

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

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969	DATE(S) OF INSPECTION 5/25/2021-5/28/2021*
	FEI NUMBER 1000121624

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph J. Merola, Secretary

FIRM NAME Bravo Packing, Inc.	STREET ADDRESS 59 N Golfwood Ave
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CITY, STATE, ZIP CODE, COUNTRY Carneys Point, NJ 08069-9710	TYPE ESTABLISHMENT INSPECTED Manufacturer
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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

You did not clean, maintain and store utensils and equipment in a manner that protects against contamination.

This is a repeat observation from the previous inspection(s) conducted on 01/21/2021-04/07/2021.

Specifically,

Your production operations generally include: deboning meat, refrigerating deboned meat, grinding refrigerated deboned meat and (b) (4) mixing ground deboned meat and (b) (4) with ingredients (such as tripe, (b) (4) vitamins, minerals, (b) (4) and egg), bagging finished product, and then freezing bagged product.

A. On 05/25/2021, your sanitation practice was observed to include (b) (4) (b) (4) sanitizer, hot water rinse, and (b) (4) application. All adhered organic debris, fat and protein was not removed prior to the sanitization of your equipment used in the deboning, grinding, mixing, in-process holding, and bagging operations for raw ready-to-eat animal food. After the application of a sanitizer in an unknown concentration, a yellow proteinaceous-like buildup was observed on the screw auger and back splash of the exit end of the screw auger conveyor. In addition,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kyle D Covill, Investigator Sean D Duke, Investigator	Kyle D Covill Investigator Signed By 2001656079 Date Signed 05-28-2021 08 48 45 X	DATE ISSUED 5/28/2021

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the sanitizer used does not control all pathogens previously identified in your product and environment, such as *Listeria monocytogenes*.

Production Room

Production Room operations for the manufacturing of raw ready-to-eat animal food include: grinding refrigerated deboned meat and (b) (4) mixing ground deboned meat and (b) (4) with minor ingredients (such as tripe, (b) (4) vitamins, minerals, (b) (4) and egg), bagging finished product, and then boxing bagged product to be sent to the freezer.

B. On 05/25/2021, a footbath was observed prior to the vinyl curtain entrance to the production room. You stated you are (b) (4) per the sanitizer's label for use in a footbath. You stated the sanitizer footbath requires a contact time of (b) (4) seconds. We observed employees entering and exiting the production room without properly following contact time during production of "Performance Dog" ready-to-eat raw dog food, lot 052521.

1. Employees were observed using the footbath for approximately (b) (4) seconds.
2. An employee was observed leaving the production room and not utilizing the footbath upon reentry.

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- On multiple occasions, employees were observed exiting and reentering the production room utilizing the footbath without the contact time of ^{(b) (4)} seconds
- An owner entered the production room multiple times without utilizing the footbath.

C. The grinder in the production room receives deboned meat, whole tripe, and ^{(b) (4)} ^{(b) (4)} from the barrel lifter. A screw auger located along the bottom of the grinder ^{(b) (4)}. The ingredients are then deposited into a screw auger conveyor. During the current inspection, we observed:

- On 05/25/2021, a white hard plastic shovel was observed staged on a stainless-steel table. The shovel was observed covered with residual dried, black meat like material from the handle, down the shaft, to the end of the blade. During production, an employee was observed utilizing this shovel to assist meat from a raw ingredient barrel into the grinder. Meat from the raw ingredient barrel was used in the production of "Performance Dog" ready-to-eat raw dog food, lot 052521. The same shovel was observed later removing meat that fell onto the production room floor during sanitation. Subsequently the same shovel was observed stored outdoors adjacent to the production room inside a bucket used to transport discarded in-process meat to a dumpster.
- On 05/25/2021, a meat hook stored on a rusty bar located on the backside of the barrel lifter was observed with cobwebs and tan extraneous material. The meat hook was subsequently used to assist deboned meat from the raw ingredient barrels into the grinder during the production of "Performance Dog" ready-to-eat raw dog food, lot 052521 without any further cleaning and sanitizing prior to use.

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3. On 05/25/2021, immediately prior to the start of production, we observed the (b) (4) (b) (4) of the grinder staged on a red t-shirt like cloth containing a black oil type stain and extraneous loose dirt-like filth material. The (b) (4) were placed on the exit end of the grinder and were used during the production of "Performance Dog" ready-to-eat raw dog food, lot 052521 without any further cleaning.
4. On 05/25/2021, immediately prior to the start of production, the basin under the screw auger in the grinder contained pooled liquid with an orange rust-like material. The grinder was used to produce "Performance Dog" ready-to-eat raw dog food, lot 052521 without any further cleaning.
5. On 05/25/2021, immediately prior to the start of production, the grinder contained heavy rust on the inside walls, basin, and screw auger. The rusty grinder was subsequently used to produce "Performance Dog" ready-to-eat raw dog food, lot 052521 without any further cleaning.

D. Raw ingredients are deposited into the mixer from a screw auger conveyor. The mixer in the production room is used to mix meat, (b) (4) and other ingredients during the production of raw ready-to-eat animal food. The mixed ingredients are (b) (4) to the bagging machine from the mixer. During the inspection, we observed:

1. On 05/25/2021, a piece of meat from the prior production run was left in the exit portion of the mixer. The mixer also contained a pooled black liquid and white fat like deposits along the basin bottom and in the auger portion of the basin bottom. The mixer was subsequently used during the production of "Performance Dog" ready-to-eat raw dog food, lot 052521 without any further cleaning.

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2. On 05/25/2021, immediately prior to the start of production, we observed the metal end piece of the mixer staged on a red t-shirt like cloth containing a black oil type stain and extraneous loose dirt-like filth material. The metal end piece was placed in the exit end of the mixer to direct the dog food into the (b) (4) leading to the bagger hopper. This metal piece was used during the production of "Performance Dog" ready-to-eat raw dog food, lot 052521 without any further cleaning.
3. On 05/25/2021, we observed prior to production that the mixer had a heavy build-up of rust on the interior walls, (b) (4), and screw auger. The rusty mixer was subsequently used during the production of "Performance Dog" ready-to-eat raw dog food, lot 052521 without any further cleaning.
4. On 5/25/2021, we observed a metal elbow pipe connector containing remnant organic debris and dark, meat like material after the completion of the firm's cleaning and sanitizing process. This elbow was used during production in the metal piping system that transports ground and mixed "Performance Dog" ready-to-eat raw dog food, lot 052521 from the mixer to the bagger hopper.

E. The bagging machine in the production room receives mixed raw ready-to-eat animal food from the mixer (b) (4). (b) (4) terminates above the hopper, where (b) (4) deposits raw ready-to-eat animal food into the open top of the hopper. The raw ready-to-eat finished product is (b) (4) at the bagging machine, where it is packaged into flexible plastic bags. (b) (4) the bags and (b) (4), where they are filled in either 2lb or 5lb bags for wholesale distribution. During the inspection, we observed:

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1. On 05/25/2021, a customized (b) (4) (b) (4). At the end of the production run we observed the (b) (4) was heavily soiled with dried, black meat like material. The (b) (4) passes through the heavily soiled (b) (4) to (b) (4) remaining mixed product into the hopper where it was packaged into (b) (4) 2lb chubs of Performance Dog ready-to-eat raw dog food, lot 052521. During the previous inspection, dated 01/21/2021-04/07/2021, an owner reported the (b) (4) was used to (b) (4) remaining product into discard barrels.
2. On 05/25/2021, we observed this same customized (b) (4) containing remnant organic debris and meat like material after the completion of the firm's cleaning and sanitizing process.
3. On 05/25/2021, immediately after production the interior chamber and components of the bagging machine were observed covered with a heavy amount of rust on their surfaces. The bagging machine was used to fill 2lb bags of "Performance Dog" ready-to-eat raw dog food, lot 052521.

OBSERVATION 2

You did not take reasonable measures and precautions related to hygienic practices to protect against the contamination of animal food.

This is a repeat observation from the previous inspection(s) conducted on 01/21/2021-04/07/2021.

Specifically,

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A. On 05/25/2021, an employee wearing work boots stepped on the horizontal guard of the screw auger conveyor, a food contact surface, while the auger was in operation during the production of "Performance Dog" ready-to-eat raw dog food, lot 052521. The guard is located above the catch basin leading from the exit end of the grinder. We observed pieces of beef and tripe hanging from the guard and falling into the screw auger. Other employees were observed adding the (b) (4) ingredient into the auger conveyor through this horizontal guard. Prior to production, we observed the employee who stepped on the guard was wearing the same boots while walking around the production room, deboning room, and outdoor areas of the facility. This employee was observed walking on the same area of the production room floor where barrel carts and raw ingredient barrels are moved and staged without being cleaned and sanitized prior to entry into the production room. The barrel carts and raw ingredient barrels are not cleaned and sanitized prior to entering the production room.

B. On 05/25/2021, an owner was seen spitting chewing tobacco on the floor of the deboning room. Deboned meat is used as an ingredient in the production of raw ready-to-eat animal food.

OBSERVATION 3

You did not take effective measures to exclude pests from your plant and protect against contamination of animal food by pests.

This is a repeat observation from the previous inspection(s) conducted on 01/21/2021-04/07/2021.

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A. On 05/25/2021, we observed a grey tabby cat sitting on exposed deboned meat housed in an ingredient barrel. The barrels were staged in an open-span breezeway area (exposed to outdoor elements) between the cooler and processing room. The barrel was subsequently used to produce "Performance Dog" ready-to-eat raw dog food, lot 052521. The cat was observed moving around the outside area of the firm at various times throughout the night.

B. On 05/25/2021, we observed 2 separate cats urinating on the outside of a raw ingredient barrel. The raw ingredient barrel was staged in an open-span breezeway area exposed to outdoor elements between the ingredient cooler and production room. The barrel was subsequently used to produce "Performance Dog" ready-to-eat raw dog food, lot 052521. These barrels were moved into the production room using a barrel cart and placed on the barrel lifter to deposit meat into the grinder. This same cart and barrel lifter were used for another 4 barrels of raw ingredients. The barrel cart and raw ingredient barrels do not undergo cleaning and sanitizing prior to entering the production room.

C. On 05/25/2021 and 05/27/2021, we observed multiple cats entering and leaving the deboning room through the sliding door left open throughout the night.

OBSERVATION 4

You did not maintain your plant in a clean manner and in good repair to prevent animal food from becoming adulterated.

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This is a repeat observation from the previous inspection(s) conducted on 01/21/2021-04/07/2021.

Specifically,

A. On 05/25/2021 and 05/27/2021, the floors in the slaughter room, deboning room, processing room, deboning room cooler, and raw ingredient cooler had large cracks, holes, and deep depressions which contained pooled blood and water. These areas are used in the production of raw ready-to-eat animal food.

B. On 05/25/2021, we observed barrels of deboned meat used as an ingredient in raw ready-to-eat animal food being stored uncovered in the deboning room cooler. The uncovered barrels were stored directly beneath a metal beam and brackets covered with flaking rust.

***DATES OF INSPECTION**
5/25/2021(Tue), 5/27/2021(Thu), 5/28/2021(Fri)

X Sean D Duke
Investigator
Signed By: 2001264221
Date Signed: 05-28-2021 08:49:13

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."