

STATE OF COLORADO OFFICE OF ADMINISTRATIVE COURTS 1525 Sherman Street, 4th Floor, Denver, CO 80203	
COMMISSIONER OF AGRICULTURE, COLORADO DEPARTMENT OF AGRICULTURE, Petitioner, vs. LYSTEN, LLC, DBA ANSWERS+ PET FOOD, Respondent.	▲ COURT USE ONLY ▲ CASE NUMBER: AG 20180011
INITIAL DECISION	

Hearing in this matter was held and recorded October 15-17, 2019 in courtroom 2 of the Office of Administrative Courts. Matthew E. Norwood, Administrative Law Judge (“ALJ”), presided. Charles J. Kooyman, Senior Assistant Attorney General, and Billy Seiber, First Assistant Attorney General, appeared on behalf of the Petitioner (“Commissioner”). Joseph A. O’Keefe, Esq., Ryan C. Gilman, Esq., and Allan L. Sodomsky, Esq., appeared on behalf of the Respondent.

Summary

The Commissioner seeks to fine the Respondent \$750 for selling adulterated dog food. Specifically, the Commissioner alleges that a sample of Respondent’s unpasteurized dog food contained *listeria monocytogenes* (“*listeria*”) and salmonella. Laboratory tests at the Department of Agriculture (“Department”) detected these bacteria in the sample. But there is insufficient evidence of *how much* *listeria* and salmonella was present in the sample tested by the Department’s lab. A “split sample” was sent to the Respondent for independent testing. The laboratory chosen by the Respondent detected no *listeria* in the sample, but did detect, on its first of two tests, 96,000 CFU (colony forming units) per gram of salmonella.

Listeria and salmonella are naturally occurring bacteria and their mere presence in dog food does not necessarily make it “adulterated.” It is not adulterated if, “the quantity of such substance in the feed does not ordinarily render it harmful to health.” Section 35-60-107(2)(a), C.R.S. Based on the test done by the Respondent’s lab and based on the testimony of one of the Commissioner’s experts, the ALJ finds and concludes that the quantity of salmonella in the Respondent’s dog food *does* ordinarily render it harmful to health. There is insufficient evidence that this is also true for *listeria*. The Respondent shall be fined \$750.

Findings of Fact

Based upon the evidence presented at the hearing, the ALJ makes the following findings of fact:

1. Respondent distributes pet food in Colorado. Raw chicken parts are some of the ingredients of its dog food.

2. There is no allegation and no evidence that the Respondent willfully added listeria or salmonella to its dog food.

3. There is no evidence that any dog or any person became ill from the Respondent's dog food.

4. In April 2018 Scott Spinks was an inspector for the Department. He now works for the Division of Motor Vehicles. On April 11, 2018 he went to a pet food store in Littleton and purchased a carton of the Respondent's dog food, specifically, "Chicken Formula For Dogs." Exhibits 2 and 23. The dog food is sold frozen in a milk carton-type container. The container states that the, "product has not been pasteurized and may contain harmful bacteria." Exhibit 23, p. 199. The dog food is raw, and not meant to be cooked before feeding to dogs.

5. The product was frozen when Mr. Spinks took it from the store and was still frozen when he handed it off to Dominika Kondratko at the Department's lab about 45 minutes later. Exhibit 3. The Department's lab is accredited to international "ISO" standards.

6. Ms. Kondratko thawed the dog food to take a sample for mixing up ("homogenizing") and testing. She returned the unsampled portion of the dog food to the freezer.

7. Ms. Kondratko ran the sample through a whole series of tests to detect the presence of listeria and salmonella. Exhibits 5, 8, 10, 11 and 16-22. The initials "DK" are hers; the initials "KM" are those of Deputy Laboratory Manager Kristi McCallum. The initials "TG" stand for "typical growth."

8. Exhibit 18 shows that the sample tested positive for listeria, and the ALJ so finds. The date of the test is April 16, 2018. The exhibit shows that a positive result must be over "0.05," but does not explain what 0.05 means; 0.05 what over what? The evidence does not otherwise explain what this number means. The test value for listeria is "2.59," but again, how much this is, is not disclosed by the evidence.

9. Exhibit 21 shows that the sample tested positive for salmonella, and the ALJ so finds. The date of the test is April 18, 2018. A positive is something over "0.23," and the test value was "2.72." Again, there is no numerator or denominator. The evidence otherwise does not explain what this positive number means.

10. The Department's lab conducts tests for the *presence* of listeria or salmonella. It does not attempt to determine the *quantity* of the bacteria. The numbers

“2.59” and “2.72” presumably represent a quantity, but the evidence does not disclose how much this is. There was no expert testimony that the “2.59” and “2.72” represents a quantity of listeria or salmonella rendering its presence in the feed ordinarily harmful to health.

11. Roxanne Stone is an owner of the Respondent with other family members. Her title is Vice President of R&D and Procurement. She asked the Department to provide a split sample of the dog food tested by it for testing by a laboratory of her choosing. She chose “HACCP Assurance Services” (“HACCP”) of Mountaintop, Pennsylvania. Ms. McCallum prepared a sample to be sent overnight to this lab. Ms. McCallum took precautions so that the sample would be kept cold in transit.

12. Exhibit 48 is the initial test of the sample by HACCP with a “date reported” of May 4, 2018. It shows a negative result for “*listeria monocytogenes*,” and 250 CFU/gram of “*listeria spp.*” There was an implication made at the hearing that HACCP may not have used the proper “matrix” for *listeria monocytogenes*.

13. The ALJ need not resolve whether HACCP’s test for *listeria monocytogenes* was correct. This is because even if the test was faulty and there was *listeria monocytogenes* in the sample, there was insufficient evidence of a quantity of listeria in the dog food that would “ordinarily render it harmful to health.” There was insufficient evidence that the quantity of listeria in the dog food met this “ordinarily” descriptor.

14. HACCP’s test of the sample showed a positive for salmonella and that there were 96,000 CFU/g present. On cross-examination, the Commissioner’s expert witness, Joshua Daniels, D.V.M., testified that this is an amount that would ordinarily render it harmful to health. The ALJ so finds. Dr. Daniels’s testimony will be discussed more fully below.

15. Ms. Stone then instructed HACCP to leave the sample out at room temperature for a period of time and to retest it. It is her contention that the Respondent’s dog food can be made safe by the growth of lactic acid bacteria. Exhibit 49 is the HACCP retest with a “date reported” of May 25, 2018. It again showed “negative” for *listeria monocytogenes*, as well as less than 10 CFU/g of *listeria spp.* Salmonella was again “positive,” and had decreased to a quantity of 32,000 CFU/g. From the first test to the second, the amount of lactic acid bacteria had increased from 16,800,000 CFU/g to 106,000,000 CFU/g.

16. Ms. Stone has called the Department’s laboratory’s treatment of her dog food an “abuse.” She objects to the thawing and freezing the laboratory used to test its sample. She notes that the container the dog food came in says: “Thaw carton on plate to serve – Good for 7 days when refrigerated.” But there was insufficient evidence that failing to comply with this warning, if such failure there was, would have compromised the Department’s testing. Ms. Kondratko and Ms. McCallum presented at hearing as highly professional and careful as far as maintaining the integrity of the Department’s testing.

17. Moreover, it is not the Department's testing that establishes the violation in this case; it is HACCP's test that does. Only HACCP tested for quantity. The Respondent does not maintain that HACCP's tests were unreliable. Ms. Stone relies on HACCP's testing to support her argument that that testing shows the growth of lactic acid bacteria. She testified that the increase in lactic acid bacteria between the two samples made the amount of salmonella in the dog food ordinarily not harmful. Ms. Stone instructed HACCP to retest the sample after it had been left at room temperature. HACCP's two tests were reported 21 days apart. If the Respondent truly believed that the Department's testing was faulty and showed listeria and salmonella when there was none (something it did not assert at hearing), it could have performed another test. Nothing prevented Lysten from having HACCP test another carton of its dog food selected by it. No such evidence was offered.

18. Dr. Daniels is a veterinarian, receiving his D.V.M. degree from the University of Wisconsin-Madison. He received a Ph.D. in veterinary science, and his specific area of study was veterinary microbiology. He wrote his thesis on the subject of salmonella and *e. coli* in dairy cattle. While he was obtaining his Ph.D. he was in a "dual program" and also was a resident microbiologist in the Washington Animal Disease Diagnostic Laboratory. Based on Dr. Daniels's testimony, the ALJ specifically finds:

- a. Salmonella causes disease in humans and animals;
- b. Salmonella is "Gram negative," which describes the cell wall.
- c. Salmonella replicates itself by "binary fission," or splitting. It can replicate over a wide variety of temperatures.
- d. Raw chicken can contain salmonella.
- e. Children under five years old are particularly susceptible to salmonella illness. The same is true for puppies. Both children and puppies have immune systems that are not as mature as those of adult humans and adult dogs. Animals can carry salmonella without becoming sick themselves.
- f. Salmonella can be tracked in or otherwise transmitted from dog feces to the floors and carpet of homes. Young children can ingest the bacteria by crawling and by putting their hands in their mouths.
- g. Single digit CFU's up to hundreds of millions of CFU's can cause disease; there is a very wide range.
- h. The 96,000 CFU/g of salmonella detected in HACCP's initial test of the dog food at exhibit 48 is approximately one hundred times less than what would be expected to be consumed by an average sized dog in a meal. This is a relatively high number of organisms.
- i. There are not good data for infectious doses of salmonella in dogs. Humans, especially children, should not ingest salmonella bacteria. The infectious dose is variable.

j. Lactic acid bacteria in the Respondent's dog food did not work because both the Department's lab and HACCP detected salmonella.

k. Any exposure to salmonella is dangerous due to its ability to replicate.

19. On cross-examination, Dr. Daniels agreed that a single cell of salmonella was likely not "ordinarily harmful to health." He testified that the 96,000 CFU/g amount was ordinarily harmful to health because a dog's meal will be more than this and because of the ability of the bacteria to replicate. At what amount the cells or colony forming units became ordinarily harmful to health, he could not say. Dr. Daniels is aware of professional literature documenting outbreaks in Europe starting with only eight colony forming units. Based on this testimony, the ALJ specifically finds that the Respondent's dog food contained salmonella in a quantity that rendered it ordinarily harmful to health.

20. The dog food at issue in this case was processed at a facility called "Hazle Park." Ms. Stone agrees that the Respondent's dog food processed by Hazle Park had salmonella on two occasions.

21. Rachel Jervis, M.P.H., is another expert called by the Commissioner. Ms. Jervis has a master's degree in public health. Her degree had a concentration in epidemiology and biostatistics. She is the "Enteric Disease Unit Manager" at the Colorado Department of Public Health and Environment. In her testimony, she echoed Dr. Daniels's concern of salmonella infection for children under five years old. Also at risk, per Ms. Jervis, are persons older than 65 and the immuno-compromised.

22. On direct examination, Ms. Jervis was asked what amount of salmonella would ordinarily render it harmful. She answered only that any amount of salmonella is harmful to human health. Her answer did not include the word "ordinarily." She was also asked what amount of listeria would ordinarily render it harmful. Again she answered that any listeria is harmful to human health. Because Ms. Jervis's testimony did not go to the "ordinarily harmful" legal test, it was not helpful to the ALJ in determining whether the Respondent was responsible for selling adulterated feed.

23. Ms. Jervis testified about an outbreak of listeria in Blue Bell ice cream. She described ten illnesses and three deaths from the outbreak. The ice cream was consumed by a population that was in the hospital and was older or already ill.

24. Ms. Stone testified as an expert for the Respondent. She has a master's degree in nutrition and food sciences. She has worked as a food scientist for Anchor Food Products, Deli Mix and Jack-in-the Box restaurants. She then ran her own consulting business. She and her family members started Lysten, Inc. in 2009.

25. Ms. Stone has written an article that appears at Respondent's exhibit 9e in the summer 2016 issue of the Journal of the American Holistic Veterinary Medical Association. It is her view that one can add fermented dairy products such as whey to dog food, which will thereby produce lactic acid bacteria. She testified that whey is added to Respondent's dog food. According to her, lactose acid bacteria can then crowd out

and deprive nutrients to salmonella and listeria in the dog food. This is an alternative to pasteurization according to her. She believes avoiding pasteurization maintains active enzymes and intact proteins. She agrees that there is professional literature that lactic acid bacteria is not effective against Gram negative bacteria such as salmonella.

26. She testified that it was a good sign that the amount of lactic acid bacteria increased between the two tests done by HACCP at exhibits 48 and 49. She testified (on redirect examination) that the amount of lactic acid bacteria in the split sample rendered the salmonella ordinarily not harmful to human health.

27. Because Ms. Stone is an owner of the Respondent along with her family, she has an obvious interest in the outcome of this case. The ALJ accords her testimony little weight.

28. Margaret E. Coleman also testified as an expert for the Respondent. She has a master's degree in biology and biochemistry and another master's degree in medical microbiology. She has worked as a chemist for the United States Department of Agriculture. She has acted as a consultant in "microbial risk analysis."

29. She testified that the 96,000 CFU/gram of salmonella found in HACCP's initial test does not provide enough information to make a microbial risk analysis. Nevertheless, she testified that the "government's conclusion" that 96,000 CFU/gram of salmonella in raw pet food is not ordinarily harmful to "human health" was incorrect. (The statute says "health"). It is not clear from Ms. Coleman's testimony how she can make this second statement if she believes there is not enough information to make a microbial risk analysis.

30. Ms. Coleman's testimony was also meandering and unresponsive. In contrast, Dr. Daniels presented as knowledgeable, reliable and more credible. His concession that a single cell of salmonella is not ordinarily harmful was sensible and supported the reasonableness of his opinion. He also has better professional credentials.

31. Based on the testimony of Dr. Daniels and Ms. Jervis, the ALJ specifically finds that salmonella is a poisonous and deleterious substance. No amount of this bacteria is safe for consumption by dogs or people.

Conclusions of Law

Based upon the foregoing findings of fact, the ALJ enters the following conclusions of law:

1. The charging document in this case is the Commissioner's September 26, 2018 "Notice of Duty to Answer, Notice to Set, Notice of Hearing, and Notice of Charges," ("Notice of Charges"). It contains two counts, one for listeria and one for salmonella. The two counts rely on Sections 35-60-107(1) and (2), C.R.S. Section 35-60-107(1)(a) provides in pertinent part:

(1)(a) No person may ... distribute in this state any feed that is adulterated

2. Dog food is “feed.” Section 35-60-102(9). Respondent distributes feed in this state. The Respondent is a “person.” Section 35-60-102(16), C.R.S.

3. Section 35-60-107(2)(a) provides:

(2) A feed is adulterated if any of the following apply:

(a) The feed bears or contains any poisonous or deleterious substance that may render the feed harmful to health; except that, if the poisonous or deleterious substance is not an added substance, a feed shall not be considered adulterated under this subsection (2) if the quantity of such substance in the feed does not ordinarily render it harmful to health.

4. As argued by the Respondent, it is not the case that *any* amount of listeria or salmonella in the feed makes it adulterated. The General Assembly has chosen by its language to exempt from liability marginal quantities that do not ordinarily render the feed harmful to health. Perhaps this represents a determination that the law would be too harsh in the circumstance where the substance is naturally present in the environment and enters the feed through no fault, or following reasonable precautions, by the feed provider. (There was no evidence of legislative intent produced at the hearing.) Such an exemption would obviously not be appropriate if the poisonous or deleterious substance was *added* to the feed. The adding of substances solely to increase the bulk or weight of the feed, for example, should not be provided this defense. But the scenario of an “added substance” is not at issue in this case.

5. In *Am. Pub. Health Assoc. v. Butz*, 511 F.2d 331, 334 (1974), the court discussed similar language: “ordinarily render it injurious to health,” as found in 21 U.S.C. Section 601(m)(1) related to meat products intended for human consumption. The court reasoned that the presence of salmonella in food did not meet this “ordinarily render” descriptor because the consumer knows to cook meat. Of course, the Respondent’s product is not pasteurized and is not cooked before serving to dogs.

6. Whether the quantity of a substance in animal feed renders it ordinarily harmful to health is an appropriate subject for expert testimony. The ALJ has adopted as a finding of fact Dr. Daniels’s testimony that the quantity of salmonella in the sample taken was ordinarily harmful. Count II is therefore established as to salmonella. There was insufficient evidence of a quantity of listeria in the dog food, or whether that quantity was ordinarily harmful. Count I as to listeria is therefore unproven.

7. That salmonella is a “poisonous or deleterious substance” is established by the expert testimony, common sense and by the Commissioner’s rule at part 13 of 8 CCR 1202-7¹:

Part 13. Adulterants 13.1.

¹ <https://bit.ly/2KLxu2x>

For the purpose of Section 35-60-107(2)(a), C.R.S., of the Colorado Feed Law, the terms “poisonous or deleterious substances” include but are not limited to the following:

13.1.1. Pathogenic bacteria, including but not limited to Salmonella sp. ... found in any detectable amounts.

8. The Respondent argues for a strained reading of “ordinarily harmful.” It asserts that the young, the elderly and the immuno-compromised are outliers and should not be included in deciding what is meant by “ordinarily harmful.” It argues that the few deaths in the Blue Bell ice cream case are insignificant in light of the total amount of ice cream that was sold. But the idea that children or the elderly are expendable, or the cost of doing business, is completely inconsistent with any reasonable food safety regulation scheme. The General Assembly could not have meant to exclude these individuals from consideration by the language “ordinarily harmful.”


Sanction

The maximum civil penalty allowed for a violation of article 60 of title 35 is \$750 per day, per violation. Section 35-60-113(1)(c). The Commissioner seeks a civil penalty in this maximum amount. The severity of the violation supports a fine in this amount. The Respondent shall therefore pay a civil penalty of \$750 for selling adulterated dog food.

Per Section 24-4-105(14)(a), C.R.S., this Initial Decision will be sent to the agency only for mailing to the parties.

DONE AND SIGNED

October 28, 2019



MATTHEW E. NORWOOD
Administrative Law Judge

Exhibits admitted:

For the Commissioner: Exhibits 2-5, 8, 10-11, 15-22, 25, 27-30, 35-40, 42, 44-45, 48-49, 56-62 and 65-66.

For the Respondent: 9e (In the front flap of the exhibit notebook.)