECTED Pet Food 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

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials.

Specifically, we observed sanitation deficiencies in the following areas:

Packaging Room:

- a.) There was food debris build-up underneath and on both sides of the conveyor belts on packing lines (b)(4). Additionally, the conveyor belts are not smooth and cleanable. The packaging conveyor belts are frayed and torn in places (observed on 9/19/12).
- b.) The hoppers used to convey finished product onto packaging lines (b)(4) had visible product build-up. Also, welds and bolts on hoppers for both packaging lines (b)(4) were not smooth and cleanable (observed on 9/19/12).
- c.) Two overhead metal pans (used as holders for pet treat packaging) had food debris build-up at (b)(4) packing lines (b)(4) (observed on 9/19/12).
- d.) At least 20 bulk metal crates (used to hold finished product before packaging) had food and grease build-up, were in general disrepair and had visibly missing pieces (observed on 9/19/12 and 9/20/12). This was observed in the following areas:
 - Packaging Room
 - Bulk Storage Room
 - Unloading/Drying Room
- e.) Finished unpackaged bulk product was stored in at least 30 torn, grease-laden, and reused cardboard totes (observed on 9/19/12 and 9/20/12) in the following areas:
 - Packaging Room
 - Bulk Storage Room
 - Unloading/Drying Room

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kathryn M. Mogen, Investigator <i>Kathryn M. Mogen</i> Laura B. Kennedy, Investigator <i>Laura B. Kennedy</i> Jennifer A. Baker, Investigator <i>Jennifer A. Baker</i> Kristen E. Szenderski, Investigator <i>Kristen E. Szenderski</i> Andrew J. Gonzales, Microbiologist <i>Andrew J. Gonzales</i>	DATE ISSUED 09/28/2012
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Bulk Storage Room

f.) At least 40 wooden pallets used to store bulk bins of finished product before packaging have a build-up of food debris and grease. The pallets are also broken, shredded, splintering and have many loose nails. Additionally, these pallets were stacked on top of other bulk bins of finished product so that the bottom of the wooden pallet was in direct contact with the finished product underneath. (observed on 9/19/12 and 9/20/12).

g.) Finished unpackaged product was stored in at least 20 non-cleanable super tote bags that were reused and fraying (observed on 9/19/12 and 9/20/12).

h.) A floor fan with accumulated dust and grease was observed blowing onto uncovered bulk bins of unpackaged finished product. (observed on 9/19/12).

Preparation Room

i.) There was finished product stored in white plastic garbage cans that had dried food accumulation and visible grease build-up (observed on 9/19/12).

Cutting Room/Retain Room

j.) (b)(4) band saws normally used to (b)(4) were stored with accumulated dried product residue. This equipment was not in use during the inspection (observed on 9/20/12).

k.) The floor drain in the rear of the room had old and dried food product stuck inside, the floors were not sealed and appeared unclean. (observed on 9/20/12).

Unloading Room (Drying Room)

l.) The metal drying racks used to (b)(4) finished product had cooked on grease accumulated, and had multiple food-encrusted strings tied on it (observed 9/20/12).

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OBSERVATION 2

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

Specifically, we observed lack of effective pest control measures and evidence of pest infestation throughout the plant including the following:

- a.) There were gaps under exterior doorways with visible daylight in the following areas:
 - The cutting room service door, at least ½" (observed on 9/20/12)
 - The loading dock door in the general storage area at the (b)(4) of the building was left wide open during the inspection on 9/19/12.
 - There were gaps under one loading dock door and on the sides of two loading dock doors on the loading dock. There was also a gap of at least ½" under the loading dock door near the dumpster and a gap of at least ½" under the service door on loading dock (observed on 9/19/12).
 - There was a gap of at least ½" under the emergency exit door in the Unloading/Drying Room (observed on 9/20/12).
 - A gap of at least ½" under the emergency exit door between the (b)(4) (9/24/12).
 - A large hole in the wall above the chemical storage room and emergency exit door aprox. 2' x 4' is wide open to the outside. This area is open to the (b)(4) room (observed on 9/24/12).

- b.) Apparent larvae-like insects were observed in the floor-drain of the Cutting Room (observed on 9/20/12).

- c.) Worm-like insects were observed on the floor approximately 6" from a pallet of finished product bones (stored in uncovered bulk bins) in the Bulk Storage Room (observed on 9/19/12)

- d.) Moth-like flying insects were observed in multiple areas throughout the facility including one live moth trapped in a plastic wrapped shipment of packaged chicken jerky in General Storage (observed on 9/20/12).

- e.) Cockroach-like insects were observed throughout the facility including:
 - Packaging Room**
 - 1 live adult along the SW wall next to a pallet of packaging (observed on 9/19/12)
 - 12 live adults and 3 nymphs in the SE corner wall (observed on 9/20/12).
 - 2 dead adults in liquid accumulated in the coving between the Packaging Room and the Bulk Storage Room (observed on 9/20/12)
 - 1 live adult on the SW floor directly next to pallets of finished product (observed on 9/27/12)

 - Bulk Storage Room**
 - 2 live adults under pallets of finished product in the NW corner (observed on 9/20/12)

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- 1 dead adult on a pallet of finished product of jerky (observed on 9/20/12)
- 1 live adult on the NW wall (observed on 9/20/12)
- 1 dead adult in under fire extinguisher (observed on 9/20/12)
- 1 live adult on the NW floor approximately 2 feet from a bulk bin of finished product (observed on 9/27/12)

Preparation Room

- 1 live adult on the floor (observed on 9/24/12)

Cutting/Retain Room

- 3 live adults (observed on 9/20/12)

Loading Dock

- 2 live adults and 1 dead adult (observed on 9/20/12)
- 4 dead adults and 1 live adult in hall between Loading Dock and Packaging Room (observed on 9/20/12)

Unloading/ Cooling Room

- 1 live adult on the wall above metal rack of cooling chicken jerky (observed on 9/24/12)

Raw Room

- 1 live adult on the wall approximately 2 feet away from in-process chicken jerky (observed on 9/24/12)

Entryway

- 1 live adult on the red wall across from the door to the front office area (observed on 9/27/12)

f.) Large flies observed throughout facility in the following areas:

- More than 15 dead flies in the light fixtures in the Packaging Room (observed on both 9/19/12 and 9/20/12)
- More than 20 live flies in the Packaging Room and also observed on finished pig ears (observed on both 9/19/12 and 9/20/12).

g.) One dead apparent mouse on the floor in the Bulk Storage Room near the north-east wall partially under a pallet of finished product (pig ears). It was located with in 5" of a bin of cooked pig ears (observed on 9/20/12).

h.) Apparent rodent excreta pellets in the following areas:

- >50 along the wall in the General Storage Room approximately 1 ft. away from a pallet of finished/packaged chicken jerky (observed on 9/20/12)
- >25 in the General Storage Room located approximately 2 ft. from a pallet of packaged chicken jerky (observed on 9/20/12)
- >25 located less than 2 ft. from a pallet of packaged ham jerky stored in the rear loading dock area near the parked vehicle (observed on 9/20/12)

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- >50 located on and under a pallet of packaged 12-count pig ears next to an approximately 3"x3" hole in the wall in the General Storage Room (observed on 9/20/12)
- >60 located on a concrete wall curb along the back of the Bulk Storage Room near the wall of the walk-in freezer. The freezer wall was bulging and a pile of shredded insulation from inside the wall was seen in the south corner where the Bulk Storage Room wall and freezer wall meet (observed on 9/24/12)

i.) Beetle-like insects were observed in the following areas of the facility:

- Apparent larvae too-numerous-to-count and 4 live beetle-like insects on top of a white fabric super tote of finished beef knuckles in the Bulk Storage Room (observed on 9/19/12)
- 1 live black beetle-like insect on the conveyor belt of packaging line (b)(4), observed on 9/19/12)

j.) Many areas of the bulk storage, general storage and preparation rooms were inaccessible to adequately monitor and treat for pests due to storage of boxes and pallets along the walls and general disorganization (observed on both 9/19/12 and 9/20/12).

OBSERVATION 3

Failure to take effective measures to protect against the inclusion of metal and extraneous material in food.

Specifically, we observed foreign objects in finished product and failure to control against contamination by foreign objects during the inspection. This includes the following:

- a.) The firm did not have a functioning metal detector on the packaging lines on either 9/19/12 or 9/20/12 while finished product was being packaged.
- b.) Metal hook-like objects were observed protruding from bully sticks stored in a cardboard bulk-tote located in the Bulk Storage Room (observed on 9/20/12)
- c.) Wooden pallets with chipping wood and loose nails were stored directly on top of uncovered bulk bins of finished product in the firm's Bulk Storage Room. In several instances pallets were stored in direct contact with the finished product (observed on both 9/19/12 and 9/20/12)
- d.) Metal fragments were observed in direct contact with chicken chips on drying racks in the Unloading/Drying Room (observed on 9/20/12)

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OBSERVATION 4

Failure to take effective measures to protect finished food from contamination by raw materials .

Specifically, during the inspection we observed the following practices that could lead to contamination of finished product by raw ingredients:

- a.) The white and yellow plastic tubs were used in both the raw production and finished product packaging areas to hold both raw and finished product. No system was in place to differentiate which tubs were to be used for which purpose. The tubs were seen stored on the floor with product in them in both the raw and finished areas of the plant (observed on both 9/19/12 and 9/20/12).
- b.) There is no dedicated warewashing equipment and no system set up to wash, rinse and sanitize the white and yellow plastic tubs and any other equipment not designed to be cleaned-in-place (observed on both 9/19/12 and 9/20/12).
- c.) Pallet jacks, forklifts, and employee foot traffic were observed travelling between the "raw" and "finished" areas of the plant (observed on both 9/19/12 and 9/20/12). The Drying/Unloading room is open to the ^{(b)(4)} room and employees were seen moving between these two areas on 9/20/12.

OBSERVATION 5

Failure to store finished food under conditions that would protect against physical and microbial contamination.

Specifically, we observed finished product stored under conditions that could present a source of contamination. During the inspection in the Bulk Storage Room we observed the following:

- a.) Finished product was stored in unlined wire bulk crates and was observed in direct contact with the floor (observed on 9/19/12).
- b.) Finished product was stored uncovered in bulk bins (observed on 9/19/12 and 9/20/12).
- c.) A nested cardboard box, two cloth work gloves, and a plastic bag were observed lying in bulk bins of the finished unpackaged products (observed on 9/19/12 and 9/20/12).
- d.) A cardboard box and pieces of plastic were observed nested in a wire crate of bulk finished product in the Bulk Storage Room (observed on 9/19/12)

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- e.) A bulk storage bin of knuckles had torn plastic pieces mixed in with the finished product in the Bulk Storage Room (observed on 9/20/12)

OBSERVATION 6

Failure to handle work-in-progress in a manner that protects against contamination.

Specifically, we observed unfinished food products handled in a manner that may contaminate the food products during the inspection including the following:

- a.) The floor sanitizer foam sprayer located between the garbage loading dock and the ovens sprayed onto an uncovered bulk pallet of frozen chicken chips. The label on the foam sanitizer states the chemical is unfit for human or pet consumption (observed on 9/20/12).
- b.) An uncovered pallet of frozen chicken was stored on the loading dock while employees loaded a truck with the loading dock door open (observed on 9/20/12).

OBSERVATION 7

Failure to maintain buildings, fixtures, and physical facilities in repair sufficient to prevent food from becoming adulterated.

Specifically, we observed the following areas of the physical building to be in disrepair:

- a.) The floors were not sealed, maintained smooth and cleanable, allowing for the accumulation of grease in the cracks and exposed aggregate concrete. Floors also had visible chipping paint. These conditions were observed on both 9/19/12 and 9/20/12 in the following areas:
 - Packaging Room
 - Bulk Storage
 - Cutting Room/Retain Room
 - Loading Dock
 - Unloading Room/Drying Room
- b.) The ceiling tiles were broken, taped, and swollen above the filling lines and throughout the Packaging Room (observed on 9/19/12 and 9/20/12). There were missing ceiling tiles, apparent watermark on ceiling tiles, and missing light shields throughout the Preparation Room (observed on 9/19/12 and 9/20/12).

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- c.) Broken and missing light shields were observed in the Packaging Room and Preparation Room. Light shields in both the Preparation Room and the Packaging Room was replaced with clear plastic wrap (observed on 9/19/12 and 9/20/12).
- d.) Walls in several areas were deteriorating and had rough, visible broken concrete that was non-cleanable in the following areas:
 -Packaging Room (observed on 9/19/12)
 -Cutting Room/Retain Room (also had peeling paint where bulk bins of finished product were stored, observed on 9/19/12)
- e.) In the Unloading/Drying Room, there was a leaking pipe wrapped in plastic wrap along the north-east wall of the room (observed on 9/20/12).
- f.) The firm's only handwash sink in the Packaging Room, located near packaging line (b)(4) was leaking drainage water onto the floor on 9/19/12. Also, both hand sinks in the Preparation Room were not functioning and were being used for storing packaging and other materials (observed on 9/19/12 and 9/20/12).

OBSERVATION 8

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility after each absence from the work station and at any time their hands may have become soiled or contaminated.

Specifically, we observed the following missed hand washing opportunities during the inspection:

- a.) At least two employees were not observed washing their hands as required after leaving the restroom and donning gloves to begin work at the finished product packaging line on 9/19/12.
- b.) At least five employees were observed leaving the employee break room and not washing their hands before donning gloves and returning to work on the finished product packaging line on 9/19/12.
- c.) At least one employee was observed picking up food off of the ground (while wearing gloves) and not washing her hands after removing gloves and donning new gloves in the Packaging Room on 9/19/12.

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