

INSPECTOR'S NARRATIVE REPORT

Date: August 29, 2018

Facility Inspected: Pony Express Foods, LLC
1016 E Main Street
Blue Ball, PA 17757

Narrative Completed By: David Dressler, Agronomic Program Specialist

On August 29, 2018 at approximately 10:15 AM, Erin Bubb (PDA Division Chief, Division of Agronomic & Regional Services) conducted an unannounced inspection at Pony Express Foods, LLC (hereinafter "Pony Express"). Upon arriving at the facility, we met with Casey Martin (plant manager), who was the most responsible person at the facility at that time. We also met with Gina Griffy (regulatory). Chief Bubb and myself displayed our PDA credentials and issued Mr. Martin a Notice of Inspection (attached).

While issuing the Notice of Inspection, it was determined that the city listed for the firm's Commercial Feed License was New Holland, PA. Mr. Martin stated that either address would be acceptable, because the firm is located in close proximity to the boundary and that both towns have the same zip code. Since Blue Ball, PA is listed on the product labels, we stated that the licensed address would be updated to reflect the correct address.

We explained the purpose of the inspection was to follow-up on complaints received by the Pennsylvania Department of Agriculture (hereinafter "PDA") involving the no-hide dog chews. According to the complaint, the no-hide products have been analyzed (by the complainant) and it was determined that the products contain animal hide.

As we were explaining the purpose of the inspection, Travis Cundiff, chief operating officer, joined the conversation. Chief Bubb and myself displayed our PDA credentials to Mr. Cundiff and explained the notice of inspection was issued to Mr. Martin. Travis Cundiff is the most responsible person at Pony Express Foods.

Mr. Cundiff stated that his company is split into two entities; a pet treat manufacturer and a human food manufacturer. The pet treat manufacturer, Pony Express Food, LLC is the parent company. The human food manufacturing is under Pony Express Enterprises, LLC, which is located at 121 Jalyn Drive, New Holland, PA 17557. The two companies combined employ approximately 130 – 140 people.

Pony Express produces pet treats for Earth Animal Ventures, 49 John Street, Unit 1, Southport, CT 06890. Products are manufactured and labeled under the brand Earth Animal Ventures. Finished product is then sent to Wear the Best, Inc, 32 Henry Street, Building #17A, Bethel, CT 06801. This firm is the distribution warehouse for Earth Animal Ventures. All customer orders placed with Earth Animal Ventures are sent to Wear The Best to be shipped. Pony Express Foods does not get involved in any of these transactions. They only supply Wear The Best when product is running low. Pony Express Foods

also distributes a rawhide product under their own label, however according to Mr. Cundiff, those products are not manufactured by Pony Express.

Mr. Cundiff stated he was familiar with the complaint that was filed against his company, because FDA received the complaint and conducted an inspection at Pony Express on January 18, 2018. Mr. Cundiff stated that the basis for the complaint was unfounded, because the tests that the complainant had done on the no-hide products was not a valid test. The basis for Mr. Cundiff saying this was from a third-party investigation requested by Earth Animal Ventures, LLC. This investigation was performed by Luna Science and Nutrition, LLC, 128 Beacon Hill Road, Trumbull, CT 06611. Mr. Cundiff provided a summary of Luna Science and Nutrition, LLC's investigation and findings (Exhibit A). Portions of this summary do contain confidential business information, such as Pony Express's formulations. I requested a copy of this investigation to Mr. Cundiff, which he stated he would email to me.

According to Luna Science and Nutrition, LLC's investigation report, DNA analysis and formaldehyde analysis were performed on no-hide products as well as store-bought rawhide. The DNA results confirm the presence of animal as well as plant proteins. This is logical, given Pony Express's manufacturing process, where meat from a several species are used in the manufacturing of the finished no-hide products. Furthermore, rice was the only plant protein found, which is the main ingredient in no-hide. Copies of the formulations for the no-hide as well as the finishing batter added to the no-hides for flavoring and nutrition were provided by Mr. Cundiff (Exhibits B – G). Mr. Cundiff stated he considers these formulas as confidential proprietary business information.

The formaldehyde test was performed on the no-hide and rawhide treats, because Dr. Ryan Yamka from Luna Science and Nutrition, LLC states in his executive summary that formaldehyde is a contaminant in the rawhide process and shouldn't be present in the no-hide products. The results of this analysis show that formaldehyde was present in the rawhides, but not in the no-hides.

Mr. Cundiff also stated that Pony Express has previously had a digestibility test performed on the products. This test was performed by PetMech, LLC, 1010 West Osage Drive, Stillwater, OK 74075. A letter from Dr. Timothy Bowser from PetMech, LLC was presented to us by Mr. Cundiff (Exhibit H), which states that the no-hide products average 80% digestibility under simulated gastric conditions, whereas rawhide averaged between 4% and 32%. Mr. Cundiff stated he would email a copy of this letter to me.

Pony Express does not consider their product to be a choking hazard, because of the digestibility test that was performed. They also manufacture product based on the size of the dog that would consume the chew, and this guidance is provided on the packages. Pony Express does realize that some dogs may quickly consume the treats, so they included a caution statement on the packages that states the dog should always be supervised while chewing on the no-hide products.

As of the date of this inspection, Pony Express has not received any other complaints involving choking. Mr. Cundiff stated that even the complainant's dog did not die due to choking. Laboratory reports obtained from the complainant's veterinarian state that the dog had died after surgery. Pony Express did not supply a copy of this report to PDA during the inspection.

Pony Express Foods, LLC manufactures 22 SKUs for Earth Animal Ventures from 9 different formulas. This includes products other than no-hide, such as sweet potato treats. The difference between the formulas is the flavor or nutritional batter that is added to the no-hide. The formula for the base no-hide chew is the same for all the no-hide products, regardless of flavor or nutritional component. The

"batter" that is added [REDACTED]
[REDACTED]
[REDACTED]

Pony Express does receive rawhide products, however according to Mr. Cundiff, those products are received and immediately placed in their market truck to be sold at The Green Dragon, 955 N State Street, Ephrata, PA 17522, which is a local Farmers Market. These products are only sold at The Green Dragon and are distributed under Pony Express Foods, LLC's own label. Earth Animal Ventures is not associated with the rawhide products sold at The Green Dragon. According to Mr. Cundiff and Mr. Martin, no rawhide products are processed at Pony Express, nor are they stored within the production area of no-hide products.

Erin Bubb and myself requested to see the manufacturing process of the no-hide products. Mr. Martin stated they are not currently making the product, however did offer to start production to demonstrate the process to us. Since it would take a bit of time until they set everything back up, we agreed to return on September 18, 2018 at 10:00 AM to witness the production. Until we could witness the complete manufacturing process of the no-hides, Chief Bubb and myself requested a tour of the manufacturing facility and an explanation of the manufacturing process.

Production at this facility follows cGMPs for human food and this facility is HACCP certified. There are three shifts at Pony Express Foods, LLC. The first two shifts are production and the third shift is dedicated for sanitation. The firm has also installed a microbial resistant floor throughout the building, which prohibits bacterial growth. Eco-Lab conducts pest control activities around the premises and the firm is installing air curtains for fly control. Current fly control methods are traps around the outside of the building, which flies were observed caught in the trap. The facility is designed so there are airlock areas between the outside and the production facility. There were a few flies observed in the production area, which is why the firm had identified the need to install air curtains.

Production at Pony Express is done based on availability of trucks to deliver product to [REDACTED]. Typically, Pony Express produces approximately 24,000 11" no-hide treats per day. The firm also produces other products. The unflavored, plain no-hides are produced in the morning. These products are placed in designated bins and stored in a room just off the production area. Around late morning/early afternoon, a protein batter will be applied to the no-hides and then baked. The products are then removed from the ovens and taken to the bagging area, where they are placed in labels provided by Earth Animal Ventures. This entire process is housed under one roof and the firm follows Appendix A guidelines, which are human food guidelines recognized by USDA. All products are produced and out the door in no more than 60 hours, however typical production time is 48 hours.

During a walkthrough of the production facility, no animal hides or bones were observed at the facility. At the time of the inspection, the firm was manufacturing sweet potato treats and placing the protein batter on the plain no-hides. These items were placed on racks and placed in a temperature & humidity controlled oven. Employees who were not involved in the production were cleaning the floors and equipment. There appeared to be very little remains of meat products on the floor or the equipment. The extruder used to manufacture the no-hide products is a custom design and was being stored in a plastic bag. Employees were wearing hairnets, lab coats and gloves. As we walked around the facility, we followed the firm's biosecurity protocols, which required us to remove loose jewelry and wear a lab

coat and hair net. We did not witness the production of the plain no-hide raw hides or the bagging of finished material.

After the tour of the facility concluded, we thanked Mr. Cundiff, Mr. Martin and Ms. Griffy for their time and left the facility. When I returned to the office, I received an email from Mr. Cundiff (Exhibit I), which contained documentation requested during the inspection (Exhibit A and Exhibit H). Also included in his email was a Certificate of Analysis for the digestive enzyme that is added to the batter (Exhibit J) and a copy of the FDA Inspection Report from January 18, 2018 through January 19, 2018 (Exhibit K). Upon reviewing the FDA inspection report, it appears to contain proprietary confidential business information.

Attachments: Notice of Inspection issued to Pony Express Foods, LLC and signed by Casey Martin
Report of Investigation and Findings from Luna Science and Nutrition, LLC (Exhibit A)
Formulation for No Hide Formula (Exhibit B)
Formulation for Salmon Batter Formula (Exhibit C)
Formulation for Pork Batter Formula (Exhibit D)
Formulation for Chicken Batter Formula (Exhibit E)
Formulation for Venison Batter Formula (Exhibit F)
Formulation for Beef Batter Formula (Exhibit G)
Letter from PetMech, LLC Discussing Digestibility Study (Exhibit H)
Email from Travis Cundiff Providing Requested Inspection Documentation (Exhibit I)
Certificate of Analysis for Digestive Enzyme (Exhibit J)
FDA Inspection Report (Exhibit K)