

THE 2011 CANTALOUPE *Listeria* OUTBREAK

A. First, a Bit of History

Although the 2011 outbreak was the first known *Listeria* outbreak associated with cantaloupe, cantaloupe outbreaks are by no means a new phenomenon. Since 1985, in fact, there have been at least 15 recognized cantaloupe outbreaks in the US, from both domestically and internationally grown cantaloupes:

No.	Year	State(s)	Confirmed Illnesses	Pathogen	Description
1.	1985	Wisconsin	16	<i>Campylobacter</i>	Melon or cantaloupe
2.	1990	30 states	245	<i>Salmonella</i>	Cut cantaloupe at salad bars
3.	1991	International, including U.S.	400	<i>Salmonella</i>	Likely Mexican cantaloupe
4.	1997	California	24	<i>Salmonella</i>	Mexican cantaloupe.
5.	1998	Ontario, Canada	22	<i>Salmonella</i>	Cantaloupe
6.	1999	Iowa	61	Norovirus	Restaurant, cantaloupe or melon
7.	2000	California, Oregon, Colorado, Washington, New Mexico, Nevada	47	<i>Salmonella</i>	Mexican cantaloupe
8.	2001	Multi-state and International	50	<i>Salmonella</i>	Viva Brand cantaloupe
9.	2002	California, Minnesota, Oregon, Arkansas, Vermont, Nevada, Texas	58	<i>Salmonella</i>	Susie Brand cantaloupe
10.	2003	New York, Ohio, New Mexico, Massachusetts, Connecticut, Missouri	58	<i>Salmonella</i>	Day care center and private homes, cantaloupe/honeydew melon
11.	2006	Multi-State and International	41	<i>Salmonella</i>	Cantaloupe cut at processing facility in Canada
12.	2007	California	11	<i>Salmonella</i>	Private home
13.	2008	Multi-State	53	<i>Salmonella</i>	Agropecuraria Mobtelibano cantaloupe, from Honduras
14.	2008	California	23	Norovirus	Restaurant, melon and cantaloupe
15.	2011	Multi-State	20	<i>Salmonella</i>	Del Monte cantaloupe

B. The CDC's Case Count

A total of 147 persons infected with any of the five (5) outbreak-associated strains¹ of *Listeria monocytogenes* were reported to CDC from 28 states. The number of infected persons identified in each state was as follows: Alabama (1), Arkansas (1), California (4), Colorado (40), Idaho (2), Illinois (4), Indiana (3), Iowa (1), Kansas (11), Louisiana (2), Maryland (1), Missouri (7), Montana (2), Nebraska (6), Nevada (1), New Mexico (15), New York (2), North Dakota (2), Oklahoma (12), Oregon (1), Pennsylvania (1), South Dakota (1), Texas (18), Utah (1), Virginia (1), West Virginia (1), Wisconsin (2), and Wyoming (4).

Among persons for whom information was available, reported illness onset ranged from July 31, 2011 through October 27, 2011. Ages ranged from <1 to 96 years, with a median age of 77 years. Most cases were over 60 years old. Fifty-eight percent (58%) of cases were female. Among the 144 ill persons with available information on whether they were hospitalized, 142 (99%) were hospitalized.

Thirty-three deaths² were reported: Colorado (9), Indiana (1), Kansas (3), Louisiana (2), Maryland (1), Missouri (3), Montana (1), Nebraska (1), New Mexico (5), New York (2), Oklahoma (1), Texas (2), and Wyoming (2). Among persons who died, ages ranged from 48 to 96 years, with a median age of 82.5 years. In addition, one (1) woman pregnant at the time of illness had a miscarriage. Seven (7) of the illnesses were related to a pregnancy; three (3) were diagnosed in newborns and four (4) were diagnosed in pregnant women.

C. The FDA's Investigation at Jensen Farms³

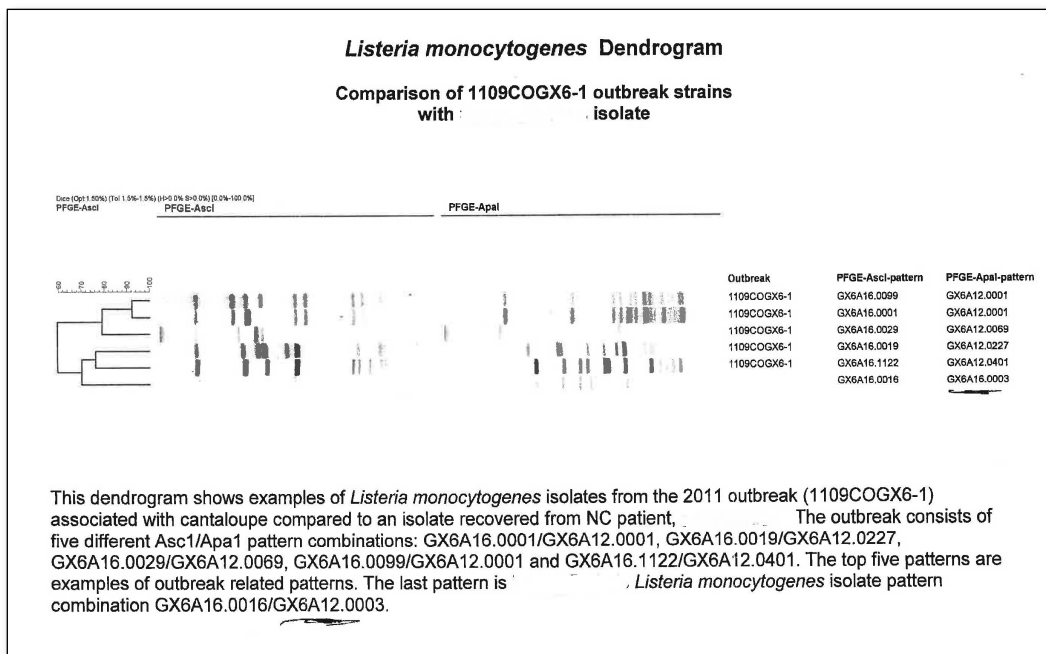
On September 10, 2011, with Colorado state officials, the FDA conducted an inspection at Jensen Farms and collected multiple samples, both product and environmental, for laboratory testing. Of the 39 environmental swabs collected from within the Jensen Farms packing facility, 13 were confirmed positive for *Listeria monocytogenes* with PFGE pattern combinations that were indistinguishable from three (3) of the six (6) outbreak strains. Of the 13 positive environmental swabs, 12 were collected at the processing line and one was collected from the packing area. Cantaloupe collected from the firm's cold storage during the inspection also tested positive for *Listeria*—in fact, five (5) of the ten (10) samples collected were positive for *Listeria*—

¹ As discussed below, we believe that, in fact, at least different 6 strains of *Listeria monocytogenes* caused illnesses in this outbreak. The CDC did, however, on August 27, 2012, in its final outbreak summary, increase the number of *Listeria* strains recognized in the outbreak from 4 to 5. The final summary is available at <http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html>

² In its August 27, 2012 final outbreak summary, the CDC stated, “The number of outbreak-associated deaths has increased by three since December 8, 2011. In total, 33 deaths from outbreak-associated cases of listeriosis have been reported to CDC.” The CDC's previous outbreak summary had included 31 deaths. We believe that number final death toll in the cantaloupe outbreak is now 38, with the additional deaths of Sharon Jones, Paul Schwarz, Michael Hauser, Betty Mills, and Dale Braddock. The CDC's updated death toll includes one additional death each in Colorado and Wyoming.

³ The Jensen Brothers are fourth generation cantaloupe farmers.

with PFGE pattern combinations that were indistinguishable from two (2) of the six (6) outbreak strains.⁴



After finding evidence of extensive contamination at Jensen Farms, the FDA, again, with the assistance of Colorado state officials, conducted an environmental assessment at the facility in an effort to identify the practices and conditions that lead to such widespread contamination. The results of the assessment, which occurred on September 22 and 23, 2011, were disclosed in a report dated October 19, 2011. Among other things, the report notes:

- a. Facility Design:** Certain aspects of the packing facility, including the location of a refrigeration unit drain line, allowed for water to pool on the packing facility floor in areas adjacent to packing facility equipment. Wet environments are known to be potential reservoirs for *Listeria monocytogenes* and the pooling of water in close proximity to packing equipment, including conveyors, may have extended and spread the pathogen to food contact surfaces. Samples collected from areas where pooled water had gathered tested positive for an outbreak strain of *Listeria monocytogenes*. Therefore, this aspect of facility design is a factor that may have contributed to the introduction, growth, or spread of *Listeria*

⁴ This dendrogram was provided to Marler Clark by the North Carolina State Public Health Laboratory as part of responsive documents related to a client who is not counted as a case patient in the Jensen Farms outbreak. It demonstrates that the sixth PFGE pattern from the top—i.e. the non-cantaloupe pattern—is different from the five known PFGE patterns in the cantaloupe outbreak at this time. On June 18, 2012, a cantaloupe sample taken on September 5, 2011 from the refrigerator of Marler Clark client, Margolin, was uploaded to Pulse Net. It returned a match to a deceased 75 year old from Montana. This would be the sixth outbreak strain.

monocytogenes. This pathogen is likely to establish niches and harborages in refrigeration units and other areas where water pools or accumulates.

Further, the packing facility floor where water pooled was directly under the packing facility equipment from which FDA collected environmental samples that tested positive for *Listeria monocytogenes* with PFGE pattern combinations that were indistinguishable from outbreak strains. The packing facility floor was constructed in a manner that was not easily cleanable. Specifically, the trench drain was not accessible for adequate cleaning. This may have served as a harborage site for *Listeria monocytogenes* and, therefore, is a factor that may have contributed to the introduction, growth, or spread of the pathogen.

b. Equipment Design: FDA evaluated the design of the equipment used in the packing facility to identify factors that may have contributed to the growth or spread of *Listeria monocytogenes*. In July 2011, the firm purchased and installed equipment for its packing facility that had been previously used at a firm producing a different raw agricultural commodity.

The design of the packing facility equipment, including equipment used to wash and dry the cantaloupe, did not lend itself to be easily or routinely cleaned and sanitized. Several areas on both the washing and drying equipment appeared to be un-cleanable, and dirt and product buildup was visible on some areas of the equipment, even after it had been disassembled, cleaned, and sanitized. Corrosion was also visible on some parts of the equipment. Further, because the equipment is not easily cleanable and was previously used for handling another raw agricultural commodity with different washing and drying requirements, *Listeria monocytogenes* could have been introduced as a result of past use of the equipment.

The design of the packing facility equipment, especially that it was not easily amenable to cleaning and sanitizing and that it contained visible product buildup, is a factor that likely contributed to the introduction, growth, or spread of *Listeria monocytogenes*. Cantaloupe that is washed, dried, and packed on unsanitary food contact surfaces could be contaminated with *Listeria monocytogenes* or could collect nutrients for *Listeria monocytogenes* growth on the cantaloupe rind.

c. Postharvest Practices: In addition, free moisture or increased water activity of the cantaloupe rind from postharvest washing procedures may have facilitated *Listeria monocytogenes* survival and growth. After harvest, the cantaloupes were placed in cold storage. The cantaloupes were not pre-cooled to remove field heat before cold storage. Warm fruit with field heat potentially created conditions that would allow the

formation of condensation, which is an environment ideal for *Listeria monocytogenes* growth.

The combined factors of the availability of nutrients on the cantaloupe rind, increased rind water activity, and lack of pre-cooling before cold storage may have provided ideal conditions for *Listeria monocytogenes* to grow and out-compete background microflora during cold storage. Samples of cantaloupe collected from refrigerated cold storage tested positive for *Listeria monocytogenes* with PFGE pattern combinations that were indistinguishable from two of the four outbreak strains.

See FDA Environmental Assessment Report, **Attachment No. 1**.

After conducting this environmental assessment, the FDA issued a warning letter to Jensen Farms, indicating, “we may take further action to seize your product(s) and/or enjoin your firm from operating. Additionally, the receipt of this warning letter and any action taken to correct the violations cited in it do not preclude a subsequent criminal prosecution by the United States Department of Justice.” See FDA Warning Letter to Jensen Farms, **Attachment No. 2**. To date, despite 38 deaths, one miscarriage, and 147 confirmed illnesses nationally, no criminal indictments have been issued in this outbreak—yet.



But the FDA did not close its file on this outbreak after issuing its very clear warning. Officials from the agency also participated in the much-publicized briefings with the House Committee on Energy and Commerce in October and December 2011. At those meetings, FDA officials cited multiple failures at Jensen Farms, which, according to the Committee Report, “reflected a general lack of awareness of food safety principles.” Those failures, several of which draw from the FDA’s Environmental Assessment Report, included:

- Condensation from cooling systems draining directly onto the floor;
- Poor drainage resulting in water pooling around the food processing equipment;
- Inappropriate food processing equipment which was difficult to clean (i.e., *Listeria* found on the felt roller brushes);

- No antimicrobial solution, such as chlorine, in the water used to wash the cantaloupes; and
- No equipment to remove field heat from the cantaloupes before they were placed into cold storage.

In particular, the FDA heavily criticized the decision not to chlorinate the water used to wash cantaloupes, despite the fact that the wash was not re-circulated, as well as the use of improper processing equipment in the packinghouse. As is discussed below, both of these factors not only contributed to the cause of the outbreak, but were the subject of discussion and recommendation by Primus Labs, and its agent, Bio Food Safety, during the latter's 2011 audit at Jensen Farms.

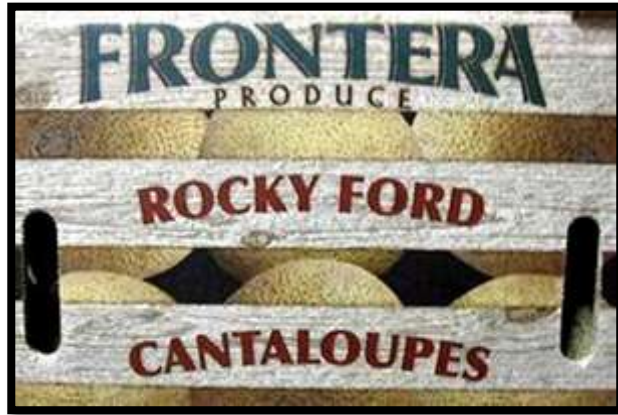
In short, the conditions, personnel, and facility, in general, at Jensen Farms, in the summer of 2011, did not just fall well short of good manufacturing practices and industry standards; they violated FDA guidance on the safe production of cantaloupes. Some even violated basic, not to mention legal, standards of human decency.⁵ In fact, this is specifically the opinion held by FDA officials who spoke with the Committee in October and December: "FDA officials stated that the outbreak could have likely been prevented if Jensen Farms had maintained its facilities in accordance with existing FDA guidance."

See Energy and Commerce Committee Report, **Attachment No. 3**.

D. The outbreak's "rogue elements": the actions and inaction of others in the supply chain, and third parties, in bringing heavily contaminated fruit to market.

Jensen Farms' inexcusable failures were its own—the Jensen brothers were, after all, fourth generation cantaloupe farmers—and certainly nobody will convince a jury that the brothers are blameless. The question of causation, however, and whose actions and inactions caused or contributed to 147 illnesses, one (1) miscarriage, and 38 deaths nationally is much broader.

⁵ As was widely reported in the press, the U.S. Department of Labor assessed a civil penalty on Jensen Farms for "failing to provide migrant worker housing that meets the safety and health requirements of the Migrant and Seasonal Agricultural Worker Protection Act." The "Gateway Motel" in Holly, Colorado, owned by the Jensen brothers, had been "renting" rooms to Jensen Farms workers that were overcrowded, lacked functional windows, lacked any laundry facilities, lacked smoke detectors, and had numerous other unsanitary conditions. The Department of Justice rejected the Jensen brothers' argument that they were "innkeepers" and thus exempt from the reach of the Act. Chad Frasier, the Wage and Hour Division's district director in Denver stated that the Jensen brothers' actions in housing their workers in such deplorable conditions was both "inhumane" and "illegal."



Frontera Produce was certainly no stranger to the Jensen Farms facility, and will not escape the duties of care that it too owed to consumers of its products to ensure that Jensen Farms' cantaloupes were being safely produced. A Frontera Produce representative, Amy Gates, visited the facility just a short time before the fateful 2011 audit, by James Dilorio,⁶ which is addressed below, clearly to ensure that the farm and facility was in a proper condition for examination by its auditor of choice, Primus Labs, through Bio Food Safety.

According to the Jensen brothers, during her July 2011 visit, Amy Gates provided them with advice about preparing for the audit, but did not note any problems. Ms. Gates could have seen the conditions of Jensen Farms' facility (from its improper equipment, to the materials from which some of the equipment was made, to the propensity for the facility to be a breeding ground for bacteria, to the improper wash system, and the FDA's list goes on) was ripe for anybody who favored safety over production to step in and prevent the most lethal outbreak in U.S. history.

To read from Frontera Produce's website about its efforts to achieve better food safety would cause the ordinary consumer to believe that safety was, at the time of the outbreak, and remains a top priority. Not only are its products dubiously billed as being "Primus Certified," Frontera Produce is stated to be GFSI compliant,⁷ SQF certified,⁸ and "Produce Marketing Association Gold Circle, Advancing Food Safety Certified."

Undoubtedly, without even delving into the question of what these compliances and certifications actually mean, these safety systems recognize the importance of ensuring, at the very least, that all entities in the chain of distribution, from farm to fork, are following good agricultural and manufacturing practices, and have a dexterous understanding of basic food safety practices.

According to Will Steele:

⁶ In addition, Will Steele, CEO of Frontera Produce, had been to Jensen Farms facility six (6) times in a 6-year period.

⁷ "GFSI" stands for Global Food Safety Initiative.

⁸ "SQF" stands for Safe Quality Food.

Regarding our food safety requirements, we require that all suppliers commit to following federal government food safety guidelines appropriate to their individual operations. These may include: FDA's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Good Agricultural Practices and Good Manufacturing Practices. Suppliers' packing facilities and growing fields are required to undergo and pass third-party audits. Finally, since 2009, we have been working with all our growers to move to third-party audits that comply with the Global Food Safety Initiative (GFSI). Our implementation timetable is for all of the produce we market to be 100% GFSI compliant by the middle of next year, and we are on track to meet that goal.

See Will Steele's November 28, 2011 Interview with The Packer, **Attachment No. 4.**⁹

But the findings of every objective observer of Jensen Farms facilities and practices stands in stark contrast to everything that Frontera Produce represented was right about its product line. The truth of the matter is that Jensen Farms was grossly negligent; it did not follow basic industry standards, it did not follow FDA guidance, and it lacked even a basic understanding of how to safely grow and process cantaloupes at high volume to meet the distribution needs that Frontera Produce set up for it. Responsibility flows to more than one's own business interests from business relationships, and Frontera Produce did not act reasonably to ensure that Jensen Farms' clear failures, which were readily apparent even before the outbreak happened, were corrected. Frontera Produce was in a ready position to do so, at Amy Gates' visit prior to the outbreak and at any other time, but did not act, instead relying on a very basic, and ultimately negligently conducted audit, designed primarily to ensure that product continued to flow so that Frontera Produce could fulfill the many distributive obligations that it had secured. After all, in what business position would Frontera Produce have been if James Dilorio had failed Jensen Farms on July 26th?

In the wake of this monumental outbreak, the prevailing system for third-party audits has come under intense scrutiny. Time and again, this firm has represented injured people, or the families of those who have died, in outbreaks where a negligent processor was given glowing reviews, only for investigating agencies later to find during unbiased, competent investigations done without the veneer of conflicting interests, that the facility in which the food was produced was not suitable for the production of CAFO¹⁰-destined animal feed, much less food for human consumption. And clearly, Jensen Farms' packing facility was no exception.

Again, Mr. Steele:

⁹ Website: <http://www.thepacker.com/fruit-vegetable-news/Frontera-CEO-discusses-companys-role-in-listeria-outbreak-134589383.html>.

¹⁰ "CAFO" stands for Concentrated Animal Feeding Operation.

In the wake of this experience, we are examining, among other things, the role of audits. Third-party audits are an important and useful tool, but they are obviously not fail-safe. Audits provide baseline information on conditions at the time they are conducted. So we are looking at possible changes that might further enhance food safety. One area of focus is whether additional steps are needed to validate the audit findings regarding food safety protocols that are in place. Validation could be in the form of a follow-up audit, or perhaps other measures that will help provide additional assurance of food safety compliance.

Id.

As has been widely reported, Jensen Farms' facility was audited by Primus Labs'¹¹ agent Bio Food Safety on July 26, 2011, mere days before the first illness was reported. Auditor James Dilorio gave the facility a "superior" rating, and a score of 96%, noting that many of the pieces of equipment, and many of the packing procedures in place that the FDA found so problematic, were in "total compliance." Undoubtedly, auditing companies will respond, and have in fact done so, that they only conduct the type of audit they are asked to do, but this argument goes only so far when juxtaposed against the egregious safety, processing, and equipment failures that lead to this outbreak.

Mr. Dilorio did identify several deficiencies in his facility audit, which lasted just over four (4) hours, including three (3) "major deficiencies": (1) wood, which is a material universally known for its propensity to act as a reservoir for contamination, was used in the construction of the unloading and packing tables; (2) lack of hot water at hand washing stations; and (3) doors left open during operating hours, potentially allowing pests to enter the facility. Dilorio also identified multiple "minor deficiencies" and non-compliances, including: (1) the storage area was left open during operating hours; (2) there were no records of corrective actions taken based on previous audits; and (3) stickers on pest control devices were in the wrong location.

These violations certainly were properly noted, regardless of the type and style of audit that Frontera Produce required.¹² But the truth, however, is that Mr. Dilorio failed to deduct points for several other non-compliances that may have caused Jensen Farms to

¹¹ Primus Labs is one of the nation's largest third-party food safety auditors. Primus Labs conducts approximately 15,000 audits per year, primarily involving fresh produce facilities, for over 3,000 clients worldwide. A typical facility is audited once per year, and a Primus Labs audit results in a pass/fail determination, a score from 0-100%, and a report that lists any violations. Passing scores can differ greatly: a company can pass with comment, pass without comment, or pass with either major or minor compliance issues. A company fails if it has one "egregious" non-compliance, or if it scores less than 80% overall. According to Primus Labs, the vast majority of the thousands of audits it conducts each year receive passing grades: 98.7% in 2010, 97.5% in 2009, and 98.1% in 2008.

¹² In fact, the "type and style" of the Jensen Farms audit required by Frontera Produce, no doubt at the insistence of major retailers like Walmart, was a checklist style audit to ensure compliance with industry standards for the *safe* production of cantaloupes.

automatically fail. All of the following must be considered alongside what is not only the obvious, but also the stated, primary concern for Primus Labs audits: “Auditors should interpret the questions and conformance criteria in different situations, with food safety and risk minimization being the key concerns.”¹³

1. Pest Control: GMP section 1.2.1 clearly states that all products must be free of pests, and that any down score in this section requires an automatic failure. Mr. Dilorio noted that, on this issue, Jensen Farms’ facility was in total compliance, and that “all products are free from pests or any evidence of them.” At section 2.5.10, however, Mr. Dilorio noted that inbound packaging loads “arrived in open bulk wagons.” Leaving aside the issue of the condition of the wagons, it was not possible for Jensen Farms to assure pest-free product at its facility using open wagons for transport when any number of birds, rodents, or other pests had open and free access. Moreover, section 2.5.13 indicates that there was no effective check for pests on incoming loads, but stated as justification for no down score on this issue that “[p]roduct arrives to the facility in open bulk wagons to be packed.” This is not merely a failure of Primus Labs’ standards regarding the control of pests; it is a clear violation of good manufacturing and agricultural practices and industry standards due to the uncontrolled potential that the system created for product to become contaminated. When coupled with the lack of an effective system for ridding incoming product of pests and other contamination prior to packaging, this failure should have been noted, and should have constituted an automatic failure under Primus Labs’ standards. Again, in Primus Labs’ own words, “each question and conformance have to be looked at individually and scored according to the severity of the deficiency, the number of deficiencies *and the associated risks.*”

2. Packing Machinery: As is detailed below, Pepper Equipment Company sold Jensen Farms packing equipment that was not in adequate repair, and was not properly designed for the safe processing of cantaloupe. The equipment was made for processing potatoes, a different agricultural commodity requiring different packing equipment. The equipment could have been updated to include new brushes designed for cantaloupes¹⁴ (clearly a different size and shape than potatoes, requiring different equipment to clean them), an injections system designed for microbiological chemicals, dryers to eliminate microbiological contamination, and the addition of stainless steel parts in place of wood,

¹³ This quotation is from Primus Labs’ audits manual, revised in November 2011, after it was sued in the *Wilcox* matter. The manual goes on to state, “[w]here laws, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source these practices and parameters should be followed if they present a higher level of conformance than those included in the audit scheme system.”

¹⁴ Pepper Equipment Company did sell Jensen Farms “½ share of brushes for washer,” so the exact configuration of this equipment is not yet fully known.

which would have allowed this machine to be effectively and regularly sterilized. This equipment implicated section 1.6.3, which asked whether “equipment design and condition (e.g. smooth surfaces, smooth weld seams, non-toxic materials, and no wood) facilitate effective cleaning and maintenance?” Clearly, as the FDA’s environmental assessment showed, the design of Jensen Farms’ equipment in place at the time of Primus Labs’ audit did not allow for this—a critical failure that was, admittedly, exacerbated by Jensen Farms’ inattention to the condition of its facility. Nevertheless, Mr. Dilorio noted that, with regard to section 1.6.3, Jensen Farms’ facility was in total compliance.

3. The Further Control of Pests: Jensen Farms’ facility was not secure, as is evidenced by Mr. Dilorio’s four (4) -point deductions at section 1.9.8. Further, raw product was stored both inside and outside the packing facility, without adequate control anywhere for pests. Although Mr. Dilorio deducted points for the several doors that were left open during hours of operation, this non-compliance must be viewed in the broader context of whether Jensen Farms’ facility and operations were properly controlling for pests and likely routes of contamination. Clearly, it was not, and Primus Labs cannot be allowed to divorce itself completely from the obligations that it undertook in auditing Jensen Farms by thinly asserting that there was not a category broad or comprehensive enough to require failure for Jensen Farms’ obvious food safety deficiencies.

4. Lack of an Antimicrobial Cleaner for Equipment: Not only was Jensen Farms not using an antimicrobial in its wash system, but, also, it was not using one to clean critical pieces of processing equipment. Instead, it favored “Simple Green Pro 5,” which does not contain an antimicrobial. Mr. Dilorio made the right observation, but stated that the failure was of no consequence (“N/A”), and that Jensen Farms’ score therefore was “not affected.” Mr. Dilorio clearly considered and appreciated the threat that this practice posed, however, as he noted specifically in his comments to section 1.4.8 that “product is washed with water only at this facility and there is no anti-microbial solution injected.”

5. Lack of Any Hot Water at Handwashing Stations: There is no more basic food safety requirement than the effective cleaning of hands. Any standard, including both the fresh produce industries and Primus Labs’, must include the use of hot water. Mr. Dilorio noted that this was a major deficiency, deducting 10 points from Jensen Farms’ score, but failed to recognize that this very elementary deficiency, by itself or in combination with Jensen Farms’ other major deficiencies, constituted an unsatisfactory condition that required automatic failure, not a superior rating.

6. Standing Water: Jensen Farms' facility may not have had standing water at the time of Mr. Dilorio's audit. Certainly, the facility was as sparkling as it could possibly have been, given that the audit was pre-scheduled and well prepared for by both Jensen Farms and Frontera Produce. But the facility was designed such that water had a propensity to pool, which created a contamination reservoir. Coupled with the lack of an effective barrier for pests, both in the facility and outside, this floor design presented a contamination risk for everything in the facility. Mr. Dilorio should have down scored Jensen Farms as a result, if not failed Jensen Farms for creating an unsatisfactory condition under USDA audit guidelines.

7. No Routine Environmental or Water Microbiological Testing: Jensen Farms did not routinely conduct microbiological testing of environmental, water, or finished product samples. This is in violation of section 1.4.8 of Primus Labs' audit manual at page 26, where the "major deficiency" categories all assume that an antimicrobial is being used in the first place. The tests contemplated in that section are to ensure that antimicrobial concentration is correct. Clearly, the lack of an antimicrobial anywhere in the facility, and the corresponding lack of microbiological testing to ensure that the equipment and water are not a source, or potential source, of contamination, must also be a major violation. Again, Primus Labs auditors are cautioned in their audit manual to have "food safety and risk minimization" as their "key concerns."

8. Failure to Precool Melons: Jensen Farms did not pre-cool its melons at all, whether by forced air, water, or any other method. This is a violation of all good agricultural and manufacturing practices for melons, and is inconsistent with standard industry practice, which may vary with respect to the practice used, but does not simply ignore cooling altogether.

9. Backflow Prevention Deficiency: This non-compliance, for which Mr. Dilorio gave Jensen Farms zero (0) out of three (3) points, must be judged, like everything else in his audit, against the backdrop of a facility washing a raw agricultural product without the use of an antimicrobial. Just as it should have suggested to Mr. Dilorio, the lack of an antimicrobial heightened the risks to consumers presented by Jensen Farms' many other safety failures. More specifically, backflow prevention is critical to ensuring that contaminated water is not recirculated. Mr. Dilorio issued zero (0) points on this item, thus establishing that there was a problem. Whether that meant that the check valve was missing entirely, or that the system simply had not been checked or monitored regularly, this is an item that, viewed in a vacuum, may seem innocuous, but viewed with the backdrop of food safety and risk minimization as "key concerns" achieved far greater significance.

This list is not intended to be an exhaustive review of the many failures, violations, and non-compliances that a rigorous audit should have identified. Again, the condition of Jensen Farms' facility on review by the FDA and Colorado state officials simply cannot be reconciled with the glowing review that Mr. Dilorio gave the facility and farms on July 26, 2011.¹⁵ Auditors cannot be as hamstrung as public comments since publication of Mr. Dilorio's audits have suggested; otherwise, the entire system is a farce. Given the incredible level of contamination that obviously occurred as a result, we feel that any reasonable jury will agree entirely.

Of course, this is clearly not Primus Labs' view, at least not according to public comments since the date that Mr. Dilorio's audit was first exposed. Robert Stovicek, President of Primus Labs, has repeatedly defended the audit. "Even though it looks as horrendous as it does," he stated in an interview with the Denver Post,¹⁶ Stovicek indicated that that he would continue using Bio Food Safety as its auditing agent, that he had full confidence in Mr. Dilorio,¹⁷ and even that Mr. Dilorio did a "good job,"¹⁸ despite not knowing whether Mr. Dilorio had ever even audited a cantaloupe operation before.¹⁹

One issue not noted in the foregoing list, instead being reserved for discussion here, is Jensen Farms' failure to use an antimicrobial in the wash system. Mr. Dilorio prominently noted on the front page of his facility audit report that this is "a packing facility for cantaloupes which are washed by a spray bar roller system, graded, sorted by size, packed into cartons and stored in dry coolers. No anti-microbial solution is injected into the water of the wash station."²⁰

¹⁵ Unlike the audits performed before the *Salmonella* outbreaks involving the Peanut Corporation of America and Wright County Egg, the Jensen Farms audit was performed during the outbreak.

¹⁶ Website: http://www.denverpost.com/search/ci_19159245.

¹⁷ Website: http://www.denverpost.com/search/ci_19159245.

¹⁸ Website: <http://www.thepacker.com/fruit-vegetable-news/jensen-farms-earned-high-third-party-audit-marks-132272688>.

¹⁹ Website: http://www.denverpost.com/search/ci_19159245.

²⁰ The July 2011 audit, however, did not mark the beginning of the relationship between Jensen Farms and Primus Labs/Bio Food Safety. On August 5, 2010, Jerry Walzel, the President of Bio Food Safety, audited the Jensen Farms packing facility and gave it score of 95% grade—another "superior" rating—despite also finding several major and minor deficiencies. One precaution that Jensen Farms took in 2010, which it dropped in 2011, was to use an antimicrobial solution, such as chlorine, in the cantaloupe wash water. The front page of the August 2010 audit stated, "[t]his facility packs fresh cantaloupes from their own fields into cartons. The melons are washed and then run through a hydrocooler which has chlorine added to the water. Once the product is dried and packed into cartons it is placed into coolers."

After the August 2010 audit was completed, one of the Jensen brothers informed Mr. Walzel that they were interested in improving their processes. According to Jensen Farms, in response to this inquiry, Mr. Walzel indicated that they should consider new equipment to replace the hydrocooler the farm used to process cantaloupe. Mr. Walzel stated that the hydrocooler, with its recirculating water, was a potential food safety "hotspot," and advised them to consider alternate equipment. Based on his comments, and input from a local equipment broker, Jensen Farms purchased and retrofitted equipment previously used to process potatoes. The Jensen brothers stated that they changed from the hydrocooler to the new food processing equipment in

This was not just a simple violation, or something that Mr. Dilorio should have down scored Jensen Farms' facility for in some fashion. It was a clear and present threat to human health, and if third-party audits, regardless of their type, are good for anything other than to rubber stamp the requirements of major retailers, it must be to identify exactly this type of hazard, and act in some fashion—e.g. *fail the auditee*—to ensure that the risk presented is not merely passed along to consumers.

The lack of an antimicrobial solution has been widely criticized by many experts, from the FDA, academia, and industry, as violating good agricultural and manufacturing practices, as well as baseline industry standards for the production of cantaloupes. Further, the lack of an antimicrobial must be viewed alongside Mr. Dilorio's observation at section 1.4.8 that no antimicrobial was being used during cleaning of Jensen Farms' equipment either. Any auditor, just like any food processor, must, in part, assume contamination of product so that he or she can objectively and effectively assess the facility's ability to remove or eliminate the contamination. Assuming contamination of Jensen Farms' cantaloupes, what could Mr. Dilorio possibly have thought would be the barrier to contamination of finished product? No antimicrobial in the wash system, and none used during cleaning of the equipment is a recipe for exactly the kind of disaster that unfolded—a risk that was only heightened by the inadequacy of Jensen Farms' operations generally.

We would of course be remiss to fail to point out that; in this case, Mr. Dilorio was more than just an auditor. Public statements made since the circumstances underlying this outbreak came to light have suggested that an auditor's role, under the prevailing system, is quite limited. Whether true or not, Mr. Dilorio's role was more than that, causing him, the company that he worked for, and Primus Labs, for whom he was also acting as agent, to undertake a further duty to those in the foreseeable zone of risk created by their actions or inactions. More specifically, in interviews with the House Committee on Energy and Commerce, Eric and Ryan Jensen stated that Mr. Dilorio actually recommended the faulty production equipment, including the potato washer sold to it by Pepper Equipment, and other practices that Jensen Farms had put in place for the 2011 cantaloupe season. *See* Committee on Energy and Commerce January 10, 2012 Letter to FDA Commissioner Margaret Hamburg, **Attachment No. 5**. "According to FDA officials, there were 'serious design flaws' with the equipment that the auditor recommended, and it did not meet basic standards spelled out in FDA guidance." *Id.*

The list of liable parties is as broad as the duties that all owed to consumers of Jensen Farms contaminated cantaloupes. Pepper Equipment Company bills itself as a manufacturer of state-of-the-art washing, sorting, and packaging equipment. Further, Pepper Equipment Company indicates on its website that it has particular expertise in manufacturing custom-built equipment "designed to fit your specific needs."

an attempt to strengthen their food safety efforts. When questioned by the Committee about his recommendations to Jensen Farms following the 2010 audit, Mr. Walzel indicated that he could not remember whether he had made these recommendations.

On May 23, 2011, Pepper Equipment Company sold Jensen Farms a dual sorting table, a Gillenkirch washer²¹ and felt dryer, a conveyor for passing fruit from the dryer to the sorting table, and two “conveyors for stickering.” See Pepper Equipment Company/Jensen Farms Sales Documentation, **Attachment No. 6**. The total price for the equipment was \$106,208.00. Thereafter, Pepper Equipment Company employees Keith, Gage, and Chet drove the equipment to Jensen Farms and spent a total of 179 labor hours preparing and installing the new, or used, equipment at Jensen Farms’ packing facility.

The equipment that Pepper Equipment Company sold, manufactured, and installed at Jensen Farms was neither in adequate repair or appropriate²² for the job it was intended to do. The FDA—in fact, just about every objective observer of this outbreak—has been highly critical of Jensen Farms’ equipment, and the responsibility for the failure of that equipment falls, in part, to the entity most knowledgeable about the proper use of the equipment. The equipment that Pepper Equipment Company sold to, manufactured, and installed at Jensen Farms’ facility was not appropriate, much less state-of-the-art. Again, like so many things in this outbreak, what was billed, prior to the outbreak, as an unwavering commitment to quality and food safety, in the end proved not to be. Pepper Equipment Company’s equipment should never have been sold to, installed at, or used by Jensen Farms for the processing of cantaloupes.

²¹ Pepper Equipment Company’s website link to this piece of equipment is currently blocked or disabled.

²² Interestingly, the Gillenkirch website does not indicate that its equipment is suitable for cantaloupe washing. Potatoes, yes, but not cantaloupes.