THE OUTBREAK: THE UNTOLD STORY OF *LISTERIA MONOCYTOGENES* AT JENSEN FARMS

I. *LISTERIA MONOCYTOGENES* STRIKE JENSEN FARMS

Introduction

(1) Between July 31, 2011, and late October of that same year, 147 people in 28 U.S. states, most over the age of seventy, were ravaged by the horrific symptoms of an insidious and malevolent foodborne pathogen *Listeria monocytogenes.*[57] Victims came down with "high fevers, headaches, stiff necks, confusion, loss of balance, diarrhea, and convulsions."[45] Soon, many began vomiting, eventually regurgitating blood; some fell into comas. Eventually, 33 people died, and one victim suffered a miscarriage. The source of the *Listeria* contamination turned out to be a cantaloupe farm in Southeastern Colorado, known as Jensen Farms.

Listeria monocytogenes

(2) *Listeria monocytogenes* or *L. mono* is one of the most virulent forms of foodborne bacteria, a unique killer that, unlike most other food bugs, grows in cold temperatures as well as in warm. While the human gastrointestinal system provides the ideal incubational environment for all kinds of foodborne pathogens, bacteria, such as *E. coli* or *Salmonella*, tend to grow quickly only when exposed to the warm and moist conditions afforded by the body. Foodborne *L. mono*, on the other hand, can grow on food in a refrigerator (though its growth is slowed), as well as in the gastrointestinal system, and if the food is not consumed for a period of time, the *L. mono* can multiply to deadly levels before it even enters the body.

(3) In addition, the *L. mono* bacteria "have a long incubation period, which means that it may take as long as four weeks for people who have eaten food contaminated with *L. mono* to feel ill."[25] Unlike other pathogens including *E. coli* O157:H7 or *Salmonella*, *L. mono* can be controlled, but not eradicated. For this reason, in Canada and the European Union, food containing the pathogen can be sold so long as quantities of the pathogen are under prescribed allowable limits (for instance in Canada the allowable limit is 100 mpn [most probable number] per milliliter). For all these reasons, *L. mono* is to epidemiology what drug cartels are to criminology – terror agents that can strike swiftly with shocking fury or slowly and menacingly for prolonged periods.

(4) Like most foodborne pathogens, *L. mono* is a discriminating assassin. Though thousands and even tens of thousands of people are often exposed to a single pathogen outbreak, only a select few people usually fall victim to its illness inducing effects. People with compromised immune systems are the most likely to be sickened. Young children, pregnant women, and especially the elderly are most at risk.[19]

(5) Furthermore, "although not a leading cause of foodborne illness, *L. monocytogenes* is among the leading causes of death from foodborne illnesses."[46] While illnesses from other foodborne bugs can result from the presence of very few pathogenic cells in the

human body, healthy persons can avoid becoming sick even when tens of millions of *L. mono* cells exist within them. For instance, for *Salmonella*, "as low a one cell, depending on age and health of host" is an infective dose. "The infective dose of *EHEC* O157:H7 is estimated to be very low, in the range of 10 to 100 cells."[46]

(6) On the other hand, "the approximate infective dose of *L. monocytogenes* is estimated to be 10 to 100 million colony forming units (CFU) in healthy hosts, and 0.1 to 10 million CFU in individuals at high risk of infection."[15] In short, though much of the food we eat may contain some amount of *L. mono,* even people with compromised immune systems must have large amounts of the pathogen within them in order for them to become ill. Unfortunately, if they do become ill, the likelihood of death is greater in *L. mono* victims than it is from any other pathogen.[46]

(7) Strangely, however, *L. mono* had never been known to contaminate any type of whole produce before the Jensen Farms outbreak.[43] Prior to Jensen Farms, most cantaloupe farmers viewed *Salmonella* as the threat. That threat most likely arose from cross contamination caused by the water used in the "dump tanks" that cleaned the melons.

(8) While many melon growers in the high plains of Southeastern Colorado had for many years used "dump tanks" to remove field dirt from their product, they had recently become aware that over time quantities of field dirt originating from the rough, netted surface of the melons tended to lessen the effectiveness of any oxidizing agent that was added to the wash water. Because the water in the dump tanks was not filtered or otherwise cleaned, as more and more dirt accumulated in the wash water, the anti-microbial additive in the water ceased to be effective in killing pathogens, particularly *Salmonella.* Farmers knew that, once in the wash water, *Salmonella* could contaminate the fruit of the cantaloupe, by entering through the melons' stem scars. In an effort to make their melons less susceptible to *Salmonella* contamination, some growers had turned to "single pass" wash systems.

The Healthiest Food on the Planet

(9) Fresh produce has long been hailed as the healthiest food produced on the planet. In general, almost all produce commodities contain high levels of vitamins, minerals, proteins, fiber, and anti-oxidants that are essential for good health, while they are also low in calories and harmful forms of cholesterol. In addition, fresh produce aids in proper digestion and maintenance of optimum electrolyte balance. Also, the fresher the produce is, the better it is for you. Doctors have long encouraged their patients to consume more fruits and vegetables in their diets, and the recent popularity of the locavore movement has put greater emphasis on the consumption of fresh produce, ensured by the purchase of fruits and vegetables grown in close proximity to the consumer's location. There is virtually universal acceptance of the benefits of eating fresh produce in every culture and society.

(10) However, because fresh fruits and vegetables are, well, *fresh*, they can carry pathogenic microbes. Fresh produce is one of the only food products that does not commonly undergo a "kill step" before it is eaten. Meat, poultry, milk, eggs, grains, and

processed and canned foods are all usually either cooked or pasteurized. Exposure to high temperatures kills any pathogens that may contaminate those foods. While fruits and especially vegetables are also sometimes cooked, they are often consumed fresh, and so eating fresh produce can expose the consumer to harmful pathogenic bacteria. It is one of life's darkest ironies that the healthiest food on the planet may also be a vector for dangerous microbes.

Jensen Farms and Rocky Ford Cantaloupe

(11) Brothers Eric and Ryan Jensen are fourth generation cantaloupe farmers. "Jensen Farms has been a fixture in the dry plains of southeastern Colorado since the early 1900s, when the first Jensen arrived from Denmark. [The brothers] inherited what was an approximately 160-acre farm from their father after he died several years ago, and they expanded it out to about 6,000 acres, growing cantaloupes along with hay and alfalfa and other grains."[8] Though the two brothers were responsible for the operation, their mother actually owned the land.

(12) Though their farm outside Holly, Colorado, is nearly 95 miles from the "Rocky Ford" area, known by cantaloupe aficionados for its sweet melons, the Jensen brothers labeled their product "Sweet Rocky Fords."[19] In response to the Jensen Farms incident, which wreaked devastating effects on it business, the Rocky Ford Growers Association (RFGA) now "holds a trademark on the brand and... [growers outside the region] are not geographically qualified to use it."[18] The harvest season for Rocky Ford and other cantaloupe growers in Colorado generally begins in early August and usually lasts until early October. During the 2011 harvest, Jensen Farms produced "300,000 cases of cantaloupes."[6]

(13) By all accounts, the melon growers whose farms occupy the Arkansas River Valley in Southeastern Colorado, like Eric Jensen, 37 and his younger brother Ryan, 33 are "good, salt of the earth, Americana people."[3] These hardworking growers tended to run family operations, and their pride in their families' histories of farming the high plains is palpable at first blush. Like most farmers, the Rocky Ford growers, some sixth generation melon farmers, saw their work as noble and dignified. For 125 years, they had grown what they considered to be the finest tasting cantaloupes in the world without a single food safety incident.[38] Far from complacent, they wanted to improve their farming practices.

Transitional Grounds

(14) One of the more neglected aspects of the story of the *L. mono* outbreak at Jensen Farms is the brothers' decision to convert from conventional farming to organics. The market for organically grown produce of all kinds skyrocketed throughout the late 1990s and into the new century. Presumably, in an effort to capitalize on that growing market and the increased profits that such a market would afford, the Jensen brothers were in the process of transitioning their operation to organics. However, growing organic produce requires different skill sets than conventional farming.

(15) In his analysis of the Jensen Farms outbreak, Dr. James R. Gorny, then Food and Drug Administration's (FDA) Senior Advisor for Produce Safety, Center for Food Safety & Applied Nutrition, made much of the Jensen brothers' decision to convert their wash system, suggesting that that change in the operation could have been responsible for the introduction of *L. mono* into their packinghouse. "What turned the operation upside-down was some significant changes they made," said Gorny. "It was a very tragic alignment of poor facility design, poor design of equipment and very unique post-harvest handling practices of those melons. If any one of those things would have been prevented, this tragedy probably wouldn't have occurred."[8]

(16) The FDA also speculated at length about a host of other possible ways in which the *L. mono* could have been introduced to the Jensen Farms operation, yet it made little, if any, mention of the more unique status of the operation, its transition to organic farming. Conventional farming relies on the application of a wide array of chemicals (soil nutrients, pesticides, herbicides, etc.) that take some of the art out of farming. Organic farming is more complex and requires greater attention to detail. Of all the factors that impacted farming at Jensen Farms throughout its 60 year history of growing cantaloupes, none was more significant than the shift to organics, because the shift changed the risk associated with the production and the product.

(17) Many types of fertilizers can be added to soil to supply it with nutrients. Of these nutrients, plants most frequently need nitrogen (N), phosphorus (P) and potassium (K). One of the issues with mineral fertilizers is the possible contamination caused by isotopes or heavy metals. With organic fertilizers, which rely on naturally-occurring sources like animal waste and/or vegetable matter, the concern shifts to the undesirable microbes that they can introduce into the soil. In the process of switching from mineral fertilizers to some type of organic fertilizer, the Jensen brothers' operation was undergoing what is known in agriculture as "transitional grounds."

(18) "Transitional grounds" refers to the three year period between the last use of conventional (naturally occurring or man-made) fertilizers, pest control materials, etc. and the point at which growers can apply to be legally certified to market their products as "Organically Grown." Audits of the three operations that the Jensen brothers farmed reveal that these growing areas were "under organic principles", but were "not certified organic." Instead, they were "in the process of becoming certified."[12] In other words, the Jensens were farming "transitional grounds", and more than anything other aspect of their operation, the transition to organics made them unique.

(19) In most cases, the shift to organic fertilizers involves the use of compost, bloodmeal, bone meal, humic acid or seaweed. The application of any of these types of organic fertilizers shifted the risk from isotopes and heavy metals to undesirable micro-organisms, including pathogens such as *Salmonella*, *Shigella*, *E. coli* O157:H7, and *Listeria monocytogenes*.

Cantaloupe Production

(20) Southeastern Colorado is a unique area for cantaloupe production. According to the Rocky Ford Growers Association, the "blazing hot days and crisp, cool nights… lock in the sweet, juicy taste of summer." Along with the "sun-drenched altitude, nutrient-packed clay soils, [and] snowmelt irrigation", the "world famous melons are the standard to which all others aspire."[38]
(21) Cantaloupe produced in Colorado and most other regions of the country is packed differently than it is in California and Arizona (two of the largest production areas in the U.S.). The melons grown in these arid regions are usually packed directly in cartons in the fields, since little dirt accumulates on them. However, even though Colorado melon farmers often use plastic sheeting, commonly referred to as plastic mulch, to keep melons from touching the ground, frequent summer rainstorms splatter significant amounts of mud on the cantaloupes. Because of that excess amount of dirt, Colorado melons are usually washed before they are packed to meet consumer preference.

(22) Another difference is that the varietals grown in Colorado (and most other U.S. regions) have a heavily "netted" or "fruit leather" rough rind. In some places (for instance in Europe) cantaloupe varietals have smoother rinds. This is significant because in theory the likelihood of pathogen contamination is greatly increased in netted cantaloupe as compared to smooth rind cantaloupe because the netted cantaloupe rinds are much harder to clean. It is important to note that smooth rind cantaloupes are not popular in American markets.

'Single Pass' Wash System

(23) Sometime between the 2010 and the 2011 growing seasons, the Jensen brothers decided to switch their operation from a dump tank to clean their melons to a seemingly improved wash system. "They acquired a set of used machinery to upgrade the way they washed and dried their cantaloupes."[24] This "single pass system" moved the cantaloupes under a spraybar on a conveyor belt. The one pass of water from the spraybar is intended to remove the dirt from the surface of the melons.

(24) The equipment the brothers purchased had previously been used in a potato operation. Jensen Farms purchased the piece of equipment from the farm machinery company, Pepper Equipment of Monte Vista, Colorado, in May 2011 and then asked Pepper to modify it to accommodate their cantaloupes.[14] Presumably their intention to convert to a single pass wash system was an attempt to address *Salmonella* contamination. Pepper fashioned it with a container to hold an oxidizing agent (e.g. bleach, etc.), but the Jensen brothers never utilized an anti-microbial in the wash during the 2011 cantaloupe harvest. Instead, they used Granada, Colorado, city water in the single pass system.

FDA Guidance on Cantaloupe Production

(25) In his testimony to the House Committee on Energy and Commerce that investigated the Jensen Farms outbreak in 2012, Jerry Walzel, the auditor who conducted a 2010 audit for Jensen Farms, stated, "FDA has no specific regulations on cantaloupe processing."[59]

(26) Instead, FDA supplies "guidance" on cantaloupe production, as it does for most other fresh produce. The FDA's currently published guidelines were written "in response to a multi-state foodborne illness outbreak of *Listeriosis* associated with consumption of fresh, whole cantaloupe" and were published in November 2011, two months after the Jensen Farms outbreak.

(27) However, even after the outbreak, those guidelines are not regulatory in nature. According to that document, "This guidance represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."[51]

(28) Even with this disclaimer, the guidance on washing melons is, at best, ambiguous. In fact, prior to the Jensen Farm outbreak, the FDA's guidelines suggested that an anti-microbial agent should be utilized if the water was not potable or if the water was recycled: "If melon cooling water is re-circulated sufficient water disinfectant should be present at sufficient levels and the levels monitored to reduce the potential risk of cross contamination" and "Single pass or one use cooling water of sufficient quality for this intended purpose may also be used."[47] A single pass system using city drinking water, such as the Jensen brothers employed, met these guidelines. The guidelines in effect in 2011 were issued jointly by the Produce Marketing Association (PMA) and the United Fresh Fruit and Vegetable Association in 2005 and were published on the FDA's website. One of the authors of the document was Dr. James R. Gorny, onetime Vice-President of Quality Assurance with United Fresh, who became FDA's principal investigator in the Jensen Farms outbreak (today, Gorny works for PMA). These industry guidelines are the basis for the FDA guidance.

(29) In the wake of the Jensen Farms incident, the FDA's guidance documents changed to suggest that all types of wash systems should use an oxidizing agent. Then, the FDA's guidelines appeared to change again – back to the original language that the Jensen brothers may well have been following when their cantaloupe sickened so many people.[50] As suggested earlier, the FDA makes clear that their guidance document "Contains Nonbinding Recommendations. "[51]

II. CANTALOUPE LOVERS AND *L. MONO*

Introduction

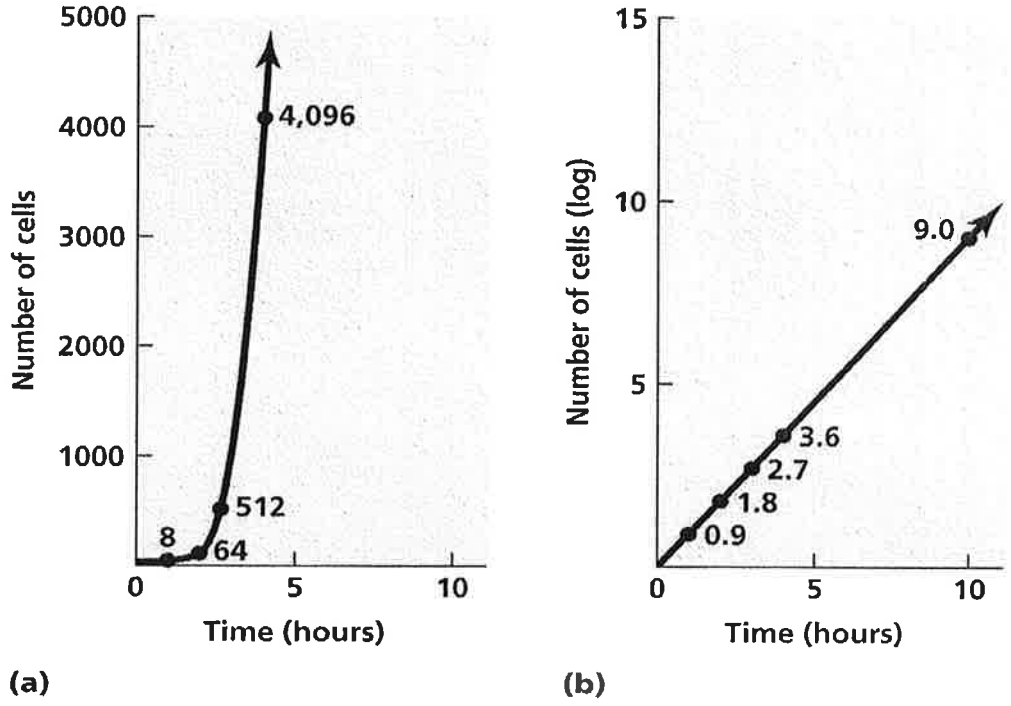
(30) One of the simple joys of life on the high plains of Eastern Colorado and New Mexico, and Western Kansas, Oklahoma, and Texas, where 96 of the *L. mono* victims lived, is the late summer arrival of "Rocky Fords." Many of the residents of these windswept plains, especially the elderly, consider Rocky Ford cantaloupes the high plains' most sumptuous treat.

(31) It is not uncommon for cantaloupe enthusiasts to cut an entire melon up into chunks, enjoy a little as a snack, and then store the remainder in the refrigerator for several more servings. Unfortunately, when an unsuspecting victim cuts up a cantaloupe whose rind is contaminated with *L. mono*, he or she has unwittingly introduced the pathogen to the fruit itself with the knife blade. Because *L. mono* can grow in cold temperatures, and because the sugar and moisture in the fruit of the cantaloupe provide a better medium for growing the bacteria than does the rind, each innocent trip to the refrigerator introduces another even more virulent dose of pathogen into the victim's system.

(32) "Growth of *Listeria monocytogenes* in food is a function of the storage time, storage condition, and rate of growth in specific foods."[55] The more time that *L. mono*-contaminated cantaloupes spend in the refrigerator, the more likely it is that the number of *L. mono* cells in the melon will grow to pathogenic levels. Higher refrigerator temperatures and the high moisture and sugar content of cantaloupe make conditions for *L. mono* growth even more conducive.

(33) The consumer who eats smaller helpings of fruit at each sitting is in greater danger than one who eats a whole cantaloupe or half a cantaloupe at a time because of the increased storage time. Elderly consumers are more likely to eat smaller helpings, and elderly consumers are more likely to have compromised immune systems that are more susceptible to fewer numbers of *L. mono* cells. Therefore, the older the cantaloupe consumer and the more helpings of contaminated fruit he or she consumes over time, the greater the likelihood that he or she will become ill from eating inoculated melons. To understand the exponential growth *L. mono* in contaminated food over time, consider Benjamin Cummings graphs below.[10] **See Figure 1 – Exponential Growth of *Listeria* Graphs.**

Figure 1.



(34) The graph on the left demonstrates that a single cell of *L. mono* multiplies to over 4000 cells within four hours time, while the graph on the right reveals that *L. mono* grows by 9 logs in 10 hours. Neither graph specifies the medium in which growth takes place or the temperature. While Cummings' graphs only demonstrate the growth of *L. mono* over several hours, FDA data on Risk Assessment reveals that within a single day fruit stored at 5° C (or 41° F) grows 0.046 log10 CFUs (Colony Forming Units) per gram per day.[55]
(35) What this means to the non-scientist is that one gram of cut fruit contaminated with eight *L. mono* cells, then stored in a refrigerator, will grow to over a million cells in one day; in one week, the number would increase to over 395 million. Over the course of several days, the growth is exponentially greater until eventually it plateaus and, finally, as it begins to compete with other micro-organisms, eventually dies off entirely. A more important point is that in an effort to protect victims from the horrors of *Listeriosis*, not just days, but hours are critically important; they may be the difference between life and death.

III. A *LISTERIA* OUTBREAK EMERGES

Introduction

(38) The first clinically confirmed case of *Listeriosis* was reported on Friday, August 12, 2011.[44] In the last few days of August, numerous cases were reported in Colorado alone. A few days later on Friday, September 2, after a total of seven cases had come to light in

their state, Colorado health officials notified the Centers for Disease Control (CDC) of their suspicions of an *L. mono* outbreak.

(39) On Monday, September 5, "cantaloupes [were] collected for *Listeria* testing by the Colorado Department of Public Health and Environment (CDPHE) from the home of an ill person", and on Thursday, September 8, "cantaloupes [were] collected by CDPHE for *Listeria* testing from retail locations where ill persons reported buying cantaloupe." Once the CDC's PulseNet system and the CDC survey of infected victims had identified Rocky Ford cantaloupe as the likely source of the *L. mono* outbreak on Thursday, September 8, the CDPHE notified the FDA of a *Listeria* outbreak that had originated within their own state. On September 11, "cantaloupe samples collected by CDPHE on 9/5/11 from the home of an ill person and on 9/8/11 from 2 retail locations yield[ed] Listeria."[45] **See Appendix 1.**

(40) "Within ten days after the outbreak was first reported to CDC [September 12]... and with only 13 cases reported, CDC issued a national consumer warning" against buying or consuming cantaloupe.[53]

The FDA Reacts

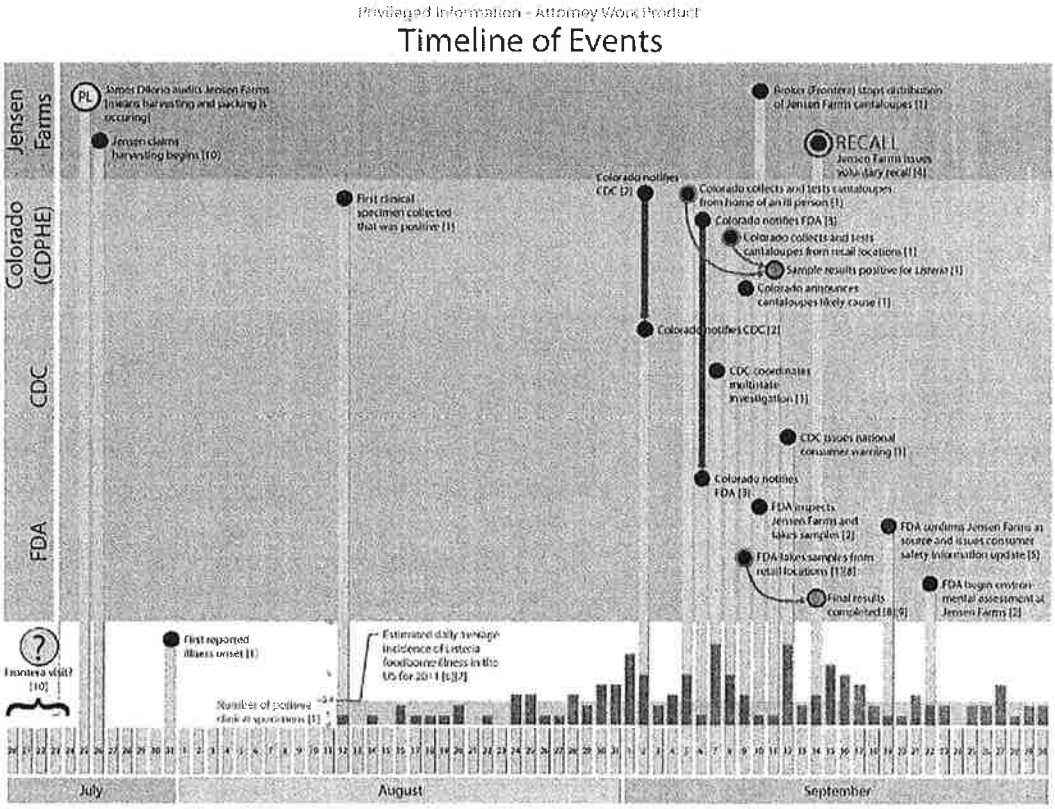
(41) On Friday, September 9, 2011, an FDA Consumer Safety Officer was dispatched to a Colorado grocery store to pull samples of Jensen Farms cantaloupes. On Saturday, September 10, 2011, federal and state officials descended on the Jensens' farms and their packinghouse in Holly and Granada, Colorado, respectively. Four inspectors from the FDA and the CDPHE, arrived unannounced at the Jensen Farms facilities.[59] The purpose of their visit was to confirm that Jensen Farms was the source of the *L. mono* contamination.

(42) These officials scrutinized Jensen Farms and its products. "On September 10... [inspectors] collected multiple samples for microbiological testing, including whole cantaloupes and 39 environmental swabs. Lab analysis confirmed 13 of the swabs were positive for *Listeria monocytogenes* with genetic coding that was indistinguishable from three of the four outbreak strains collected from affected patients. Of the 13 positive environmental swabs, 12 were collected at the processing line and 1 was collected from the packing area. Cantaloupe collected from the firm's cold storage during the inspection was also confirmed positive for *Listeria monocytogenes* matching two of the four outbreak strains."[48]

(43) The day of the FDA inspection was the last day that "Jensen Farms... shipped cantaloupes."[63] On Wednesday, September 14, Jensen Farms ordered a 17 state recall of their product.[44] The same day, after Jensen Farms had ordered their recall, the FDA published a warning (Consumer Safety Information Update) to consumers not to eat Jensen Farms cantaloupe. "Unfortunately, much of the damage was already done."[57] Recalls by retailers which had sold the Jensen Farms cantaloupes included Kroger - September 15,[21] Safeway – September 15,[40] Aldi – September 16,[1] US Foods - September 16,[60] and Walmart (Date has not been confirmed).

(44) On Thursday, September 22 and Friday, September 23, the inspectors returned again to Jensen Farms, this time announced and in an even larger force of 13 from the FDA, the CDPHE, the Colorado Department of Agriculture, and the Prowers County Health Department. Their purpose on the second visit was to determine the root cause of the *L. mono* outbreak. **See Figure 2 - Timeline of Events (for Citations for Timeline, See Figure 2b in Appendices).**

Figure 2.



(45) The Jensen Farms recall (presumably ordered by the FDA) and the FDA Consumer Safety Information Update occurred 12 days after the CDPHE notified the CDC of the *Listeria* outbreak, nine days after the CDPHE collected the first samples of Jensen Farms cantaloupes, six days after the CDPHE notified the FDA of the *Listeria* outbreak, four days after the FDA had concluded their initial inspection of Jensen Farms, three days after the first positive tests for *L. mono* were confirmed, and two days after the CDC issued a nationwide warning.[52] The next day, "on September 15, a lawsuit was filed against Jensen Farms by the first victim of the contaminated cantaloupe."[64] On September 24, 2013, more than two years after the recall, the United States District Attorney for the District of Colorado brought criminal charges against Eric and Ryan Jensen for introducing contaminated food into interstate commerce.[35]

(46) Events developed rapidly, and information was generated in lightening-fast time. Throughout these events, the CDC and the CDPHE seem to have reacted as quickly and as efficiently as they could to prevent greater suffering and more fatalities.

FDA Comments

(47) It did not take long before the reactions to the outbreak began to fly from all corners. In particular, the FDA's comments concerning the Jensen brothers' culpability were swift, predicable, and brutal. Far from being painted as "salt-of-the-earth" farmers, the Jensen brothers were vilified, and their operation was excoriated by the FDA as "demonstrating widespread contamination… and poor sanitary practices."[7] In testimony to the Congressional Committee for Energy and Commerce, "FDA officials stated that the outbreak could have likely been prevented if Jensen Farms had maintained its facilities in accordance with existing FDA guidance."[59]

(48) On October 19, 2011, the FDA held an open hearing on the Jensen Farms outbreak – *Results of the FDA-Led Root Cause Investigation of the Multi-State Listeria Outbreak Related to Jensen Farms Cantaloupe*.[53] This hearing introduced the FDA's thinking on Jensen Farms to the public and the press. The investigation into the source of the *L. mono* contamination contained some factual findings, but also much speculation. Then, in the Jensen brothers' criminal court case, FDA officials repeated these facts along with their conjecture as legal evidence against the brothers. One of the leading voices in these FDA statements to the District Court was Dr. James Gorny, "the FDA chief investigator who led a team to Jensen Farms."[8]

Criminal Charges and Legal Significance

(49) The criminal charges against the Jensen brothers were especially unusual considering the paucity of criminal cases previously brought against American citizens for introducing contaminated food into the marketplace. What makes the Jensen brothers convictions all the more frightening is that this case likely will create a pattern for federal prosecutors to start regularly filing criminal charges against individual suppliers who unknowingly and unintentionally sicken consumers with food they have grown or manufactured. Theirs is one of the only cases in which supply chain actors were convicted for having produced contaminated food, and one of the only cases in which an American citizen was convicted of a criminal act for unintentionally introducing contaminated food into the marketplace.

(50) Previously, the most famous example of a criminal charge being brought against a supply chain actor was the 1975 case United States v. Park that was decided by the Supreme Court (attorneys need to confirm this). John Park was the President and CEO of Acme Markets, Inc., a nationwide food chain. Park was found criminally responsible for introducing contaminated food into the marketplace. The food had been tainted in a warehouse through exposure to rodent contamination. Park claimed that he had left supervision of Acme's warehouses to subordinates who had failed to do their due diligence, and that he was, therefore, innocent of any criminal charges because he was not aware of the contamination.

(51) However, U.S. prosecutors were able to prove that prior to criminal charges being brought against Park, Acme Markets, Inc. had received several warning letters from the FDA about unsanitary conditions at several of its warehouses. Since Acme, including

Park, its President and CEO, had been warned previously, the Court held that despite Park's lack of "awareness of some wrongdoing", it was "dispensing with the element of 'wrongful action'" because of the previous warning the defendant had received. Prior to the Jensen Farms case, United States v. Park was one of the only examples of someone that had been held criminally liable for introducing contaminated food without "awareness" of "wrongful action."[20]

(52) United States v. Park is considered a landmark Supreme Court decision, as it established "the Park Doctrine." "The Park Doctrine stands for the proposition that a corporate officer who is in a position of authority to prevent or correct a violation of the Food, Drug and Cosmetic Act (FDCA), but who fails to do so, may be convicted of a [criminal offense] by virtue of such authority even if the officer was unaware of the violation."[42] Interestingly, it appears that the Park Doctrine was not used again to prosecute anyone in the food supply chain until the Jensen brothers were charged in 2013.

(53) Clearly, the Jensen brothers' situation was far different from the Park case, because the Jensen brothers had never been warned or even visited by the FDA prior to the *L. mono* outbreak and because the contamination of their product was invisible and undetectable without microbiological testing, unlike the contamination in the Acme warehouse. Still, the Department of Justice's decision to criminally prosecute the Jensen brothers was more than likely influenced by the statements made by FDA officials, industry leaders, and academic specialists. Since the Park doctrine requires no intent, nor knowledge, the party introducing an adulterated product into the food supply is automatically guilty. The conviction of the brothers stands as perhaps the most striking event in the history of American agriculture, because it opens the door for anybody to be charged criminally if food that they produce makes people sick. Unfortunately, if it does not undergo a kill step, as is the case with many, if not most, fresh produce items, eating fresh food *will* inevitably make some people sick. At the very best, producers of raw agricultural commodities can reduce the odds, but nothing can absolutely ensure safe produce.

The FDA Speaks Out

(54) The bottom line is that no one knows when or how the *L. mono* contamination was introduced to Jensen Farms or how it was spread to cantaloupes, but beginning on October 18, 2011, Dr. James Gorny became the FDA's chief spokesman on the Jensen Farms investigation and over the next few months, he and his colleagues offered numerous theories, as well as criticism of the Jensen brothers farming practices – farming practices that by most agricultural standards were pretty representative of the melon industry, at least the melon industry outside of California and Arizona. The FDA "team found, among other things, that the packing house floor allowed water to pool, the design of equipment made it difficult to clean and sanitize, and the temperature of the cantaloupe when they were refrigerated allowed moisture to form on them and may have allowed bacteria to grow. To inform the food industry and help them avoid similar problems, FDA made these findings public."[16]

(55) Instead of depicting Jensen Farms as typical, Dr. Gorny (as cited in the U.S. District Court of Colorado's Sentencing Statement) claimed precisely the opposite. "Jensen Farms significantly deviated from industry standards by failing to use an anti-microbial, such as chlorine, in the packing of their cantaloupes during the summer of 2011."[57] This claim is disputed in a letter from the Produce Marketing Association (PMA) which was sent to the FDA when it solicited comments concerning implementation of the Food Safety Modernization Act (FSMA). It stated, "Observations [in FDA investigations] are included and cited as potential contributing factors to potential contamination even though those same observations could be made at hundreds or perhaps thousands of production operations around the world. For example, water on floors of packing houses, cracks in concrete floors, animals in proximity to fields and other observations of a similar nature are reported, yet these conditions are common to many fruit or vegetable production operations."[36] Considering that the FDA's own guidance did not require an anti-microbial wash, the statement that Jensen Farms "deviated from industry standards" is baffling. Rather than attempting "to inform the food industry and help them (sic) avoid similar problems," FDA officials seemed more intent on decrying the Jensen brothers and their farming practices.

(56) At times, some of Dr. Gorny's statements as to the causation of the *Listeria* outbreak seem to contradict others that he made, and most of the statements are conjectural in nature. "Where did it really come from? We'll probably never know", Gorny said. "But [investigators suggested] that it might have been in the soil or on the cantaloupe at levels that were undetectable."[57] Then later, "...the *Listeria* was spread inside the facility, probably when water got splattered by employees as they walked in the area or attempted to clean it with hoses," Dr. Gorny said.[57]

(57) "Gorny added that the conveyer used in the process spread contamination and essentially 'inoculated' the cantaloupes with *Listeria monocytogenes.*"[57] The FDA seems surprised that when they arrived to inspect Jensen Farms at the height of the cantaloupe harvest, they found the conveyer was dirty. Sherri McGarry, Senior Advisor at the FDA Core Network, went on to say that, "The packing equipment was not easily cleanable and sanitized." McGarry never defines what she means by "not easily cleanable and sanitized."

(58) Dr. Gorny and his FDA colleagues were also critical of the Jensen brothers' use of the modified piece of equipment, purchased from Pepper Equipment immediately prior to the 2011 harvesting season and previously used to sort, wash, and dry potatoes. Gorny suggested that this was another deviation from industry standards. "What turned the operation upside-down was (sic) some significant changes they made," said Gorny, referring to the sorting, washing and drying equipment. "It was a very tragic alignment of poor facility design, poor design of equipment and very unique post-harvest handling practices of those melons. If any one of those things would have been prevented, this tragedy probably wouldn't have occurred."[8]

(59) Another piece of information that the FDA seemed to zero in on was a truck that was discovered at the packinghouse when the FDA arrived for their inspection on September

10, 2011. According to the Jensen brothers, the truck had been used to carry "cull piles" of cantaloupe to a nearby cattle ranch.

(60) A "cull pile" refers to rejected product that the grower does not want to take to market for a host of reasons. Culled cantaloupes may be discolored, misshapen, bruised, etc. Culled produce is usually thrown into a trailer or bin and later hauled away. In an effort to promote sustainability, the Jensen brothers, like most farmers, fed their culled fruit to livestock. "The FDA does not know exactly how the *Listeria* made its way into the packing plant", said Gorny, "but investigators suggested that… a truck that carried culled cantaloupe to a cattle farm might have driven through animal feces and dragged back *Listeria* on its tires."[41]

(61) The bottom line is that while cull piles, modified equipment, standing water, and other issues that the FDA noted at Jensen Farms are commonplace in most farming operations, Gorny and the FDA found them suspicious and indicative of "unsanitary conditions." No mention was ever made of Jensen Farms' transitional grounds.

(62) Finally, Gorny was critical of the method that Jensen Farms used to cool their melons, arguing that the brothers had "no equipment to remove field heat from the cantaloupes before they were placed into cold storage" and that the failure to properly cool the fruit "may have contributed to the Outbreak."[59] Yet, the 2009 FDA guidance for cantaloupe production states that "Cooling and cold storing melons [should occur] as soon as possible after harvest because delays in cooling when melons with netted rinds (such as cantaloupe) are wet from washing operations may allow for multiplication of human pathogens on the rind surface." Nothing in this section of the guidance mentions pre-cooling. However, later, the guidance does mention cooling fruit with wash water, "Using single pass (or one use) cooling water of sufficient quality for this intend purpose also may be used to cool product."[50] It appears that Jensen Farms followed both of these FDA guidance instructions, because they initially cooled the melons with their single pass wash system that utilized potable water from the City of Granada, dried them, packed them, and then immediately placed them in cold storage. Again, Gorny himself helped to write this draft guidance.

(63) While the FDA investigation of Jensen Farms proposed many possibilities, there were a few possibilities it did not mention. Perhaps the *Listeria* was introduced through the Jensen brothers' organics methods. Perhaps the new skills and changes associated with transitional farming detracted from the historical practices with which the Jensen brothers had effectively controlled *L. mono*. If as Dr. Gorny states "any one of those things [facility design, wash equipment, and post-harvest handling practices] would have been prevented", at what level of production was Jensen Farms single pass wash and cold storage systems, among other factors, overwhelmed? Was it when production reached 50% capacity? 70%? 90%? What other factors (besides the facility design, and wash and cold storage systems) may have contributed to the spread of *Listeria*?

IV. THIRD PARTY AUDITING UNDER ATTACK

Introduction

(64) In addition to the vilification of Jensen Farms, the news that the brothers' operation had been audited by a third party auditing company nearly three weeks before the first illnesses from the outbreak were clinically confirmed and had received an audit score of 96, shifted the spotlight to the third party auditor and to a third party food safety auditing system that was "slammed as an inherent conflict of interest by safety experts."[28]

From Farm to Fork: The Produce Supply Chain and Legal Liability

(65) When food is produced, it passes through the hands of several entities before it ends up on the plate of the consumer. This supply chain moves food "from farm to fork." In the case of fresh produce, the grower may send the product to cold storage, then to a packer or a processor. The packer or processor usually moves the product to a produce distributor, who, in turn, distributes the product to retailers or food distributors. Retailers then sell directly to consumers, and food distributors then sell to end users, such as restaurants, hospitals, and schools etc.

(66) Each of the entities within this supply chain has strict liability for their products. That is, if the product makes the consumer ill, the grower, packer, processor, shipper, distributor, retailer, and the restaurant can be held financially responsible for the consumers' damages.

(67) In the case of Jensen Farms, their cantaloupe was grown and packed at their Granada, Colorado, operation, sold to Frontera Produce, who, in turn, distributed to a number of retailers, including, but not limited to Walmart and Kroger. They advertised their product as "Sweet Rocky Ford" cantaloupe, and that it was "pesticide free." Both assertions were false. **See Figure 3 – Jensen Farms Label.**

(68) Third party auditing and farm equipment firms, such as PrimusLabs, Bio Food Safety, and Pepper Equipment, are not held to the standard of strict liability of food producers, distributors, and retailers, such as Jensen Farms, Frontera Produce, Walmart, and Kroger, and some of the other defendants in the Jensen Farms cases. Unlike producers, distributors, and retailers, they exist outside the supply chain. Prior to the Jensen Farms tragedy, no U.S. courts have ruled that for-profit private audit companies or government agencies have "a duty of care" to consumers that eat food produced by their clients, as the suppliers' production and methods are outside of the control of the auditor.

Figure 3

The Development of Third Party Food Safety Auditing

(69) During the 20th Century global food production became increasingly more complex. More food was being produced by greater numbers of food producers, and technological advances allowed a greater amount of food to be traded internationally. Consequently, oversight of the safety of food expanded to include not only the governments of states and nations where the food originated, but also the nations that imported global food shipments. Soon, international trade organizations developed to set standards for food safety.

(70) In 1961 the United Nations' Food and Agriculture Organization (FAO), later joined by the World Health Organization (WHO), established the Codex Alimentarius Commission to harmonize international food standards. While the Codex did not have the force of law, participating nations recognized it as an international reference point for the resolution of disputes concerning food safety and consumer protection.

(71) As trade between international companies became a common way for food to move about the world, more and more frequently private companies became involved in verifying the food safety practices of suppliers and processors, since food safety was regarded as a trade issue just as much as it was a health concern. In addition, in many places the involvement of private companies was necessitated by the inability of governments to inspect all of the food produced within their borders, much less food being imported. Instead, government agencies established guidelines and regulations for food production, based on the standards used for growing and processing that were developed by the Codex Alimentarius and the International Organization for Standardization (ISO). In the U.S., FDA issued "Good Agricultural and Manufacturing Practice" guidelines in 1998, and has since developed commodity-specific guidance outlining specific control measures for commodities with the assistance of industry

groups. These guidelines, regulations, and standards are reflected in the private audits that certifying bodies develop and perform for the food industry.

(72) Three types of audits emerged as a means to inspect food safety practices. A first-party or self-audit is conducted by the grower, packer, or processor of his own operation. A second party audit is an inspection of a growing, packing, or processing operation by a buyer or buyer's representative, usually in advance of the purchase of food from that operation. Generally, a third party audit is considered the most objective and transparent type of audit because the "third party" has no financial connection to the operation being audited as does a "first party" or a "second party." A third party audit can be conducted by an auditor working for a private auditing company, by an auditor working for a not-for-profit auditing company, or by a government auditor.

Proprietary, Benchmarked, and Consultative Audits

(73) This private sector approach to food safety augments, but does not replace, the regulatory agencies' enforcement function. The government establishes the minimum standards and buyers and suppliers establish industry accepted practices that exceed those standards. These types of audits are sometimes termed "proprietary" audits, because they are usually owned and copyrighted by the certifying body that develops them (PrimusLabs, however, does not copyright its "proprietary" audits). In addition, sometimes specific buyers will establish their own standards with specific questions that can be added to a "proprietary" audit as an addendum. For domestically produced and traded food, PrimusLabs' "proprietary" audits are often utilized. The audit's function is to confirm that the operation is functioning under the industry's standard practices, but not its best practices.

(74) On the other hand, internationally traded food usually needs to meet "benchmarked" standards. The 2000 Global Food Safety Initiative (GFSI) established a benchmarking system for audit schemes that meets these agreed-on standards. Such an audit is referred to as a GFSI-Benchmarked audit. GFSI is overseen by an organization made up of the world largest retailers that approves the benchmarking of the audit and the audit owner. Therefore, while a "Benchmarked" audit is not necessarily more or less rigorous than a "proprietary" audit, the management of audit companies is more structured and controlled under GFSI. GFSI-Benchmarked audits also require that the certifying bodies have achieved ISO 65 certification. Like "proprietary" audits, GFSI-Benchmarked audits are assessed against the standard practices of the industry, rather than the industry's best practices.

(75) The determination of whether a food supplier, packer, or processor should conduct "proprietary" audits or GFSI-Benchmarked audits is usually left up to the supplier with direction from buyers: distributors, who sell to end users, such as restaurants, or retailers, who sell to consumers. Ultimately, buyers enforce the level of stringency that they seek to maintain for the products they intend to sell. If a supplier does not conduct food safety audits or product testing to the degree they expect, they have the freedom to refuse to buy those suppliers' products.

(76) Regardless of the type of audits they conduct, the role of auditors is limited to observing and reporting the procedures used by the operations that they audit. However, there are differences in the way in which the two types of audits address non-compliances and corrective actions. In PrimusLabs "proprietary" audits, non-compliances are reported to the auditee, and the auditee is responsible for deciding if and how to address corrective actions for the non-compliances. In addition, buyers who have access to the audit report may hold the auditee responsible for taking corrective actions. In a GFSI-Benchmarked audit, GFSI requires the auditee to address the non-compliances and the certifying body to consider those corrective actions and approve or reject them.

(77) Since these third party audits are often conducted by private certifying bodies and the reports are prepared for the auditee, the auditor and certifying body do not report non-ISO compliances to government agencies, be they local, state or federal entities. In fact, auditors do not report anything they observe to any third party unless instructed in writing to do so by the auditee. This is a requirement of ISO. The exceptions to this are the various third party audits offered by non-ISO accredited government or state agencies, which purport to notify the FDA when violations are observed.

(78) Finally, some audit companies will offer a variant of the third party audit, a consultative audit. These audits are usually performed by highly skilled and experienced food safety auditors, who use the audits to make recommendations to the auditee about food safety issues, including, but not limited to, equipment, agricultural or manufacturing practices, pathogen or pesticide residue analyses, etc. These audits may not follow written audit schemes. ISO 17065 requirements prohibit a firm from consulting and auditing.

Scheme Development

(79) PrimusLabs, like several other entities throughout the globe, has produced its own audit schemes. These include a set of "proprietary" audits, while Azzule Systems developed and owns a set of "PrimusGFS" audits. PrimusLabs does not conduct consultative audits.

(80) According to the PrimusLabs facility audit template, which provides Standard Operating Procedures (SOPs) for the development of packinghouse and greenhouse, processing, cooler and cold storage, and storage and distribution facilities "audits are designed to evaluate an auditee's food safety program, including: documented policies and procedures, compliance to these policies and procedures, previous and current monitoring records along with preventative and corrective actions as well as the operation's physical condition at the time of the inspection."[30]

(81) An audit scheme is not static. It is "a living document requiring periodic review and update. Changes to audit content originate from several sources: [including] Changes in regulations and government/industry developed guidelines related to growing, processing and handling of fresh produce commodities; Specific changes specified by buyers and retailers of fresh produce; Feedback from supply chain stakeholders including informal

and formal audit appeals, auditee surveys, buyer expectations, auditor input, industry issues/outbreaks/recalls and journal articles."[30]
(82) Consequently, governmental regulations and industry standards dictate what audit schemes and the auditors who apply those schemes require of auditees during farm and facility inspections. If governmental agencies or produce buyers want more stringent standards applied in audits, they have the absolute power to affect audit questions, scoring, etc. and in turn, the agricultural or manufacturing practices of food suppliers, packers, processors, and distributors. This is critical in light of the debate over the rigorousness of third party food safety audits.

The Scope of Audits

(83) In addition to audit schemes, audits also vary in scope. Since the supply chain consists of various types of operations that handle fresh produce (each potentially owned by different entities), different types of audits were developed to assess the food safety procedures taken at each point along the supply chain. In general, audits that look at farm issues address Good Agricultural Practices (GAPs), while audits that look at facilities issues address Good Manufacturing Practices (GMPs). For instance, GAP audits include ranch/farm, as well as harvest crew, and greenhouse. Additionally, GMPs audits include greenhouse, packinghouse, cold storage, processing, and storage and distribution audits.

(84) Since audits are concerned with risks created in growing, harvesting, packing, processing, and shipping food, some of the facility audits, such as packinghouse or processing audits, can include assessment of the facility's Hazard Analysis and Critical Control Points (HACCP) plans.

V. AUDITING JENSEN FARMS

Introduction

(85) Frontera Produce is a produce grower and distributor from Edinburg, Texas. As recently as 2010 (and possibly earlier), Frontera began purchasing cantaloupes from Jensen Farms and began shipping them to various retailers across the U.S. As a buyer, Frontera Produce had an important role to play in establishing their expectations for Jensen Farms. They, or the retailers they sold to, could have demanded GFSI-Benchmarked audits. They could have expected audits to be conducted more frequently. They could have specified the timing of the audits. Likewise, they could have expected Jensen Farms to conduct microbiological testing of their facilities and/or products. They could also have required pesticide residue analyses. Most importantly, they could have required that Jensen Farms perform corrective actions on any issues identified within audits before purchasing their products.

(86) What Frontera Produce, and the retailers they sold to, did accept was that Jensen Farms submit to PrimusLabs "proprietary" audits, first in 2010 and then again in 2011. Jensen Farms hired PrimusLabs to conduct those audits, and PrimusLabs, in turn, subcontracted with individual auditors to perform the audits, both of whom worked for the Texas firm, Bio Food Safety. It appears that Frontera did not require any

microbiological testing or pesticide residue analyses, nor did Jensen Farms have any performed.

(87) Additionally and as previously mentioned, Frontera distributed what it bought from Jensen Farms to various retailers, including, but not limited to, large companies, such as Walmart and Kroger. Many large grocery retailers, large fast food chains, and food service firms have their own expectations of suppliers, requiring certain audit schemes or scopes, the frequency of audits, and microbiological or pesticide residue analyses.

(88) Walmart is a retailer that maintains its own buyer requirements. On November 29, 2010, in a letter to its suppliers, Walmart stated, "In December 2007, Walmart and Sam's Club became the first U.S. retailer to require our Private Brand suppliers to achieve prevention-based certification against one of the Global Food Safety Initiative (GFSI) internationally recognized food safety standards." **See Appendix 2.** However, the retailer also extended the deadline for compliance "to November 1, 2011", nearly four years after its original insistence on GFSI-Benchmarked audits and a month and half after the Jensen Farms outbreak. **See Appendix 3.**

(89) However, Walmart also revealed an exception to its own policy for "small suppliers in the local purchase program" **(See Appendix 3).** These small suppliers (no definition was offered for "small suppliers in the local purchase program") were allowed to conduct "proprietary" audits, including a "PrimusLabs.com Standard Packhouse Audit w/ HACCP" Version 8.04 in place of a GFSI-Benchmarked audit.

Subcontracted Auditor Qualifications

(90) PrimusLabs requires its subcontracted auditors to meet a series of strict requirements before they begin conducting audits for the company. These include the following: 1) Acceptance of an agreement to abide by all PrimusLabs rules and policies regarding auditing (more on that later); 2) Education - a college degree in a food-related discipline: agriculture, food science, or microbiology [PrimusLabs reserves the right to accept a degree in another field, based upon the agricultural background and experience of the prospective auditor]; 3) Experience - a minimum of two years of experience working in a food/agriculture industry in some type of food safety capacity; 4) Training in food safety auditing to cover any gaps in education or experience – training could include courses or seminars in good agricultural or manufacturing practices (G.A.P.s or GMPs); trainings required include Food Safety/Hygiene, HACCP, and auditor trainings of a variety of audit schemes; 5) Familiarity with Local, State, Federal Regulations regarding food safety; 6) Language Fluency (depending on clients being audited); 7) Computer Literacy – the ability to submit audits using the PrimusLabs Online Audit System (OAS); 8) Auditing Skills – Observation, Questioning and verbal communications, Listening, Tenacity, Interpretation, Reporting and written communications, Detail-orientated, Organizational and time-keeping, Interpersonal skills and ability to handle confrontation, Ability to work under pressure and meet tight deadlines; and 9) Ethical Standards.[31]

(91) One of the most important PrimusLabs policies regarding it subcontracted auditors is that those auditors do not conduct consulting work as a part of their duties in auditing a

farm or facility, as dictated by ISO requirements. Consultation creates a conflict of interest in which the consultant's recommendations are in conflict with their objectivity to "observe and report." Though many auditors do consulting work, it is against PrimusLabs policy for an auditor to accept an audit for a client for whom he has performed consultation within the previous three years.

Auditors at Jensen Farms

(92) Jerry Walzel, the owner of Bio Food Safety of Rio Hondo, Texas, conducted the first ranch and packinghouse audits of Jensen Farms in 2010. Walzel had worked as an auditor for many years, and through Bio Food Safety, he also supplied consulting services. According to the Jensen brothers in testimony given to the House Committee on Energy and Commerce, "after the August 2010 audit was completed, one of the Jensen brothers informed Mr. Walzel that they were interested in improving their processes."[59] Walzel allegedly suggested that Jensen Farms consider converting their wash system from a dump tank that utilized chlorinated water to a single pass system, because "the hydrocooler [dump tank]... was a potential food safety 'hotspot.'"[59] If Walzel did, in fact, recommend a new wash system, he did so as a consultant, which would disqualify him from conducting future audits of Jensen Farms for at least three years. Though PrimusLabs was unaware that Walzel had engaged in consultation of any form, if, in fact he did so, he appears to have followed PrimusLabs' policy for not engaging in consultation and auditing simultaneously. It also appears that in offering the advice that he is alleged to have offered, Walzel was simply trying to be helpful and did not accept any compensation for his advice.

(93) The following year, in July 2011, Jensen Farms, at the insistence of Frontera Produce, again requested audits of their fields and packing facility. "Jensen Farms noted that it received a visit from a representative of Frontera Produce, its distributor, shortly before the 2011 audit. According to the Jensen brothers, this representative provided them with advice about preparing for the audit, but did not note any problems."[59]

(94) This time PrimusLabs sub-contracted James DiIorio to conduct the audit. James DiIorio had been around agriculture his entire life. He started an internship at Bio Food Safety in 2009, joining Jerry Walzel and his son Allen Walzel in the small firm. He had grown up on a Texas farm and had developed his family operation's first food safety plan. He also attended Texas A&M University in College Station, Texas, and graduated in 2009. DiIorio had interned at Bio Food Safety for a year and a half, before being hired on by Jerry Walzel. By all indications, DiIorio was a serious and diligent auditor.

Audit Scoring

(95) It is important to understand the scoring system that James DiIorio used for the "Ranch" and "Packinghouse" audits he conducted of Jensen Farms. Each question on the audit is worth a certain number of points. Answers to some of the questions can result in major or minor deficiencies that cause "downscores" for a farm or facility that does not comply to a greater or lesser degree with the question; other questions can result in (NC) non-compliances ("zero" points) or N/A (Not Applicable). The auditor is directed to note

each NC and N/A with narrative explanations. The NCs result in down scores and the N/As are unscored and removed from the denominator and numerator in the audit scoring process. Finally some NC questions can result in automatic failures if they reveal that the operation is not consistent with governmental regulations.

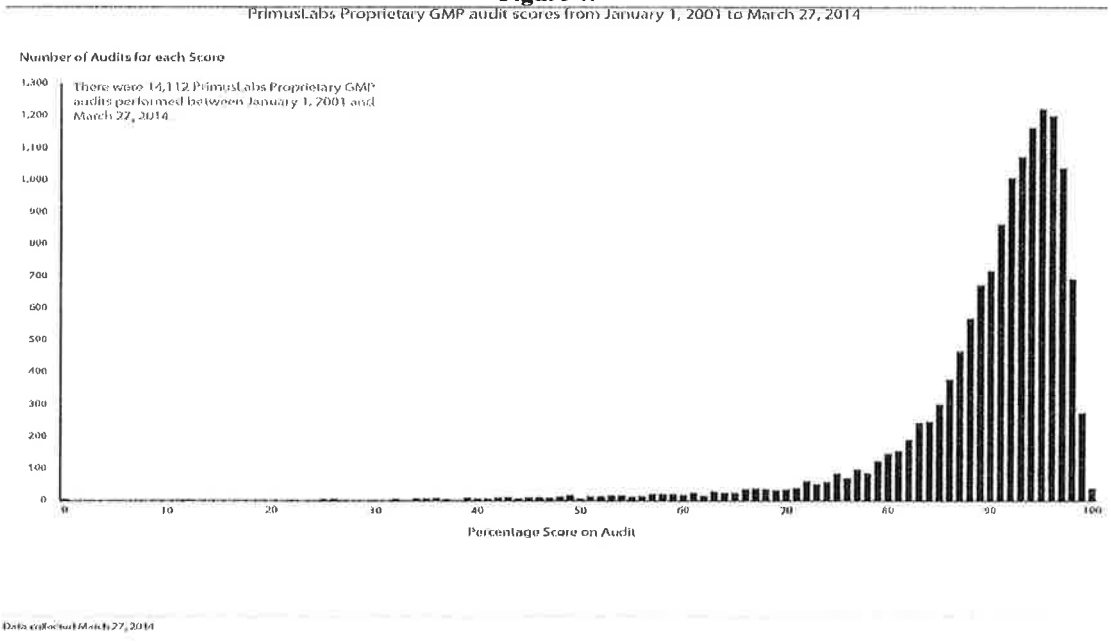
(96) The score of an audit is determined by a percentage of the total number of points earned divided by the total number of points possible on all relevant audit questions. Though PrimusLabs originally wrote its "proprietary" audits without point values, instead focusing only on non-compliances and the narrative explanations included in the audit reports, the fresh produce industry's buyers and suppliers requested that it convert its audits to a point system.

Standard Practices, Not Best Practices

(97) However, with a scoring system, any audit score needs to be understood to be a measure of the farm or facility's compliance with the standard practices of the industry, a less rigorous bar than the industry's best practices. Consequently, a score of 100 percent is nothing more than an acknowledgment that the farm or facility meets the standards of the industry. Anything less than 100 percent indicates that the farm or facility is functioning below the standards. In addition to questions that can result in automatic failures, any total score less than 80 percent is usually considered a failure by buyers, and the supplier's buyers are automatically notified of that failure if the supplier has authorized in writing for PrimusLabs to release the results of the audit.

(98) Some buyers choose to set different "minimal" scores for these audits. For instance, one major retailer will not accept product from suppliers who score below an "85" on a PrimusLabs "proprietary" audit. Other buyers have higher minimal requirements.

Figure 4.



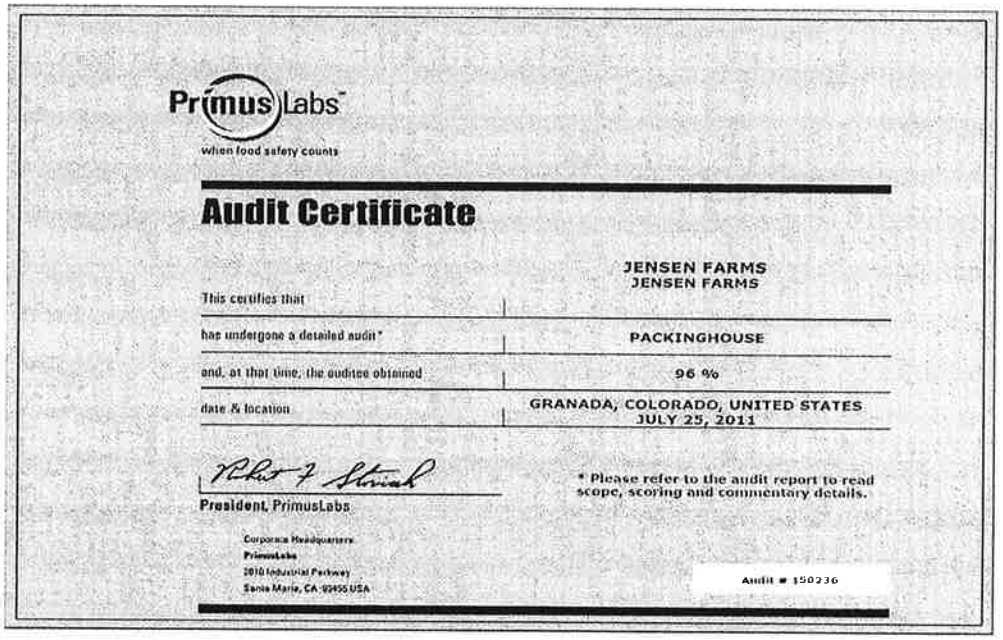
(99) Because a "proprietary" audit measures the degree to which an operation meets the standard practices of the industry, almost all audit subjects score below 100, with the vast majority scoring within a few percentage points near 100 percent". Any score below 100 percent is "less than standard." Therefore, a graphical representation of a "proprietary" audit using real world values reveals a curve in which the highest frequency of scores is close to 100 percent. **See Figure 4 – PrimusLabs Proprietary GMP Audit Scores.**

(100) It is also important to recognize that the purpose of both "proprietary" and GFSI-Benchmarked audits is to further the relationships between business entities, thereby facilitating trade between those businesses. Hence, audits serve a business to business function. Buyers must weigh several considerations in determining whether or not to buy produce: quality (both taste and appearance), quantity, availability, and price. The decision also hinges, in part, on the suppliers' food safety practices. While no verification can ensure that food is safe, the content of an audit report including its ("scope, scoring and commentary details") helps buyers to make more informed decisions about purchasing.

(101) The audit certificate, produced by PrimusLabs and distributed to auditees upon completion of the audit, makes this point absolutely clear. Beyond general information, including the name of the auditee, the date and location of the audit, the type of audit, as well as the assigned audit number and audit score, the most significant language and only complete sentence that appears on the PrimusLabs audit certificate is the following statement: "Please refer to the audit report to read scope, scoring and commentary details." **See Figure 5 - Actual Certificate for PrimusLabs Proprietary Audit #150236 of Jensen Farms' Packinghouse.** As with all audits, PrimusLabs cannot and does not promise that its audit is a verification of safe food. Instead, reading the audit report and, in particular, the comments provided by the auditor can help buyers to better understand how a supplier's operation implements food safety practices.

(102) Third party food safety audits are performed by auditors and audit companies for suppliers and packers, etc. to meet the demands of buyers. The success or failure of the auditing firms is measured by the level of buyer acceptance. By far the most successful auditing format has been the standard practice audit. These audits are not designed to influence consumer decisions. Historically, most buyers would prefer that safety is an assumption and not part of the consumer buying decision. In this sense, audits designed to observe and report on safe production and handling practices do not function in the same way that a Good Housekeeping Seal of Approval or a J.D. Powers Rating functions. Both are designed to influence consumers, while food safety audits serve the industry: producers, distributors, and buyers. In addition, Good Housekeeping and J.D. Powers ratings measure the best practices of the industry, not its standard practices. The development of a best practice audit requires a considerably more subjective assessment of numerous uniquely exceptional practices. Best practice audits are not only far more dynamic, but are subject to frequent reversals as the effectiveness of novel practices is confirmed or discredited. The variances among various best practice audits will be wider than among standard practices audits. The variance is the result of competing industry leaders proposing innovative systems, as well as the various experts' attempts to standout with respect to their competitors.

Figure 5.



Primus Labs
when food safety counts

Audit Certificate

This certifies that	JENSEN FARMS JENSEN FARMS
has undergone a detailed audit*	PACKINGHOUSE
and, at that time, the auditee obtained	96 %
date & location	GRANADA, COLORADO, UNITED STATES JULY 25, 2011

President, PrimusLabs

* Please refer to the audit report to read scope, scoring and commentary details.

Corporate Headquarters
PrimusLabs
2010 Industrial Parkway
Santa Maria, CA 93455 USA

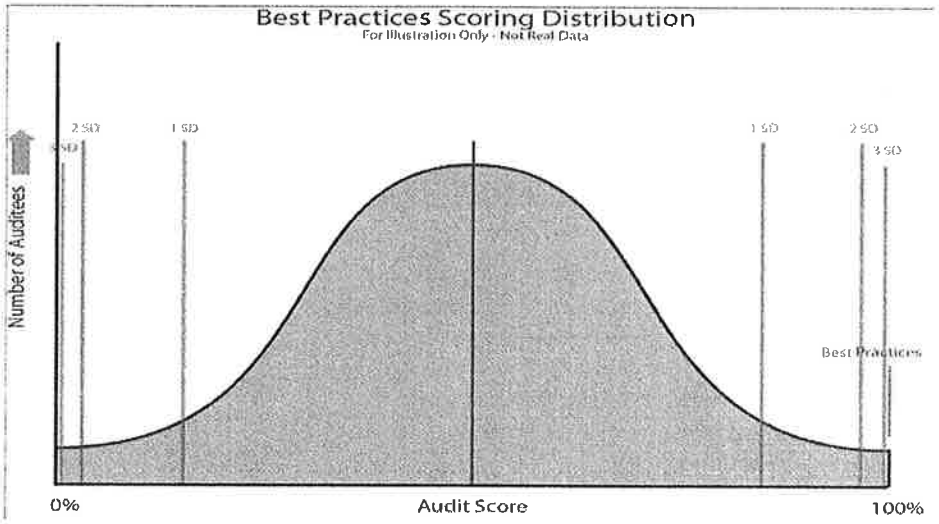
Audit # 150236

(103) Were food safety certifying bodies to create ideal "Best Practices" audits, a graphical representation of scores on such audits would reveal a "bell curve" distribution, with the majority of scores falling in the "middle of the curve" and smaller numbers of scores well above and well below the mean. In the traditional "bell curve", 68.2 percent of all subjects fall within one standard deviation of the mean, with 34.1 percent above the mean, and 34.1 percent below the mean. 95.4 percent of all subjects fall within two standard deviations of the mean, with 47.7 percent of subjects above the mean, and 47.7 percent below the mean. Finally, 99.6 percent of all subjects fall within 3 standard deviations of the mean, with 49.8 percent of subjects above the mean, and 49.8 percent of subjects below the mean. Only .4 percent of all subjects will score more than three standard deviations above or below the mean. **See Figure 6 - Best Practices Scoring Distribution.**

(104) It should be noted that the produce industry's (buyers and suppliers) decision to support "standard practice" audits over "best practices" audits is made clear by the level of support or recognition granted one version over the other. The reason for that is that if buyers required "Best Practices" audits, the number of auditees that would receive the highest audit scores would be greatly reduced, and buyers would then be logically expected to buy only from suppliers who had received the highest scores. "Best Practices" audits would create a system of winners and losers for buyers with no buyer wanting to be labeled a loser (someone who purchased from a supplier with lower scores). Consequently, since the third party audit system is dependent upon the needs of the

industry to establish its standards, the companies requiring food safety audits, i.e. buyers, are logically going to avoid the establishment of "Best Practice" audits.

Figure 6.

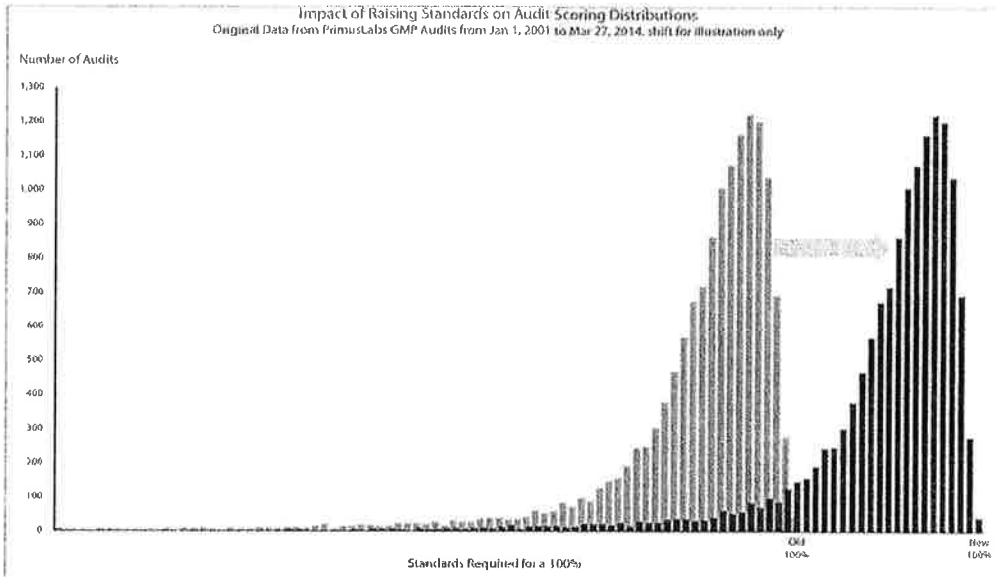


(105) Rather than implement "Best Practice" audits, some major producers opt instead for consultative audits that are usually performed by highly trained food safety experts. Consultants may make recommendations for better equipment, more microbiological or pesticide residue testing, or more rigorous agricultural or manufacturing standards. Unlike other types of audits, consultative audits are not subject to ISO 65 review by accrediting agencies. In addition, participation in the GFSI benchmarking system, the most widely supported auditing recognition organization prohibits consultative auditing.

(106) This tendency to avoid best practices may seem to be a dismal commentary on the direction of food safety in our nation and world, but that need not be the case. Recall the earlier discussions of how food safety has evolved in recent history and how audits are developed. Governmental agencies (in the United States that refers to the United States Department of Agriculture [USDA] for meat, poultry, and dairy products, and the United States Food and Drug Administration [FDA], an agency of the Department of Health and Human Services, for most all other foods) have regulatory powers over food production. If those regulatory agencies raise the standards for the legal production of food, the standards of the industry will be raised to accommodate regulatory compliance. Offered below is a graphical model representing the comparison of current "proprietary" audit scores to future "proprietary audit scores in a future where food safety standards are raised. **See Figure 7 – Impact of Raising Standards.** It is not the role of an auditing company to effect changes in industry standards. At best, auditing firms facilitate change by assisting in the communication among suppliers and buyers. The role of change agents falls on the regulatory agencies such as the FDA, buyers, and possibly trade associations.

(107) Finally, any audit is a "snapshot" of an operation's food safety at a given time; it does not suggest anything about how the auditee will perform during the next audit (although statistically and/or historically the more often an auditee is audited, the lower the number of non-compliances). An audit is an evaluation of how that operation's food safety practices were judged in a moment frozen in time, based on the auditee's preparation and a host of other variables. This is precisely why buyers expect that operations that they choose to do business with will submit to repeated audits at intervals often of the buyer's own choosing.

Figure 7.



The July 25, 2011 Audit

(108) Understanding the concept that an audit is a snapshot in time may help to explain what James Dilorio likely saw when he arrived at Jensen Farms on July 25, 2011. What he observed would logically have contrasted sharply with what the FDA and other investigators saw when they arrived on September 10. According to Ryan Jensen, as presented in the FDA Environmental Assessment of Jensen Farms, the 2011 cantaloupe harvest began on July 26, 2011, the day after James Dilorio's audit.[23] This statement was contradicted by a cheery post that was added to the Jensen Farm Facebook page on July 25, 2011. It reads, "Happy Monday Everyone! Cantaloupe Harvest starts today!" **See Figure 8 – Jensen Farms Facebook post.**

Figure 8.

	James Dilorio's PrimusLabs Standard Audits	FDA *et al.*'s Regulatory Inspection	FDA *et al.*'s Regulatory Inspection

(109) The date of the beginning of the 2011 harvest at Jensen Farms is also confirmed by James Dilorio's observations of cantaloupe being harvested on the morning of July 25, 2011, in his Ranch audits of Jensen Farms. Later that afternoon, his Packinghouse audit reports that he observed the cleaning and packing of cantaloupe as required in a PrimusLabs Proprietary Packinghouse audit.

(110) This confirmation is significant because it demonstrates that cantaloupe production was in its earliest stage when Dilorio arrived for the audit on July 25, probably under 10% capacity. Furthermore, as Jensen Farms had made the request for the audit several weeks prior, they were ready for Mr. Dilorio's arrival and had already been inspected by Frontera Produce only a few days earlier in preparation for it. Consequently, what James Dilorio saw on July 25, 2011 is almost certainly dramatically different than what the FDA saw on September 10, 2011, when its personnel arrived unannounced at Jensen Farms, at the height of harvest time, after having already been informed by the CDC that Jensen Farms was the source of an *L. mono* outbreak. Logic suggests that when James Dilorio audited Jensen Farms packinghouse, it was in the best condition it could have been during the 2011 harvest season.

(111) Comments by the FDA, as well as the members of the Congressional Committee on Energy and Commerce that investigated the Jensen Farms outbreak revealed how troubled many government officials were by the differences between the July 25, 2011, packinghouse audit "by only one individual, a subcontractor for Primus Lab (sic)... conducted over four hours" and the investigations conducted after the outbreak had been discovered on September 10, 22 and 23, 2011, "by multiple officials from FDA, as well as from the Colorado Department of Public Health and Environment, the Colorado Department of Agriculture, and Prowers County Department of Health... which occurred over three separate days."[57] Members of the Congressional Committee used the stark contrast between the two inspections to question the third party food safety auditing system.

Date	July, 25, 2011	September 10, 2011	September 22-23, 2011
Resources	PrimusLabs/Bio Food Safety	FDA[1]/CDPHE[2]	FDA/CDPHE CDA[3]/Prowers Co. DOH[4]
Human Resources	One Auditor	Four Inspectors	Thirteen Inspectors
Announced or Unannounced Visit	Announced	Unannounced	Announced
Man Hours	≈ 10-12 Hours	≈ 32 Hours	≈ 208 Hours
Objective	Observe and Report	Source Confirmation	Determination of Cause
Status of Completion	Same Day Exit Interview/Audit Reports Filed 8/2-3/2011	Resulted in Class I Recall on 9/14/2011	Failed to Determine Cause
Micro Samples Taken?	No	Yes	Yes
Date of Receipt of Micro Tests Confirming Jensen Farms as *L. mono* source	N/A	September 14, 2011	September 27, 2011
Production Capacity at Jensen Farms During Visit	≈ 10% Capacity	≈ 90-100% Capacity	N/A
Knowledge of Listeria Outbreak at time of visit?	No	Yes	Yes
Knowledge of CDC Link between *L. mono* & Whole Produce at time of visit?	No	Yes	Yes
Knowledge of CDC Link between *L. mono* & Cantaloupe at time of visit?	No	Yes	Yes
Authority to Stop Operation's Production?	No	Yes	N/A
Awareness of Victims' Illnesses at time of visit?	No	Yes	Yes
Awareness of Victims' Deaths at time of visit?	No	Yes	Yes
Awareness that *L. mono* grows on refrigerated fruit?	Yes	Yes	Yes

Table 1: Dilorio's PrimusLabs Audits vs. FDA Inspections

[1]United States Food & Drug Administration [2] Colorado Department of Public Health & Environment [3] Colorado Department of Agriculture [4] Prowers County Department of Health [5] Centers for Disease Control and Prevention

Hindsight is 20/20

(112) Do statements made by FDA officials, U.S. Congressmen, and industry figures suggest a kind of "Hindsight is 20/20" perspective? It seems logical to assume that there would be differences between what James DiIorio and the FDA *et al.* saw at Jensen)Farms, considering that the federal, state, and county officials that conducted these inspections had the benefit of the CDC's Pulsenet data that had already identified Jensen Farms' cantaloupes as the source of the *L. mono* outbreak before they commenced those inspections. James DiIorio did not have that advantage. Logic also suggests that a daylong unannounced inspection on September 10 by four officials and a return visit on September 22 and 23 conducted by thirteen people are going to be more thorough than the pre-scheduled four-hour packinghouse audit and the six-hour ranch audits conducted by a single auditor in a single day, especially considering that Jensen Farms had been advised by a Frontera representative prior to and in anticipation of those audits. But those differences should not imply that the third-party auditing system lacks thoroughness and "may not be adequate to identify potential food safety problems" as the committee suggested.[58] **See Table 1 – DiIorio's PrimusLabs Audits vs. FDA Inspections.**

(113) The scope of the final audit that James DiIorio was hired to perform was a "Packinghouse audit without HACCP (or a competitor's equivalent)." This is worthy of note, because of the aforementioned Walmart buyer requirement that mandated any participant in the "small supplier of local produce program" to have at minimum a "PrimusLabs.com Packhouse w/ HACCP" audit. Furthermore, it is unclear whether or not Jensen Farms qualified as a "small supplier in the local produce program", considering that in 2011 "the company said it shipped out more than 300,000 cases of cantaloupes that contained five to 15 melons… [or] 1.5 million to 4.5 million pieces of fruit."[63]

(114) If Jensen Farms did not qualify for the program, it should have been required to conduct a GFSI-Benchmarked audit, based on Walmart buyer requirements. Remember that a GFSI-Benchmarked audit requires the certifying body to monitor the supplier's corrective actions for any non-compliances. Had Walmart, or their buying agent Frontera, required a GFSI-Benchmarked audit, PrimusLabs would have been responsible for the review and the acceptance or rejection of Jensen Farms' corrective actions for non-compliances in its audits. Because Walmart apparently accepted a PrimusLabs "proprietary" audit instead, the current growing season review of the grower's response to non-conformances was left to the auditees and any buyers that chose to do so. It is unclear why Walmart did not hold firm to several of its requirements.

(115) Mr. DiIorio arrived at Jensen Farms' packinghouse at 2:10 p.m. He stayed until 6:30 p.m. Since Jerry Walzel had identified seven non-compliances in the Jensen Farms operation in his 2010 "Packhouse" audit, one of the audit questions on the July 25 audit was to review those non-compliances. DiIorio noted that Jensen Farms had not recorded any corrective actions for any of the seven non-compliances identified in Jerry Walzel's audit, stating, "There are not documented corrective actions for their PrimusLabs audit report on file." And as an admonishment to Jensen Farms, DiIorio wrote, "It is important to keep these records on file to show that the company fixed deficiencies and it also

verifies good practices. Corrective actions should be recorded."[13] There is no indication that any corrective actions from the 2010 audit were ever taken, and they were definitively not recorded. Since Jensen Farms requested a non-GFSI audit, taking action on the non-compliances was left with them and their buyers.

(116) On the first page of the 24 page audit report in the section designated "Audit Scope", DiIorio noted that "This is a packing facility for cantaloupes which are washed by a spraybar 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."[13]

(117) Again, on page 13 of the report in a question that asked, "Are there specific Standard Operating Procedures (SOPs) for the changing and testing of water and ice systems e.g. washing flumes, hydrovacuums, hydrocoolers, ice making machines, ice injectors, etc.?"[13], DiIorio made note of the wash system again, stating, "N/A. Score not affected. The spraybar roller wash station does not have a (sic) anti-microbial solution injected or a dump tank installed. All used water drains continuously into a drain pipe which is installed into the facility drainage system. There is no changing and testing of the water required at this station."[13] Three more times, once on page 5 and twice on page 14 of the audit report, DiIorio makes mention of the lack of an "anti-microbial" or "sanitizing agent being used"[13] in the water. In all of these questions, DiIorio designated the questions "Not Applicable." These are not the only questions that DiIorio determined to be "Not Applicable" for this particular audit (and for which the audit score was unaffected). Of the 193 questions on the audit, 42 were deemed "Not applicable." For every one of those 42 questions, DiIorio offered an explanation for the "N/A" question.[13] Some of these explanations are critical to understanding what James DiIorio saw when he audited Jensen Farms. However, none is more important than the explanation of the absence of an anti-microbial in the water used in the wash system. Recall that FDA's guidance documents did not require the use of antimicrobial in the wash water Jensen Farms was using, yet DiIorio pointed out that no antimicrobial was not used five times in the audit report and also included mention of it on the front page of the report in the description of the "Audit Scope." Nothing in James DiIorio's audit stands out more than those five references to the wash water. Had the Jensen brothers or any of their buyers acted on DiIorio's emphasis on the lack of an anti-microbial in the wash water, the Jensen Farms tragedy would probably have been averted.

(118) The mysterious truck that hauled culled cantaloupe to a cattle farm and that "might have driven through animal feces and dragged back *Listeria* on its tires" is not mentioned in James DiIorio's audit. It is almost certainly not mentioned in the audit because on the day DiIorio visited Jensen Farms, there was no culled cantaloupe. DiIorio noted this on his comments on Question 1.3.4 on page 4 where he states "there was not rejected or on-hold product during the time of the audit."[13] This is significant because it adds to the apparent confirmation that July 25, 2011, was the first day of Jensen Farms' harvest and packing for the 2011 season, which would explain why on that day there was not yet any culled cantaloupe, and more importantly, why on that day James DiIorio likely saw Jensen Farms in its most pristine condition. If Dr. Gorny's speculation regarding the contamination being caused by the truck that transported culls to the cattle operation is

correct, then there were no contaminated cantaloupes present when Mr. DiIorio conducted the audit of Jensen Farms.

The Score That Should Not Have Been

(119) In the end, DiIorio noted a grand total of 11 non-compliances with the audits scope and criteria: three major deficiencies, three minor deficiencies, and five total non-compliances. Ultimately, James DiIorio's audit of Jensen Farm totaled 926 points out of a possible 961, equaling approximately 96 percent of the total points possible in the 151 applicable questions on the audit. The score of "96" was labeled as "Superior" under the scoring guidelines of that audit.[13] The score was one point higher than the audit score that Jensen Farms' packinghouse received from Jerry Walzel in 2010.

(120) Far from being a glowing review of Jensen Farms, as the FDA and the media has portrayed this audit, James DiIorio showed an operation that, at that specific point in time, with its cantaloupe production barely underway, operated within the framework of industry norms. Again, the Jensen Farms score of "96" is four percentage points below a score that would meet the standards of the industry. The score was also similar to the mean score for all PrimusLabs "proprietary" GMP audits conducted in the past 13-plus years. **Again, see Figure 4 - pg. 21.**

(121) Yet, the score that DiIorio assigned to Jensen Farms is the aspect of the Jensen Farms outbreak that many in the FDA, the media, and the produce industry have focused on the most. Considering that point, it is ironic that, of all the players in the industry, it was PrimusLabs that had previously eschewed assigning scores for audits, arguing instead that attention should be focused on the auditors' comments and on non-compliances in the audit.

(122) The reason for PrimusLabs' rejection of scores was based on the industry's tendency to rely on pass/fail scores to signify a threshold for "safety." Risk analysis is far too complex to set thresholds. Unfortunately, there is no way of absolutely ensuring that food is "safe", and even if there was, it is unlikely that anyone could agree on just what score would confer "safety." For instance, on the PrimusLabs "proprietary" audits, one retailer sets the number at "85", while another identifies it at "92". Many others accept audit scores as low as "80."

(123) Dr. Robert Whitaker, Chief Science and Technology Officer at PMA, summarized this danger when he reminded the FDA in a 2014 letter that, "So much emphasis is placed on whether the audited entity 'passes' or 'fails' the audit, that we lose track of the fact that the audit is only a tool to measure compliance of the operation against their food safety plan."[35]

Safe for Whom?

(124) Whatever the number, it is purely an optimization, because safety is relative. The question that the food industry and individual consumers must ask is not "How Safe?", but rather "Safe for Whom?

(125) The decision as to whether or not a human being should eat any particular food must be determined based on the person's tolerance for risk which ideally should closely relate to the health of that person's immune system. People with compromised immune systems: young children, pregnant women, those with medical conditions, and especially the elderly, must be very conscious of what they eat because they are more susceptible to any kind of pathogen contamination than are other people with stronger immune systems.

Risk is Relative and So Are Audit Scores

(126) The notion that a food producer, distributor, or retailer can say that an audit score of "80" is going to ensure safety is absurd, but it is just as absurd to argue that an "85" or a "92", or even a "100" will guarantee safety. Ultimately, one man's "100" is another man's "75" and vice versa. Would anyone logically conclude that food produced by a supplier whose audit score is "80" is "safe", while the food produced by a supplier whose audit score is "79" is not? Or that "85" is safe, but "84" is not?

(127) Risk is relative. Some people can eat sushi; others are only comfortable consuming foods that are subject to a "kill" step (e.g. cooked, etc.). This, of course, sounds shocking to many, because not only do our immune systems vary in susceptibility to disease, but our attitudes and biases toward risk and how food is produced and consumed also vary. Since risk is relative (e.g. controlled or uncontrolled risk, seen or unseen risk, acute or chronic risk, etc.), audit scores are relative as well. **See Figure 9 – Individual Food Safety Risks and Demographic Shifts**.

Attitude is Everything

(128) Some food consumption decisions can be made based upon scientific analyses of risk, but others are often made based upon our own perceptions and bias. Ultimately, our attitudes are everything, when it comes to food safety. For instance, some people think that organically grown food is much safer than what is conventionally grown. Others believe exactly the opposite. Some people talk about the potential risks posed by genetically modified foods; others obsess over pesticide residues in everything that they eat. Most people think that fresh produce is the healthiest food on the planet, but other people make conscious decisions to avoid consuming foreign grown fresh produce or limit their consumption to canned fruits and vegetables.

(129) Consequently, any discussion of putting scores on or setting minimal standards for audits is ultimately an arbitrary exercise that ignores the real issues of relativistic risk analysis. Unfortunately, most consumers and many in the fresh produce industry do not understand this reality, or if they do understand it, choose instead to opt for convenient solutions.

"Efficiency and Business Benefits"

(130) At several meetings of the United Fresh Harmonization Initiative Calibration Committee held after the Jensen Farms outbreak, industry interests met to discuss

numerous aspects of proposed "harmonized" audits. These meetings are indicative of the push by the industry to maintain audit scoring, even in light of what had happened at Jensen Farms. This same thinking had already pervaded the industry many years prior to the Jensen Farms outbreak, so almost all third party audits are scored, and minimal standards are determined for each audit.

131) In one meeting of the United Fresh group, held at their headquarters in Washington, D.C., on November 22, 2011, "It quickly became apparent that there could be no consensus on weights and scores; every participant had their own opinion of what was important. However, several customers have indicated that the harmonized standards must have a scoring platform for them to use it. [Henna] Patel [of SCS Global Services] and others noted the dangers in relying on scores, where a significant safety deficiency could be overlooked because of an otherwise high score." **See Appendix 4.**

(132) Nonetheless, at a later meeting on December 8, 2011, the decision to implement a scoring system was agreed upon. As the minutes of that meeting reflect, "While all agreed that the auditor's comments are the most important part of the report, there are efficiency and business benefits to have a rank or a score for the audit." **See Appendix 5.**

(133) Also ironic is that in their efforts to create a "harmonized" audit that would hold all auditees to the same standards, the retail groups that were parties to the United Fresh effort agreed to disagree on the minimal scores that each would require of their suppliers. As that audit currently exists, every auditing firm or retailer sets their own minimal standard.

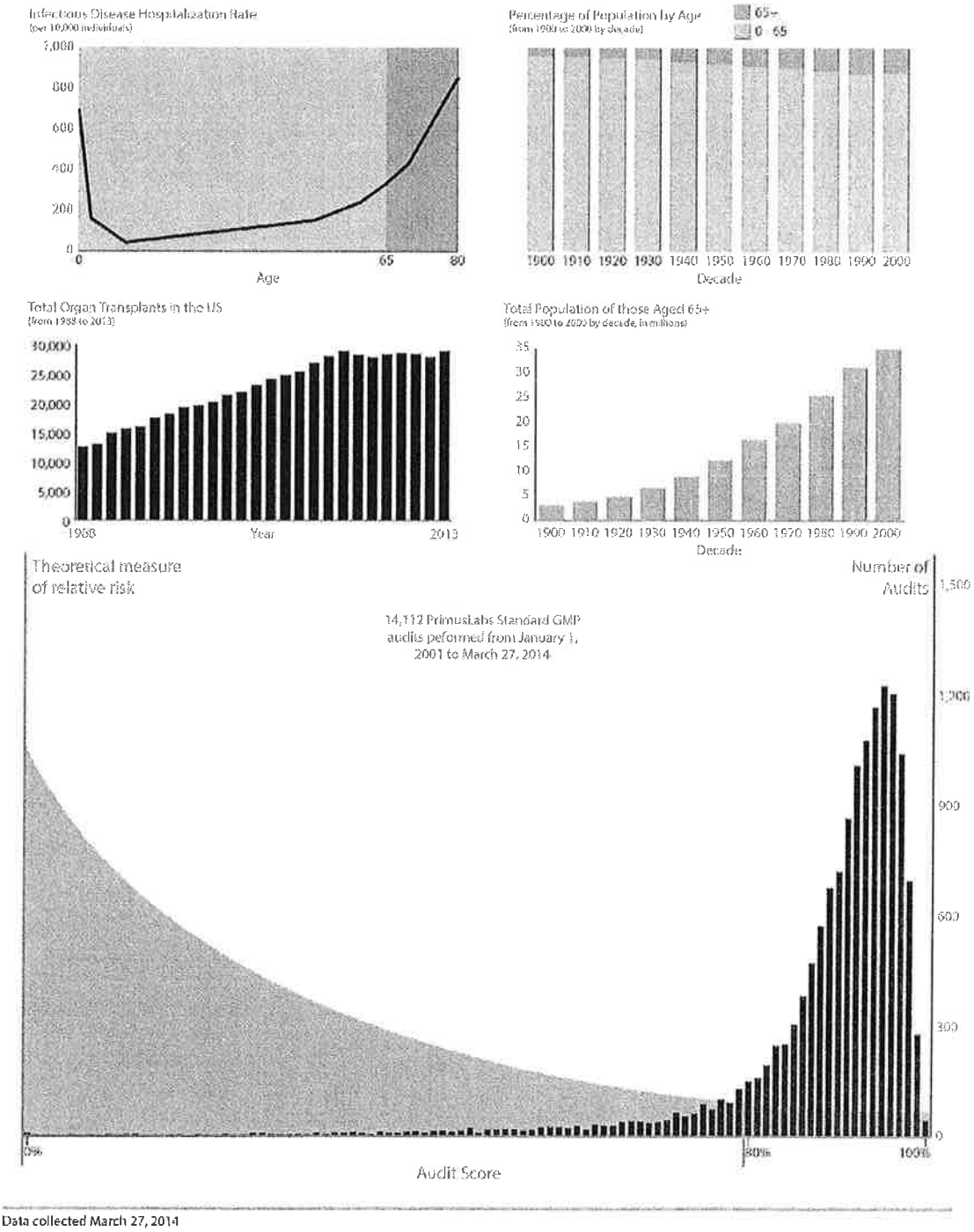
(134) What is confusing is that the industry apparently agrees that "the auditor's comments are the most important part of the [audit] report", but that same industry argued that Jensen Farms' score of "96" blindsided them into believing that the Jensen brothers' food safety practices were exemplary. Considering that the Jensen brothers did not address non-compliances from the 2010 audits and considering that the 2011 audit made five comments about the absence of an anti-microbial in the wash water, in addition to numerous other comments for which James DiIorio assigned "Not Applicable" designations which did not result in downscores, but raised concerns, it is hard to understand how can anyone suggest that James Dilorio's audit was misleading.

Labeling Audit Scores

(135) Much was made of the word "Superior" to describe Jensen Farms' audit score of 96. While PrimusLabs was opposed to the practice of audit scoring, in its effort to meet the needs of the industry, it adopted scores in its "proprietary" audits. Also, at the behest of the industry, it labeled the scores that it gave auditees. Audit scores between 95 and 100 percent were labeled "Superior", while scores between 90 and 94 percent were labeled as "Excellent." Scores between 85 and 89 percent were termed "Good", and any scores between 80 and 84 percent are referred to as "Standard."

Figure 9.

Individual Food Safety Risk and Demographic Shifts



Data collected March 27, 2014

'Motives, Probability for Success, and Incentive Value'

(136) Why label scores at or below industry standards with such euphemistic terms? The answer to that question has as much to do with an understanding of human motivation as it does with audit scoring.

(137) Many sectors of the fresh produce industry are relatively new to food safety audits. Many have operated for years without auditing and are submitting to them for the first time at the request of buyers. Data will confirm that as the frequency of audits increases so do auditees' scores. Still, early in the process of acclimating growers, packers, and processors to the auditing process, creating a climate of fear in auditees is likely to promote self-fulfilling prophesy and resignation of failure, while creating a climate that encourages and rewards success is likely to promote achievement and has the best opportunity to lead auditees to realize a culture of food safety.

(138) The preeminent authority on motivational psychology is the American theorist John William Atkinson, a longtime researcher at the University of Michigan. Atkinson proposed that behavior was "a multiplicative function of three components: motives, probability for success, and incentive value." Anticipation of success reflects a subject's "capacity to experience pride in accomplishment."[4] Further research into "self-perceptions of competence and ability" by Paul R. Pintrich suggests that reinforcing positive self-perceptions through language can promote competence and ability.[27]

(139) Because certifying bodies and buyers wanted to promote food safety, they agreed to use language labels for audit scores that offered auditees positive reinforcement to continue to implement food safety practices that would lead each to develop a culture of food safety within each operation.

VI. LESSONS TO BE LEARNED

Introduction

(140) The American philosopher George Santayana once famously said, "Those who cannot remember the past are condemned to repeat it." For the sake of all Americans, everyone connected to the Jensen Farms tragedy must learn from what happened in 2011 and what is continuing to happen today. Only by moving forward toward common sense solutions and practical applications of guidance, standards, and regulations in the form of audits that are clearly understood can food industries improve.

(141) Of course, no one wants another tragedy to occur, but we need to be equally vigilant not to exacerbate a tragedy with a slow response or through ill-conceived and misguided actions after the fact. In short, there are lessons to be learned to address both future issues and to prevent the kinds of injustices that occurred in the wake of the Jensen Farms outbreak.

What Took So Long?

(142) Several important questions remain about how the FDA handled the investigation of Jensen Farms and the recall of its cantaloupe. After its investigators left Jensen Farms on September 10, why did it take four days for the FDA to insist that Jensen Farms issue a Class I Recall of their cantaloupe and to publish a Consumer Safety Information Update for those cantaloupes?

(143) Why did the State of Colorado's Department of Public Health and Environment begin testing samples of Jensen Farms cantaloupe on September 5, while the FDA didn't begin testing samples until September 9? Why did the FDA wait for three days for positive *L. mono* test results on the cantaloupes that it pulled from a grocery store and from Jensen Farms before acting, when the CDPHE already had positive test results on cantaloupe that it pull from a victim's home and from a grocery store where another victim had purchased cantaloupe? Are FDA tests better than CDPHE tests? Why did Jim Gorny state about the positive FDA test results that "It truly was an 'Aha!' moment?"[8] Shouldn't the "Aha! moment" have come three days earlier when the CDPHE found *L. mono* on Rocky Ford cantaloupe, presumably from Jensen Farms?

(144) Furthermore, why did it take the FDA five days to get *L. mono* test results, when the CDPHE got their results in as little as three days? Why does it take PrimusLabs 48 hours in a normal testing request to produce a "presumed positive" test for *L. mono*, while it takes the FDA 120 hours in the midst of a crisis? As mentioned earlier, in a crisis, not just days, but hours, are critically important and may be the difference between life and death.

(145) With that in mind, should there have been a greater sense of urgency? By the time the FDA was involved, several people had already died. Many others already lie in hospital rooms. People were going into grocery stories in 28 states and buying contaminated cantaloupe that could kill them. Many of the victims of this crisis had to go no farther than their refrigerators to eat cantaloupe that was growing lethal amounts of *L. mono* with each passing hour.

(146) The FDA response is also puzzling in light of the Food Safety Modernization Act (FSMA), passed by Congress on January 4, 2011, which gave the FDA sweeping powers to intervene to protect American food supplies. Prior to FSMA, FDA could not unilaterally order a mandatory recall of food, but could only urge the producer to order a voluntary recall. FSMA changed that, allowing the FDA to order a mandatory recall if it had requested the supplier to order a voluntary recall, and the supplier refused.[49] Did the FDA request that Jensen Farms order a voluntary recall prior to September 14? If not, why not?

(147) According to Roberta Wagner, FDA's Deputy Assistant Commissioner for Regulatory Affairs of Field Operations, in her comments on Jensen Farms, "with the Food Safety Modernization Act we did get some new tools that we could use with this firm. We didn't need to use them this time. We have mandatory recall authority."[52] Ultimately, why did the FDA not order a nationwide recall when, according to the provisions of FSMA,

they could have done so, and why did they wait until after Jensen Farms ordered a voluntary recall to issue a safety warning? Why didn't they issue a warning in conjunction with, or at least at the same time as, the CDC? If there was ever a time to put the provisions of FSMA into effect, wasn't this the time?

(148) In the days, weeks, and months after the Jensen Farms outbreak representatives of the agency heaped praise on themselves for their response to the outbreak. Margaret Hamburg, Commissioner of the FDA, in her comments on the Jensen Farms outbreak, stated, "I do think that the response to this outbreak was quick and effective. We - meaning the collective 'we' - were able to trace back the contamination to the implicated farm and did everything possible to ensure that people would not eat contaminated cantaloupe and become ill. So, all of that is very good news."[53]

What Did You Know? When Did You Know It? And What Did You Do About It?

(149) The Watergate scandal of the 1970s introduced two memorable phrases into our collective lexicon: "What did you know, and when did you know it?" If we can borrow those phrases and add to them a third – "What did you do about it?" – we might make some progress in truly understanding the Jensen Farms tragedy.

(150) What did James Dilorio know and when did he know it? On July 25, 2011, when he visited a Colorado cantaloupe operation on their first day of production, Dilorio did not know or have reason to believe that *L. mono* was contaminating cantaloupes in the operation's packinghouse. He probably did not learn this fact until the contamination at Jensen Farms became national news. There is no evidence to suggest that on July 25, 2011, there was *L. mono* contamination in the Jensen Farms' packinghouse, but even if there was, James Dilorio would have had no way of knowing it.

(151) What else did James Dilorio know? He knew that Jensen Farms was not using a dump tank to wash its melons. He knew instead that Jensen Farms was utilizing a single pass wash system without an anti-microbial, even though their apparatus was equipped with the capacity to use chlorine etc. He also knew that there was no FDA regulation requiring the use of an anti-microbial, and that FDA guidance suggested that it was not necessary so long as the water used in the single pass system was "of sufficient quality", e.g. potable. He knew that Jensen Farms used potable water. He knew that the Jensen Farms packinghouse was generally clean and sanitary and that there was no standing water in the facility. He did not know anything about a truck hauling culled cantaloupe to and from the packing facility. He did not know anything about a cull pile, but, in fact, knew that there was no culled fruit on the first day of packing.

(152) What did he do? He observed and reported on the packing facility in Granada, Colorado, and filed his audit report on August 3, 2011. He noted his observation of three major deficiencies, three minor deficiencies, and five total non-compliances in the Jensen Farms packinghouse and determined that Jensen Farms had earned 926 out 961 relevant points on a standard practice packinghouse audit without HACCP. He assigned the report a score based on the scoring guidelines of the audit. That score was "96" and was labeled as "Superior." He noted five times in his report that the operation was operating without an oxidizing agent. In short, James Dilorio did his job.

(153) On the other hand, what did FDA personnel know, and when did they know it? FDA officials knew that in all likelihood *L. mono* was present on Jensen Farms cantaloupe prior to September 10, 2011, the date when they arrived unannounced at the Jensen Farms packinghouse. They had been informed of that likelihood by the CDC as early as September 6, 2011, based on all of epidemiological evidence compiled by the CDC. By September 11, 2011, they knew for certain that *L. mono* had contaminated cantaloupes from Jensen Farms.

(154) What did the FDA personnel do about the suspected and later confirmed *L. mono* contamination at Jensen Farms? On September 9, 2011, they sent inspectors to a grocery store in Colorado to pull 10 samples of "Sweet Rocky Fords." This is interesting in light of the fact that the CDPHE had already pulled cantaloupe from the shelves of a Colorado grocery store the day before, and they were already being tested for *L. mono*. Furthermore, why did FDA people go to grocery stores to pull samples before inspecting Jensen Farms? Was the FDA more interested in building a criminal case of introducing adulterated food into the marketplace against the Jensen brothers than it was in protecting consumers from getting sick? Then, the next day, they inspected the packinghouse and farms at the peak of production, took 39 environmental samples and 10 more product samples and sent all the samples to their Denver laboratory for testing. On September 11, 2011, the FDA learned that the cantaloupe sampled and tested by the CDPHE had been confirmed positive for *L. mono*. What did FDA do with that knowledge? It waited three more days until September 14, 2011, until it had the results of its own pathogen tests before it insisted that Jensen Farms initiate a Class I recalled of their cantaloupes. Once the recall had been announced, the FDA issued a Consumer Safety Information Update. Then, they returned to Jensen Farms on September 22 and 23, 2011, to complete an "Environmental Assessment", and they eventually filed a report that assessed the Jensen Farms operation as "demonstrating widespread contamination… and poor sanitary practices."

(155) What else did the FDA personnel do? On October 18, 2011, they sent a warning letter to Jensen Farms. They went on to hold a press conference on October 19, 2011, where they stated that "Jensen Farms significantly deviated from industry standards…", effectively bestowing upon the Jensen brothers pariah status in the melon industry and villainy in the public consciousness. This despite the fact that FDA staffers had had a questionable level of experience with cantaloupe operations outside of California and Arizona, despite the fact that it had no regulations for cantaloupe production, and despite the fact that its guidance for cantaloupe production was, and still is, ambiguous. And in all probability, they repeated their statements about the supposedly abhorrent conditions that they found at Jensen Farms to the U.S. District Attorney from Colorado, resulting in the first-ever criminal charges brought against American farmers for introducing adulterated food into the marketplace, even though those same farmers did not know they were doing so.

(156) Figure 9 demonstrates that, based on over 14,000 Good Manufacturing Practice audits conducted by PrimusLabs over a span of more than thirteen years, Jensen Farms was far from the aberrant player that "significantly deviated from industry standards." Jensen Farms' scores fell into the most common decile rank (90-100%), which included

nearly two-thirds of all audit scores. If the FDA believes that Jensen Farms "significantly deviated" from industry standards, what would it say about the 1.5% of operations that scored in the lowest five deciles (0 – 50%)? Based on these statistics, do the FDA's statements about Jensen Farms reveal a lack of objectivity about the norms of the produce industry? Having seen a relatively small number of cantaloupe operations nationwide, but more operations that were utilizing best practices, should the FDA have characterized Jensen Farms as "deviant" because they had modified equipment, cracked concrete, and standing water, etc., conditions that are commonplace in produce operations all across this country? **See Figure 10 – PrimusLabs Proprietary GMP clustered audit score.**

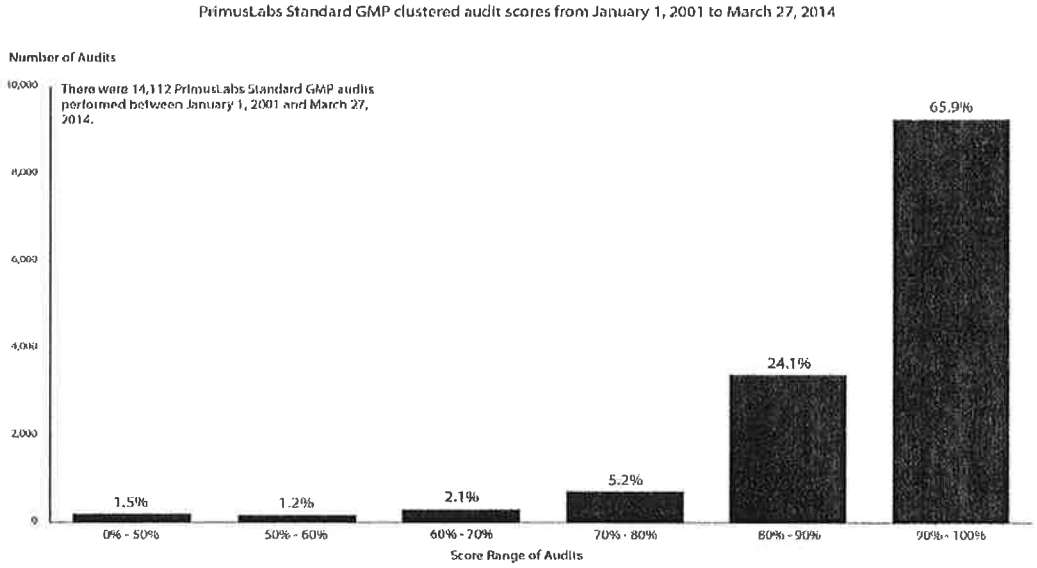
(157) Recently, the Produce Marketing Association (PMA) lamented the tendency of some in the FDA to suggest, after the fact, that what is actually fairly commonplace is aberrant. Consider this statement in its filed comment to the FDA on FDA's proposed regulations for FSMA: "It is often interesting and frustrating to read FDA investigative reports following a foodborne illness event where conditions in the field or packing facility are described. Observations are included and cited as potential contributing factors to potential contamination even though those same observations could be made at hundreds or perhaps thousands of production operations around the world. For example, water on floors of packing houses, cracks in concrete floors, animals in proximity to fields and other observations of a similar nature are reported, yet these conditions are common to many fruit or vegetable production operations."[36] It is worth noting that, at the time that this comment was submitted to FDA, PMA's Vice-President of Food Safety and Technology Division was Jim Gorny.

(158) In addition to what the FDA did, consider what FDA officials didn't do. Despite all epidemiological evidence pointing directly to Jensen Farms as the *L.* mono source, they didn't shut down Jensen Farms on the day of their first visit on September 10. They didn't ask Jensen Farms to order an immediate recall on September 10, or even on September 11, when they had lab confirmation of the presence of *L. mono*, and they didn't issue a Consumer Safety Information Update until September 14, after Jensen Farms had issued their voluntary recall. Meanwhile, people continued to purchase "Sweet Rocky Fords" in grocery stores in 28 different states; people, some of them with compromised immune systems, continued to walk to their refrigerators and eat the contaminated cantaloupe inside them; and people continued to get sick and die.

Absent Visual Confirmation

(159) Why did the Jensen Farms recall occur on September 14, not on September 10 or on September 11? The samples of whole cantaloupe (pulled by an FDA employee from a grocery store where an *L. mono* victim had purchased cantaloupe) came back from the FDA laboratory in Denver, Colorado, on the same day as the recall, Saturday, September 14. The timing of those two events is probably not coincidental. Of the 10 cantaloupes pulled from the store on September 9, nine tested positive for *L. mono*.[54] The samples of whole cantaloupe taken from Jensen Farms itself had not yet yielded test results. The results from the samples taken from Jensen Farms on September 10 were received the day after the store sample results came back - on September 15.

Figure 10.



(160) The dates are critically important because they seem to indicate that FDA needed its own laboratory confirmation of *L. mono* on Jensen Farms cantaloupe before they felt they could force a recall. Apparently, the lab results from the CDPHE samples that came back positive on September 11 were not adequate, presumably because state, not federal employees had collected and tested those samples. As it turned out when the FDA confirmation did arrive, it came from samples taken from a store by an FDA employee, which was less convincing than if the samples had been taken from Jensen Farms itself. The former could have been contaminated after leaving the packinghouse. Note that the CDPHE confirmation was also from samples pulled from a grocery store and also from a victim's home. Nonetheless, considering that the test results from samples taken at Jensen Farms were not yet available, and considering that the results from CDPHE were not being considered, FDA was not ready until September 14 to set the recall in motion and issue a Consumer Safety Information Update.

(161) What makes this decision interesting is not that the FDA insisted on lab results before ordering the recall, or even that it insisted on its own lab's results before order the recall. What is most interesting is that if, in fact, Jensen Farms was "demonstrating widespread contamination… and poor sanitary practices" when the FDA arrived on September 10, why did FDA not shut down the operation on that day or insist upon a recall on that day? This is an action that FDA has taken in other places at other times, including the Texas plant of Peanut Corporation of America in 2009, and a Seattle salmon smokehouse earlier this year (confirmation needed for both examples). If Jensen Farms' packinghouse was operating under "rogue conditions... unsanitary cantaloupe handling [that] flouted industry norms with dirty equipment, pooled water and lack of a cooling system,"[7] the FDA could have either shut that packinghouse down and/or forced an immediate recall of its products.

(162) The fact that they didn't suggests that nothing that the FDA saw on September 10 warranted such drastic action, and absent visual confirmation of an operation that was obviously contaminating food, the FDA felt they could not act.

(163) But apparently the FDA had a different set of expectations for James Dilorio than they did for themselves. James Dilorio didn't have the benefit of pathogen testing results, yet it has been suggested that he should have confirmed that the Jensen Farms packinghouse was spreading *L. mono* contamination based solely on visual evidence that he gleaned from his audit on July 25. This despite the fact that, as has been explained in depth already, James Dilorio almost certainly saw quite a different scene when he audited Jensen Farms than the FDA did when they investigated it some 40 days later at the height and towards the end of Jenson Farm's production season. **See Table 2 – Audit - Inspection Comparisons.**

Class I, Class II, and Class III Recalls

(164) As mentioned previously, FSMA changed the way in which recalls may be handled by the FDA, though at the time of the Jensen Farm outbreak, the FDA was still presumably operating under its old policy for food recalls. Under that old policy, FDA could only order a recall of a product if it requested that the supplier order the recall and that supplier refused (unless it had statutory authority to order the recall unilaterally). FDA defines recalls as follows:

(165) "Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.

- **Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. (Continued pg. 42)

Table 2: Comparisons in Observations of Jensen Farms Ranch & Packinghouse

Report Descriptors	James Dilorio's Observations	FDA's Observations
Anti-microbial in Product Wash Water?	**Observed? No. Reported? Yes, mentioned twice "no microbial in use." Not downscored. (See p. 25)**	**Observed? No. Reported? Yes, no microbial in use.**
Sorting/Washing/Drying Equipment is cleaned & sanitized?	Observed? Yes. Reported? Yes, "all food-contact surfaces... clean."	Observed? No. Reported? "Not easily cleanable" equipment.
Presence of Standing Water in the Packinghouse?	Observed? No. Reported? Observed no standing water.	Observed? Yes. Reported? Yes, observed standing water.
Cracked, hard to clean Packinghouse Floor?	Observed? Yes/No. Reported? Floors cracked, but not hard to clean.	Observed? Yes. Reported? Cracked, hard to clean concrete, seen as deviation from industry standards.

Enclosed Storage Area?	Observed? No. Reported? Storage area not enclosed - Downscored as deficiency.	Observed? No. Reported? Yes, seen as deviation from industry standards.
Truck Hauling Culled Cantaloupe?	Observed? No. Reported? No culled fruit & no truck. (See p. 26)	Observed? Yes. Reported? Yes, attributed to possible cause of *L. mono.*
Sorting/Washing/Drying Equipment modified & previously used for another purpose?	Observed? No. Reported? No mention of modified equipment.	Observed? Yes. Reported? Yes, attributed to possible cause of *L. mono.*
Records of Corrective Actions for Seven Non-compliances from August 5, 2010 audit?	Observed? No. Reported? Yes - Downscored as deficiency.	Observed? No. Reported? No.
Records of Equipment Calibration Procedures?	Observed? No. Reported? Yes - Downscored as Non-compliance.	Observed? No. Reported? No
Transition to Organic Farming?	Observed? Yes. Reported? Yes, mentioned; not downscored.	Observed? No. Reported? No.
Backflow Prevention Devices on Main Water Lines?	Observed? No. Reported? Yes - Downscored as Non-compliance.	Observed? No. Reported? No.
Certificate of Inspection for Backflow Prevention System?	Observed? No. Reported? Yes - Downscored as Non-compliance.	Observed? No. Reported? No.
Adequate Employee Hand Washing Stations?	Observed? No. Reported? Yes - Downscored as deficiency.	Observed? No. Reported? No.
Adequate and maintained Pest Control Devices?	Observed? No. Reported? Yes - Downscored as deficiency.	Observed? No. Reported? No.
Pest proof Doors?	Observed? No. Reported? Yes - Downscored as deficiency.	Observed? No. Reported? No.
Signed Employee Compliance Policy Letters?	Observed? No. Reported? Yes - Downscored as deficiency.	Observed? No. Reported? No.
Records of Employee Training?	Observed? No. Reported? Yes - Downscored as Non-compliance.	Observed? No. Reported? No.
Background Checks of Employees?	Observed? No. Reported? Yes - Downscored as Non-compliance.	Observed? No. Reported? No.

- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- **Class III recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

- **Market withdrawal:** occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.[56]

(166) Based on the evidence that had been gathered by the CDC, the Jensen Farms outbreak was appropriately categorized as a Class I recall, "a situation in which there is a

reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

(167) Considering that "serious adverse health consequences or death" were the reasonably likely result of consuming Jensen Farms cantaloupe, when should the recall have occurred? Would the right thing to do have been for the FDA to have requested that Jensen Farms recall its cantaloupes on September 10, 2011, the day that it first inspected Jensen Farms? FDA officials were probably being understandably cautious in waiting for microbiological testing results that confirmed *L. mono* contamination before requesting the recall. On the other hand, would it have been better to have ordered the recall on the 10th? Would lives have been spared by the decision or could it have ruined a business before it had been proven to have done anything wrong? It is difficult to say when the FDA should have required Jensen Farms to recall their cantaloupe. It is often confronted with extremely difficult decisions, and the Jensen Farms case was certainly no exception.

(168) However, what the decision (to wait until the FDA had its own microbial confirmation that *L. mono* contamination had occurred before ordering the recall) does show is that what the FDA and other food safety "experts" expected of a third party auditor was more than what they expected of themselves, because some "experts" suggested that James Dilorio should have stopped his audit on July 25, 2011, almost before it started and should have immediately contacted the FDA to report Jensen Farms for distributing contaminated food. And these "experts" thought this even though James Dilorio had no reason to conclude that Jensen Farms was not operating within the accepted standards of the cantaloupe industry, much less that it was packing and distributing tainted cantaloupe. Perhaps the FDA was acting appropriately, but was speaking incorrectly.

What They Said

(169) Another one of the lessons to be learned from this tragedy is that everyone should temper their words until the complete facts and full details of a crisis situation are revealed. Failure to do so can foster a mob mentality that will invariably produce simplistic, convenient, and misleading explanations. It is probably human nature to create villains and heroes out of catastrophic events, but such reactions are inevitably wrongheaded and unproductive and will never produce solutions with which people can move beyond the pain and suffering. Looking back at the Jensen Farms case with a detached objectivity suggests that maybe the roles of the villains and the heroes could be reversed.

(170) Beyond the illnesses and deaths that the outbreak caused, one of the saddest aspects of the Jensen Farms tragedy was the vilification of people that did not deserve to be pilloried. Numerous entities added to the frenzy with comments that were short-sighted and irresponsible. These included government and industry officials, and members of academia and the media. Some of the worst offenders ruined the reputations of others, while either attempting to burnish their own reputations or to protect their or their organizations' interests. These pages have already detailed some of the comments that

individuals made about Jensen Farms and the Jensen brothers, but the revelation that Jensen Farms had undergone a third party audit at the beginning of the 2011 harvest season shifted the demonization to James DiIorio, PrimusLabs, and third party auditing in general. Luckily, there was at least one person who saw what happened more objectively and reported the facts. What follows are some of the comments.

Dr. James Gorny

(171) At the time of the Jensen Farms outbreak, Dr. James Gorny was, as previously mentioned, the FDA's Senior Advisor for Produce Safety, Center for Food Safety & Applied Nutrition. He is currently Vice-President of Food Safety & Technology for the Produce Marketing Association (PMA). Prior to his role at FDA, "Gorny was the executive director of the Postharvest Technology Research and Information Center at the University of California - Davis. He also served as senior Vice-President of food safety and technology for the United Fresh Produce Association/International Fresh-Cut Produce Association, which merged in 2006. He received his Ph.D. in plant biology from the University of California - Davis and his bachelor's and master degrees in food science from Louisiana State University."[37]

From Davis Fresh to United Fresh to the FDA

(172) Dr. Gorny's professional life shifted between government/academia and private businesses, including work for two major U.S. produce associations. These moves put him in the awkward position of investigating and researching industries and individuals whom he had previously championed and with whom he had worked and/or competed. Gorny's time at UC-Davis led him into business with Dr. Devon Zagory, an academic who was also working with the Postharvest Technology Research and Information Center. Together they founded the firm Davis Fresh Technologies in 1999. Davis Fresh was a third party food safety auditing and consultation company whose business interests eventually expanded into numerous countries, including markets in several South American nations.

(173) Dr. Gorny's jump to United Fresh in 2006 preceded the sale of Davis Fresh Technologies to NSF International, a global, independent organization for public health and food safety solutions. The October 2006 sale, prompted by Davis Fresh's presence in Chile and Peru in particular, produced a new company NSF-Davis Fresh, now operating as NSF Agriculture,[17] and reportedly netted Zagory millions. Gorny's move to United Fresh had cost him dearly.

(174) Gorny's doctoral degree in plant biology served him well in his roles in both government and academic circles, but food safety auditing and production agriculture were not his strongest suit. Even when he was involved in running an auditing firm with Davis Fresh, most of his experiences were in Californian and Arizonan operations, so his comments about Jensen Farms' audits and their production methods were based on limited practical expertise and certainly narrow exposure as a scientist, regulator, and association staffer.

'Dr. Gorny Opines'

(175) In the days, weeks, months, and years following the Jensen Farms outbreak, Dr. Gorny chastised a third party auditing system in which he himself was once a player. "Gorny opined that the Primus Labs [audit] of Jensen Farms was seriously deficient in its inspection and findings."[5]

(176) Dr. Gorny alluded to the "FDA released draft guidance to the industry to minimize the risk of foodborne illness from melon production and distribution" when he suggested that James Dilorio should have failed Jensen Farms because they had, "significantly deviated from industry standards by failing to use an anti-microbial." [57] Gorny's statement that the Jensen brothers "significantly deviated" from the "FDA released draft guidance" is misleading because, in fact, they followed it to the letter. The statement is made even more unsettling considering the fact that Jim Gorny was one of the principal authors of that draft guidance.

(177) Gorny also suggested that Jensen Farms deviated from the FDA draft guidance on the pre-cooling of melons, but, as has been mentioned previously, FDA's pre-cooling guidance is as ambiguous as is its guidance on use of an anti-microbial wash. In those comments about the cooling of melons, Dr. Gorny also fails to acknowledge that the cold storage facility that James Dilorio saw was not comparable to the one the FDA observed 40 days later, because of the differences in the level of production during those two occasions. Because harvesting and packing at Jensen Farms had only just begun on July 25, 2011, the small supply of packed cantaloupes that were placed in Jensen Farms' cold storage facility may well have ensured that the facility was adequate at that time to prevent condensation that could exacerbate *L. mono* contamination. Conversely, a cold storage facility at full capacity, filled with product that had not been sufficiently pre-cooled, could very well have caused condensation that provided a breeding ground for *L. mono* and a means to spread the contamination.

(178) Another criticism that Dr. Gorny leveled in the Jensen Farms investigation was against Jerry Walzel, the owner of Bio Food Safety, who had conducted a 2010 audit of Jensen Farms. Gorny and his FDA colleagues raised concerns about the advisory relationship between PrimusLabs, Bio Food Safety, and Jensen Farms, noting that, "when a third party auditor gives consulting advice, that's a conflict of interest."[58] On the surface, Gorny's statement is entirely correct, which is why simultaneous consultation and auditing is disallowed by PrimusLabs.

(179) However, according to the Jensen brothers in their testimony to the House Committee on Energy and Commerce that investigated the Jensen Farms outbreak, "after the August 2010 audit was completed, one of the Jensen brothers informed Mr. Walzel that they were interested in improving their processes,"[59] so Walzel allegedly advised them to switch to a single pass wash system to address "a potential food safety 'hotspot."[59] If, in fact, Walzel did so, he was functioning as a consultant, which, based on PrimusLabs policy, would prevent him from auditing Jensen Farms for the next three years. There is no evidence that Walzel accepted a consultation fee for the advice, and he offered it after the audit had ended and only at the behest of one of the Jensen brothers. Based upon the findings of the Congressional Committee, Jerry Walzel followed

PrimusLabs protocols by avoiding simultaneous auditing and consulting, and did not engage in any consultation within three years of the time he offered his advice. Moreover, Dr. Gorny's criticism is also notable, since Gorny's Davis Fresh firm engaged in both auditing and consultation.

Mr. Stephen Patricio

(180) Stephen Patricio is chairman of both the California Cantaloupe Advisory Board, as well as the Center for Produce Safety, and has served as president and CEO of Westside Produce since 1993. He received a bachelor's degree in accounting from the University of Santa Clara and was certified as a public accountant in California beginning in 1976. He previously served as Chief Financial Officer at Tri Produce.[62]

'Packinghouse 101'

(181) As the head of the California Cantaloupe Advisory Board, Mr. Patricio's understanding of cantaloupe production is understandably provincial, but this narrow comprehension did not stop him from passing judgment on Jensen Farms and James Dilorio. The problems that were found at Jensen Farms are "Packinghouse 101", he said. "Every common surface must be cleaned, rinsed, and sanitized. These are all just known, recognized practices."[61]

(182) "It's just disgusting to me," Patricio said of both Jensen Farms and Primus Labs. "I think of the damage that they've done to our industry as the result of this oversight. No, I won't even talk about it as oversight; it's abuse."[61] Mr. Patricio's reaction reveals his self-serving bias, namely that a pathogen outbreak at a cantaloupe operation in Colorado – assessed using the standards of California operations - might have negative implications for "our" cantaloupe producers in California.

Dr. Trevor Suslow

(183) Dr. Trevor Suslow is the extension research specialist at the University of California – Davis, Department of Plant Sciences. Dr. Suslow's program involves pre-harvest and post-harvest research and outreach on diverse fresh and fresh-cut horticultural foods.

(184) Suslow earned Bachelor's and Master's Degrees, as well as his Doctorate in Plant Pathology from the University of California – Berkeley. He has served on numerous produce safety boards and committees and has advised the USDA and the FDA on a variety of issues. He has also done significant industry research into food safety and cantaloupes and is perhaps the foremost authority on cantaloupes and food safety. Some of that research contributed to the 2005 *Commodity Specific Food Safety Guidelines for the Melon Supply Chain: 1st Edition,*[47] which was the basis for the 2009 *FDA Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance.*[49] Like Jim Gorny and Stephen Patricio, however, prior to the Jensen Farms outbreak, most of Suslow's expertise in cantaloupe operations was in California and Arizona, where cantaloupe production practices are "the Gold Standard."

'The Gold Standard'

(185) Like Jim Gorny, and Stephen Patricio, Dr. Trevor Suslow reacted with outrage to the details of the audit of Jensen Farms. According to a "speechless" Suslow, "having antimicrobials in *any* wash water, particular the primary or the very first step, is absolutely essential, and therefore as soon as one hears that that's not present, that's an instant red flag. The removal of an antimicrobial would be cause for an auditor or inspector to shut down an entire operation", he said. Suslow's reaction may be consistent with his experiences in operations in California and Arizona, but not the cantaloupe industry at large. Jim Prevor made this point clear in one of his articles about the Jensen Farms case in *Jim Prevor's Perishable Pundit*, "The media is portraying it [standards on washing cantaloupes] as if the Gold Standard practices of a half-dozen large California/Arizona firms are standard throughout the industry. They are not."[34]

(186) "What I would expect from an auditor," Dr. Suslow went on to say, "is that they would walk into the facility, look at the wash and dry lines, know that they weren't using an antimicrobial, and just say: 'The audit's done. You have to stop your operation. We can't continue.'"[8] Unfortunately, Suslow's get tough policy on food safety audits was simply not consistent with any of the audits utilized by certifying bodies, and well beyond any authority of auditors in the United States. Ironically, the FDA who did have the authority "to stop [the] operation", chose not to do so.

(187) James Dilorio, like all private food safety auditors, had no authority to "shut down" Jensen Farms at anytime, and he could only have called an end to the audit if the answer to one of the audit questions would have revealed an automatic failure. An automatic failure means that the auditee is in violation of an FDA regulation. Since there were no FDA regulations on cantaloupe production, James Dilorio had no right to issue an automatic failure and to call an end to the audit on July 25, 2011.

(188) Furthermore, the PrimusLabs audits are specifically designed to reduce auditor subjectivity. The audits are written so that the auditor is simply responding affirmatively or negatively to the questions based upon what he or she has observed, thus preventing PrimusLabs and auditors from interjecting biases. Conducting audits in this manner also provides support for the presiding regulatory authority. Therefore, suggesting that an auditor should unilaterally determine that an auditee has automatically failed an audit based upon an action that is not a violation of government regulation would have the effect of reducing the subjectivity of the audit and undermining the regulatory agency's credibility. For example, if PrimusLabs defined the lack of an oxidizing agent in a single pass spray system using potable water as an automatic failure, it would be in direct conflict with FDA's guidelines and would undercut the FDA and confuse the industry.

(189) Dr. Suslow went on to say, "You have these tremendous hiding places, if you will, nooks and crannies, lots of areas for microbes to get in and attach and hide." He added, "It is best to keep cantaloupes dry to reduce the possibility that bacteria will grow on them. In California, growers typically do not immerse melons in water to wash them and use chilled air to cool them."[29]

(190) Dr. Suslow's point about netted cantaloupe providing hiding places for pathogens to grow is well taken, but he seems to ignore the fact that American cantaloupe buyers are not particularly fond of smooth rind cantaloupe, even though the netted varietals are intuitively more prone to carry more contaminated soil, etc. Smooth rind cantaloupes show bruises more easily, and cantaloupes often suffer visible damage during shipping. Consumers will simply reject bruised melons, and that is why there is a preference for netted cantaloupe.

(191) Dr. Suslow also seems to ignore the fact that not all cantaloupes are grown in California or Arizona. As previously mentioned, in places like Colorado, rain during the growing season leaves too much dirt on the melons. Cantaloupes, grown outside of arid climates simply have to be washed if the supplier expects to sell them.

Suslow Recants

(192) Unlike Jim Gorny and Stephen Patricio, who have not publically recanted their earlier statements, Dr. Suslow came to recognize that he had misspoken. After his public condemnation of the Jensen brothers and James Dilorio in the wake of the outbreak, Suslow walked back his comments two months later. After speaking to the Jensen brothers, he acknowledged "that they believed the postharvest system used in conjunction with the outbreak was an improvement over their previous methods", though he continues to disagree. Furthermore, Suslow has recognized "that the FDA [did] not make a definitive statement in its growing guidelines on the safest method of cleaning, cooling or packing cantaloupe."[11]

(193) Dr. Suslow's recantation spoke loudly of the dangers inherent in condemning others' behavior before bothering to understand it, but the silence of Dr. Gorny and Mr. Patricio spoke even louder, particularly considering the possible impact their comments might have had on the Jensen brothers' criminal case, including their sentencing.

James Prevor

A Cooler Head Prevails

(194) On the other hand, cooler heads did prevail in some corners of the produce industry. One of those cooler heads belonged to James Prevor, currently CEO and Editor-in-Chief at Phoenix Media Network, Inc., the Florida-based publisher of *Jim Prevor's Perishable Pundit* and *The Perishable News*.

(195) Prevor lamented the tendency of some in the industry (Patricio and Suslow in particular) to oversimplify what happened at Jensen Farms and to pillory the auditor and the third party auditing system, "... an audit is not like a grade in high school. One can score very high against a particular standard — say 'standard industry practices'— yet very low against another standard – say 'best practices' — so a grade on an audit means nothing unless you understand fully against what standard one is being graded."[32]

(196) Prevor also understands that, ultimately, it is buyers that determine what to do with a third party audit, and that the role of the auditor is simply to observe and report. "It is worth noting, however, that they [Patricio and Suslow] have not succeeded in persuading Wal-Mart or Costco of [the need for an anti-microbial in single pass wash water]. Neither retailer, nor any other retailer that we are aware of, has a specification on procurement of cantaloupes that all cantaloupes must be washed with an anti-microbial if the water is non-recirculating."[34]

Speak Truth to Power

(197) Finally, Prevor understands that the standards assessed by an audit are not the purview of the auditor, the audit company that employs him/her, or the certifying body, but rather for the FDA to establish and buyers to demand. "Auditors don't write standards and don't write POs. Any buyer has the right to go to Primus or any auditor and say, 'We don't want standard industry practices... we only want to buy world-class best practices. We have no doubt Primus would gladly change its audit and fail people left and right."[34]

(198) Prevor goes on to say, "To expect auditors to impose such standards on the trade without the support of either government regulation or buyer demand is to place bizarre weight on a very thin reed."[34]

(199) "The government, media and academia should understand, though, that, almost by definition, everyone cannot be 'best of class', so demanding a 'best of class' standard will mean flunking lots of producers, indeed most producers. It would mean Wal-Mart would, during the domestic season, buy from the half dozen or so largest packers. Of course, nothing is stopping Wal-Mart from doing that right now."[34] Mr. Prevor's objectivity and common sense truly serve to "speak truth to power," and that power is in the hands of the FDA that establishes regulations, and large retailers that enforce their expectations of producers. The question that ultimately remains is: will the powerful listen?

(200) In perhaps both the most empathetic and the most pragmatic comment about the Jensen Farms tragedy to date, Prevor wisely stated, "May God grant comfort to those who have suffered loss in this affair, and may He grant the industry the wisdom to find a path toward a safer tomorrow."[32]

Litigation Nation

(201) Unfortunately, for some in America today, "comfort" often takes the form of litigation. As has come be expected, the Jensen Farms tragedy resulted in a flurry of lawsuits brought by victims of the cantaloupe contamination, and rightly so. However, in addition to the suits brought against the businesses that are a part of the supply chain, for the first time in U.S. legal history, attorneys for the plaintiffs have brought cases against parties outside of the supply chain that provided services and supplies to the actors in the supply chain. The victims' attorneys are claiming that in providing services to the Jensen brothers, these "third parties" have "a duty to care" for the consumers who ate Jensen

Farms cantaloupe. Pepper Equipment, Bio Food Safety, and PrimusLabs are now named in those lawsuits. All three are being sued for negligence.

(202) Even more incredible, attorneys for some of the supply chain actors are now attempting to sue Pepper, Bio Food Safety and PrimusLabs, contending that those three companies' alleged negligence negatively impacted their brands, and ultimately will cause them to suffer financially. Another lesson to be learned from the tragedy is how flawed this logic is, and how dangerous its consequences may be.

Strict Liability for Supply Chain Actors

(203) Because proving negligence is a far higher legal threshold than strict liability, in the past no U.S. courts have held auditors and audit companies liable in food safety cases. The Jensen Farms tragedy has the potential to change that, and if that happens, it will only exacerbate this tragedy.

(204) So why have the courts previously held that participants in the supply chain are strictly liable for damages done to consumers, while those outside the supply chain are not? The answer to that question may be understood by considering the decision-making that supply chain actors make and the impact that those decisions have on the profit margins of each actor. In the Jensen Farms case, consider some of those decisions.

Financial Upsides and Risk-related Downsides

(205) Jensen Farms chose to label its cantaloupe "Sweet Rocky Fords" to capitalize on the reputation of "Rocky Ford" cantaloupe, even though its melons were not grown in the Rocky Ford appellation. It also labeled its cantaloupe "Pesticide Free" even though there are no means for confirming that anything is "pesticide free." Food suppliers can claim that pesticide levels in their products are "not detectable", but no one can truthfully use the phrase "pesticide free."

(206) Yet, by labeling its cantaloupes as "Pesticide Free" and "Sweet Rocky Fords", Jensen Farms, as well as all the other actors down the supply chain, could garner higher prices for their product. Thus, an exaggeration, oversimplification, or outright lie made by an actor in the supply chain financially benefits each actor farther down the supply chain. In these two cases, the decision-making enhanced the revenues of each actor in the supply chain. In other cases, the decision-making reduced the overhead costs of the supply chain actor, and in so doing, financially benefitted each actor farther down the supply chain.

(207) Despite them having their processing equipment fitted with the tools to include an anti-microbial in their spray wash system, the Jensen brothers chose not to manage and monitor an anti-microbial wash. That decision saved them money, and thus benefitted them financially. It also benefitted every other actor down the supply chain, because if the Jensens' cost of producing cantaloupes was reduced, it could presumably sell its product for less to its buyer Frontera, who could, in turn, sell to its buyers, like Walmart

and Kroger for less money. Every actor in the supply chain benefitted financially from the Jensen brothers' decision to skip the anti-microbial wash.

(208) Notice, however, that while this decision had a financial upside, it had a significant risk-related downside. The same can be said for numerous other production decisions made by the Jensen brothers and the other actors down the supply chain. For instance, Walmart could and, based on their own published protocols, should have required that Jensen Farms conduct a GFSI-Benchmarked audit instead of a "proprietary" audit. The decision saved Jensen and the buyers money. Alternatively, the PrimusLabs "proprietary" audit that Walmart did require of its small growers was also supposed to have included a review of the supplier's HACCP plan. The decision to have a Packinghouse audit without HACCP saved those throughout the supply chain money.

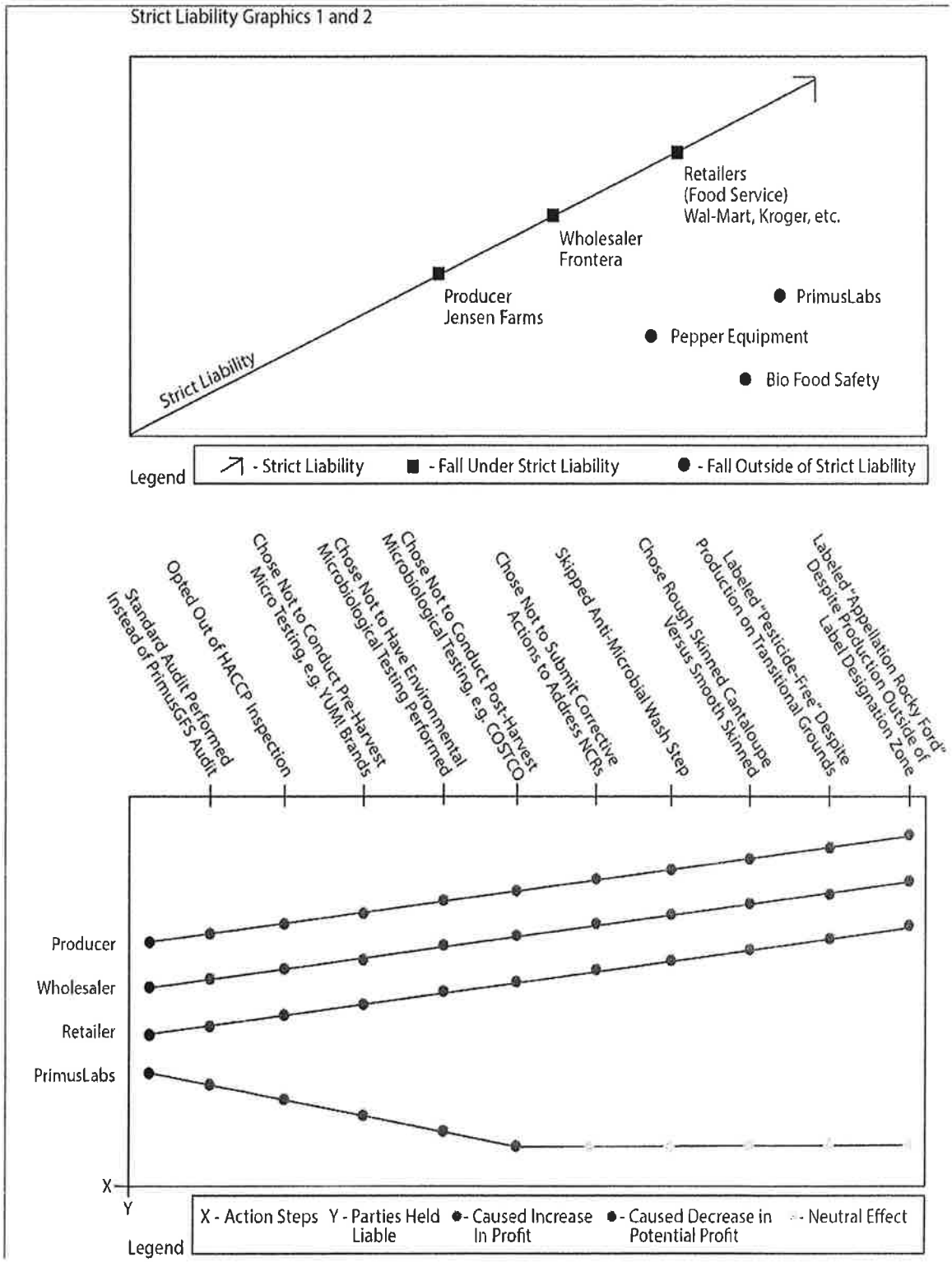
(209) Jensen Farms' buyers could have required pre-harvest microbiological testing. The decision to forego testing saved money, but left everyone ignorant of risk. The Jensen brothers could have submitted corrective actions for their non-compliances, and their buyers could have insisted upon those corrective actions, but they did not. That decision saved money, but left everyone ignorant of risk. Jensen Farms could have produced smooth rind cantaloupe, and their buyers could have insisted on buying smooth rind cantaloupe. Neither did so. The decision increased their revenues, but also left everyone ignorant of risk. This kind of decision-making flies in the face of what has become conventional wisdom in business, namely the implementation of risk-aversion, the avoidance of risky business decisions. It illustrates that a culture that emphasizes safe production and handling constantly competes with other market pressures.

Legal Cases

(210) The point to this discussion is that one of the realities of functioning as a part of the supply chain is that all this decision-making benefitted the actors in that chain, but, in some cases, also increased their liability risks or left all unaware of the invisible hazards present. Since they benefitted financially from the decisions that increased risk, it seems appropriate that they should suffer financially for their decision to reject risk-aversion. Therefore, in the past courts have viewed supply chain actors as strictly liable for their food.

(211) Conversely, the parties who are not a part of the supply chain have previously not been held strictly liable. This seems appropriate because these parties are not a part of the decision-making made by supply chain actors, do not benefit financially from that decision-making, and have no control over the supply chain parties' actions. PrimusLabs, Pepper Equipment, and Bio Food Safety did not, in any way, benefit from the decision-making outlined above. In fact, in some cases, they may actually have been hurt financially by those decisions.

Figure 11.


Strict Liability Graphics 1 and 2
Strict Liability
Producer
Jensen Farms
Wholesaler
Frontera
Retailers
(Food Service)
Wal-Mart, Kroger, etc.
PrimusLabs
Pepper Equipment
Bio Food Safety
Legend
- Strict Liability
- Fall Under Strict Liability
- Fall Outside of Strict Liability
Standard Audit Performed Instead of PrimusGFS Audit
Opted Out of HACCP Inspection
Chose Not to Conduct Pre-Harvest Micro Testing, e.g. YUM! Brands
Chose Not to Have Environmental Microbiological Testing Performed
Chose Not to Conduct Post-Harvest Microbiological Testing, e.g. COSTCO
Chose Not to Submit Corrective Actions to Address NCRs
Skipped Anti-Microbial Wash Step
Chose Rough Skinned Cantaloupe Versus Smooth Skinned
Labeled "Pesticide-Free" Despite Production on Transitional Grounds
Labeled "Appellation Rocky Ford" Despite Production Outside of Label Designation Zone
Producer
Wholesaler
Retailer
PrimusLabs
X
Y
Legend
X - Action Steps
Y - Parties Held Liable
- Caused Increase In Profit
- Caused Decrease in Potential Profit
- Neutral Effect

(212) For instance, when Jensen Farms, Frontera Produce, Walmart, and Kroger decided not to conduct PrimusGFS audits, decided not to conduct an audit that reviewed Jensens HACCP plan, and decided not to conduct microbiological tests of their products or their packinghouse environment, PrimusLabs and Bio Food Safety lost potential revenues. All of the decisions made by the actors in the supply chain had positive financial effects on them, but had either negative financial effects or neutral effects on the third parties that function outside the supply chain.

(213) For this reason, historically, the entities that exist outside of the supply chain have not been held financially liable for the decision-making that was conducted by actors within the supply chain. Thus, it is difficult to understand why PrimusLabs, Bio Food Safety, and Pepper Equipment should be party to any of the lawsuits that have been brought by plaintiffs in the Jensen Farms cases, and, even more difficult to understand why they would be liable to the other supply chain actors who, unlike them, had control over the tainted products that they distributed. **See Figure 11 – Strict Liability Graphics.**

Opening Pandora's Box

(214) Considering all of the issues associated with liability, what are the broader implications of suing third parties? Do the lawsuits filed against PrimusLabs, Bio Food Safety, and Pepper Equipment open the door to government agencies being sued for audits that they perform or inspections they conduct? If a city, county, or state health department grades a restaurant with an "A" rating and that restaurant's food causes sickness or death, can the victims or the victims' families sue those government agencies? Does a broader definition of "a duty to care" mean that the USDA or the FDA can be sued for their failure to prevent a food producer from distributing contaminated food?

(215) Witness the recent outbreak of *Salmonella* at the facilities of Foster Farms, a California poultry producer. USDA officials are present during all times of operation at each and every Foster Farms plants. Despite the distribution of *Salmonella*-tainted chicken in October 2013, USDA did not ask Foster Farms to recall their products. Instead, the agency's inspectors allowed the company's plant to remain open, but instead warned consumers to increase the temperature at which they cooked their chicken in an effort to kill the *Salmonella*.[26] Apparently, that strategy did not work. Since that warning, Foster Farms chicken, contaminated with *Salmonella,* has continued to sicken people in a number of states. If PrimusLabs can be sued for a single audit performed for one of its clients on a single day, shouldn't the USDA be sued for failing to control *Salmonella*-tainted chicken that has been distributed for over five months under their direct supervision every hour of every work day?

(216) These are, of course, all hypothetical and possibly even absurd questions, but they pose valid concerns about the precedent established by suing third party auditing companies or a farm equipment company because they have done business with a farmer whose food has made people sick. Do these cases have the potential to set a legal precedent that may have severely detrimental and far-reaching consequences? Are these lawsuits opening a Pandora's Box that can never be closed?

More Lessons To Be Learned

(217) Another lesson that the Jensen Farms tragedy taught the fresh produce industry is the truth that Jim Prevor spoke of with respect to improving standards. In the produce industry, the only entity that has regulatory powers is the FDA. Rather than initiating industry changes that are reflexive and reactionary, FDA needs to take the lead in proposing changes before tragedies occur.

(218) For instance, if using an anti-microbial in all kinds of wash systems will reduce the risk of pathogen contamination, then the FDA should make that practice a regulation. People like Jim Gorny, Stephen Patricio, and Trevor Suslow have excellent hindsight, but if it was so obvious that an anti-microbial wash could have prevented *L. mono* at Jensen Farms, why wasn't using an anti-microbial an FDA regulation? If it had been, Walmart, Kroger and Frontera would not likely have purchased from the Jensen brothers *unless* they were using an anti-microbial wash, and the industry standard would have been raised. The same could be said for regulations regarding the pre-cooling of melons.

(219) Note that adding regulations would not have appreciably changed audit scores, the distribution of audit scores, or auditor behavior. **See Figure 7 on pg. 25**. What it would have done, however, is far more important. It would have raised the industry's standard practices, and subsequently the audit standards, and in so doing decreased the risks of contamination and possibly saved lives.

(220) If the lives lost and the suffering incurred in the Jensen Farms outbreak are not to be in vain, then government agencies must work together with the industry to change food safety standards. But it is the FDA that must precipitate that change through regulation.

All Boats Rise with the High Tide

(221) If there is any good that can come from the Jensen Farms tragedy, for the sake of American consumers, change needs to occur within the FDA. FDA knows well that it cannot inspect every farm, packinghouse, cold storage and processing facility, or distribution center in the United States. Dr. Gorny himself conceded this point when he said, "We [the FDA] can't be everywhere all the time. It's just not possible."[39] It has to rely on third party auditors to perform most of those inspections and buyers to hold producers to the standards that the industry agrees must be upheld. But instead of generating only "guidance", which "Contains Nonbinding Recommendations", the FDA needs to find the appropriate balance between guidance and regulation. Distinguishing the difference between the appropriate guidance and the appropriate regulation for the melon industry might be as simple as a review of the FDA's pre-crisis and post-crisis comments in the Jensen Farms tragedy. Its Monday morning quarterbacking on issues like the use of an anti-microbial agent in all melon wash water or the pre-cooling of melons before cold storage would seem an appropriate place to begin the development of regulations for the melon industry. The agency's hindsight was crystal clear when it came to these two issues, so why not make them regulations that the industry is obliged to follow.

(222) Furthermore, when it comes to shifting from guidance to regulation, it would seem appropriate for the FDA to climb out of its Beltway cocoon and seek the input of organizations that function at the grassroots of the fresh produce industry – those with "boots on the ground." There is much that government officials can learn from the industry itself, and it does not all have to be filtered through the largest, most affluent, or most powerful entities in fresh produce.

(223) Finally, if a suppliers' failure to follow government regulations causes illnesses and death, that supplier *should* be prosecuted. But when the FDA "guidance" is so vague that even the FDA inspectors themselves don't know what the guidance specifies, its "guidance" isn't guiding anyone. If it knows what needs to be done to prevent food contamination, FDA needs to put the force of law behind at least some of its "guidance", and turn some of that guidance into regulation.

(224) The people at the FDA are undoubtedly like everyone else in society. They have their strengths and their weaknesses. Still, some of their comments suggest that they don't understand how the fresh produce industry operates. They see one or two or three or ten farms operating in the most affluent agricultural areas of the nation, and then assume that the "standards" implemented there are in place everywhere else in the United States. To quote Jim Prevor, "They are not." They also don't seem to understand the role that the FDA itself plays in setting and, when science dictates, strengthening standards. If FDA believes that standards are not stringent enough, it knows full well how they can be raised, and it knows full well that everyone who wants to be successful will rise to meet those higher standards. Ultimately, all boats rise with the high tide.

(225) In the aftermath of the Jensen Farms tragedy, Dr. Gorny candidly stated the role of officials at the FDA. "Our job is not to make food safe. Our job is to set the standards and make sure that people are complying with them" said Gorny, "a private auditor before joining the FDA."[39] Unfortunately, if the FDA does not successfully perform the former, it cannot accomplish the latter.

Farming Is Hard Enough As It Is

(226) Farming is hard enough as it is, so when something bad happens to our nation's food supply and that, unfortunately, is inevitable, why make matters worse by vilifying honest people, especially the people who are trying to follow the rules? Eric and Ryan Jensen obviously made mistakes, but no one believes that they wanted to see others get sick and die. So why did the Federal government criminalize conduct like theirs that everyone knows is "without malice or forethought?" If the District Attorney who brought the charges against the Jensen brothers was considering giving up law to pursue farming, would he have thought differently about bringing these charges?

(227) The statute says that introducing adulterated food into commerce is against the law. That alone made the legal prosecution of the Jensen brothers "an open and shut case." But when the adulteration is invisible and undetectable, when the farmers have followed all regulations and tried to follow all the guidance that the government offers, and when the farmers are working on "improving their processes", why should they be punished for

their honest mistakes? As Dr. Trevor Suslow recently asked, "The FDA itself noted that their food safety guidance specifically states single-pass, non-recirculated wash water from a municipal source does not require further antimicrobial treatment... so how is this a criminal misdemeanor to have failed to 'chlorinate'? [33]

Sometimes Actions Speak Louder than Words...

(228) Ultimately, the people in the FDA must be judged by their own actions. In the Jensen Farms outbreak, let's review those actions. The FDA had no regulations on cantaloupe production. The guidance that it wrote was vague and/or overly complex and was poorly and often inaccurately communicated to the victims, the industry, and the media. When two farmers sickened hundreds and killed dozens with *L. mono* contaminated cantaloupes while following that FDA guidance, the FDA spent huge sums of money to investigate them at the height of their production season, found their operation "demonstrating widespread contamination... and poor sanitary practices" (20 October, 2011, *The Denver Post*), but chose to do nothing to warn consumers until, as Jim Gorny proclaimed, they had "evidence... [of] a smoking gun."[8]

(229) Then, the FDA spent considerably more money conducting a second "root-cause investigation" of the farmers' fields and packinghouse, which produced much speculation, but ultimately provided no determination of the root cause of the *L. mono* contamination.

(230) Next, the FDA, with questionable knowledge or understanding of the majority of the cantaloupe producers nationwide, proclaimed loudly and widely that these farmers were bad players in the industry. They went on to vilify the auditor who had observed and reported on these farms and packinghouse as "seriously deficient" in his audit. They came to this conclusion, because, among other things, they focused their attention on the score he assigned and on the simplistic belief that the audit is a pass/fail assessment of food safety. They felt that because he only commented on, but did not fail, the farmers for implementing a process that included a piece of equipment that they had purchased to improve their operation, he must have been incompetent. Instead of understanding that the comments that he made provided direction to the farmers so they could act on his observations, FDA suggested that he was too young and too inexperienced to do his job well. Most egregiously, the FDA wasted an opportunity to help the industry to understand how to use an audit to improve food safety. Finally, FDA officials repeated their misleading statements that these farmers were aberrant players in the cantaloupe industry to federal prosecutors.

(231) For one of the only times in U.S. history, a U.S. district court brought criminal charges against fresh produce supply chain actors who had never before harmed anyone with their food, had never before been inspected or warned by the FDA, but had inadvertently, unintentionally, and quite tragically produced contaminated food that made some people sick and others die.

… But Sometimes Words Speak Quite Loudly

"This is a packing facility for cantaloupes [Jensen Farms] which are washed by a spraybar 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." – **James Dilorio, Auditor, Bio Food Safety, PrimusLabs Audit #150236 – July 25, 2011**

"Jensen Farms significantly deviated from industry standards by failing to use an anti-microbial, such as chlorine, in the packing of their cantaloupes during the summer of 2011." – **Dr. James R. Gorny, FDA, Senior Advisor for Produce Food Safety- Cited on January 17, 2014**

"They [those who were critical of Jensen Farms] have not succeeded in persuading Wal-Mart or Costco of [the need for an anti-microbial in single pass wash water]. Neither retailer, nor any other retailer that we are aware of, has a specification on procurement of cantaloupes that all cantaloupes must be washed with an anti-microbial if the water is non-recirculating." – **Jim Prevor, Editor, *The Perishable News* and *Jim Prevor's Perishable Pundit* – October 23, 2011**

"The FDA itself noted that their food safety guidance specifically states single-pass, non-recirculated wash water from a municipal source does not require further antimicrobial treatment… so how is this a criminal misdemeanor to have failed to 'chlorinate'"? – **Dr. Trevor Suslow, Extension Research Specialist at the University of California – Davis, Department of Plant Sciences - November 22, 2011**

"We want to emphasize that there's no reason to believe that these factors [Jensen Farms manufacturing practices] are indicative of practices throughout the industry. I'd say that they were fairly unique." - **Sherri McGarry, FDA, Senior Advisor of the Core Network – October 19, 2011**

"Observations [by FDA] are included and cited as potential contributing factors to potential contamination even though those same observations could be made at hundreds or perhaps thousands of production operations around the world." – **Dr. Robert Whitaker, Produce Marketing Association, Chief Science and Technology Officer – January 27, 2014**

"It's just disgusting to me. I think of the damage that they've [Jensen Farms and PrimusLabs] done to our industry as the result of this oversight. No, I won't even talk about it as oversight; it's abuse." – **Stephen Patricio, Chairman, California Cantaloupe Association and Center for Produce Safety – October 20, 2011**

"The FDA [did] not make a definitive statement in its growing guidelines on the safest method of cleaning, cooling or packing cantaloupe." — **Dr. Trevor Suslow, Extension Research Specialist at the University of California – Davis, Department of Plant Sciences – November 22, 2011**

"The Primus Labs subcontractor that conducted the pre-harvest inspection of Jensen Farms was seriously deficient in its inspection and findings." – **Dr. James R. Gorny, FDA, Senior Advisor for Produce Food Safety – October 24, 2013**

"What I would expect from an auditor is that they would walk into the facility, look at the wash and dry lines, know that they weren't using an antimicrobial, and just say: 'The audit's done. You have to stop your operation. We can't continue.'" – **Dr. Trevor Suslow, Extension Research Specialist at the University of California – Davis, Department of Plant Sciences – October 20, 2011**

"To expect auditors to impose such standards on the trade without the support of either government regulation or buyer demand is to place bizarre weight on a very thin reed"– **Jim Prevor, Editor, *The Perishable News* and *Jim Prevor's Perishable Pundit* – October 23, 2011**

"Our job is not to make food safe. Our job is to set the standards and make sure that people are complying with them" – **Dr. James Gorny, FDA Senior Advisor for Product Food Safety – August 14, 2012**

(232) Since those events, the FDA has done little to significantly improve its guidance to the cantaloupe industry and has still not written a single regulation on cantaloupe production. It has failed to disavow the misleading statements made by its employees, statements that have been repudiated by perhaps the foremost authority on cantaloupe production in the United States and one of the leaders of the one of the largest produce associations in the nation.

Accountability Is a Two Way Street

(233) Why is the FDA's investigation of Jensen Farms not held to the same standards that James DiIorio's audit was? If it had been, it would be clear that the FDA failed to meet those standards. Then, it turned around and blamed James DiIorio who had no business being held to those standards. James DiIorio did his job – he observed and reported - nothing more and nothing less. He may not be a hero, but he certainly is not a villain. He should not be treated as if he is one.

(234) Nearly everyone involved in this case is being held accountable to some standards of conduct and scrutiny, whether they are legal, liability, or industry-related standards or public or media scrutiny. The Jensen brothers are being held to legal standards. The Jensen brothers, Frontera Produce, Walmart, Kroger and other retailers are being held to liability standards. James DiIorio, Bio Food Safety, Pepper Equipment, and PrimusLabs are being held to the standards of the industry and the scrutiny of the media and the public at large. Only the FDA seems to be above any standards and any scrutiny. If the well-meaning people at the FDA subscribe to "the Golden Rule", God forbid that they be held to the standards to which that they have held James DiIorio and private sector auditors, because those standards far surpass those to which they hold themselves.

VII. CONCLUSIONS – WHERE DO WE GO FROM HERE?

(235) Moving forward is always a difficult proposition in a situation in which so many people have been hurt, but using what happened at Jensen Farms to make the fresh produce industry better is one of the best ways in which to honor those who were lost. Nearly every entity involved in this tragic set of circumstances – growers, distributors, buyers, academics and Federal officials - can gain valuable insight into how to work smarter and produce better products. In an appropriate conclusion to this tragic story, let us turn our attention to three areas of focus.

Audit Reading and Comprehension

(236) Audits are only as good as the depth of attention paid to them. Reading an audit report should mean more than looking at the score on the front page, and assuming that the score ensures the safety of the food produced by the auditee. If buyers really believe that "the auditor's comments are the most important part of the report", they need to read those comments. Frequently, as in the case of James DiIorio's Jensen Farms audit, critically significant comments are made on issues that have absolutely no effect on the audit score. Case in point, Mr. DiIorio mentioned the absence of an anti-microbial in the

Jensen brothers' wash water five times in his audit, but the absence did not affect the score of the audit one iota.

(237) Furthermore, everyone down the supply chain from the auditee needs to read and comprehend the audit fully. Since all distributors and buyers, as well as the suppliers themselves, are strictly liable for the food that they handle, their reputations, as well as their financial well-being, are dependent on a true understanding of the audit report. If the buyer has particular demands, someone within the buyer's organization needs to be sure that those demands are met. If buyers do not have an individual or individuals to perform this task, they can hire someone outside the organization to do so. Buyers can pool their resources by sharing a subcontractor to supply these services. It does no good to expect auditees to meet buyer requirements if those buyer requirements cans be flouted without consequences. To do so can only serve to create confusion for both entities. Most importantly, the audit report must be used by the supplier to upgrade his food safety practices. Even if the supplier earned a score of "100", there is almost certainly information in the audit report that can help him or her to address risk and improve production and handling practices related to food safety. Buyers want auditees to address audit information and to improve their practices for the benefit of their customers. Farmers, distributors, retailers, and other end users all have a "duty to care" for consumers. Caring means paying attention to the content of food safety audits.

(238) Finally, everyone needs to know exactly what the audit is measuring. If the audit is an assessment of the standard practices of the industry, the reader can not comprehend it to confer the implementation of best practices. As Jim Prevor said, "an audit is not like a grade in high school", therefore, a "96" on a standard practice audit is not an "A" that suggests excellence.

Utilizing All Available Resources

(239) If American business and government have learned anything in the past 50 years, it should be that we all have to accomplish more with fewer resources. Therefore, it only makes sense that we should utilize all of the resources that could be available to us, rather than relying only on our own individual human resources or technical expertise. Jim Gorny is right to say that the FDA "can't be everywhere all the time." Therefore, FDA should take advantage of the work that other agencies of government or other private businesses produce, so that it can do its job better. For instance, the CDPHE began pulling samples for *L. mono* testing of Jensen Farms' cantaloupe on September 5, and though it was fine for FDA to have pulled its own samples four days later, it seems odd of them to have ignored the CDPHE's confirmation of *L. mono* contamination on September 11. Had it relied on the work that the CDPHE had done, the FDA would have been able to address the crisis three days earlier than it did.

(240) If a private business can get work done faster than the Federal government, why not take advantage of that resource? If the FDA needs lab results that will take its scientists five days to generate and a private firm can produce those results in two days, the FDA should utilize the services that the private firm can supply. If a private firm has a more complete picture of an industry, why not solicit their services? That does not suggest that

one is better than the other, but by working together business and government can accomplish more and produce better results.

(241) Conversely, if government agencies develop procedures or processes that can benefit private business and enhance profitability, doesn't everyone benefit by that sharing of that information? More profitable businesses generate more tax revenues which benefits government agencies, and government agencies with greater financial resources can advance innovation and scientific study that can provide private business with valuable information with which to grow and prosper.

(242) Finally, intergovernmental cooperation, and collaboration between government and private business has benefits beyond the conservation of resources. Working together generates relationship building that can have efficacious effects on future collaboration. Agencies that work with other agencies are simply more effective than those that do not.

Using Data to Advance Food Safety

(243) The most valuable resource that can be offered to the fresh produce industry is data, and the analysis of that data is the future of food safety. Scientific information has value for every entity involved in food production, so it only makes sense that growers, distributors, buyers, academia, and government officials utilize the analysis that science can generate for the advancement of all. For instance, farmers can benefit tremendously from data analysis of audit results to examine which areas of audits are most overlooked. Then, educators, such as agricultural outreach offices, can focus on those areas in their farmer training courses. Likewise, buyers can examine environmental and product testing results for pathogen detection to pinpoint which pathogens are most likely to occur at particular stages of processing.

(244) Governmental oversight agencies that rely on validation studies done at the university level or by private businesses will be better able to conduct regulatory inspections that can prevent contaminated food from making its way into the marketplace.

(245) The data is already available. It is already being compiled and analyzed. It just needs participants in the industry to read it and, based upon its findings, to act. Doing so can effect many changes to agricultural and manufacturing processes that can improve food production and safety.

(246) Dr. Gorny may well be right when he says, the FDA's " job is not to make food safe", but for the sake of the people who got sick or died from eating Jensen Farms cantaloupe, it has to be somebody's job.

Figure 1.

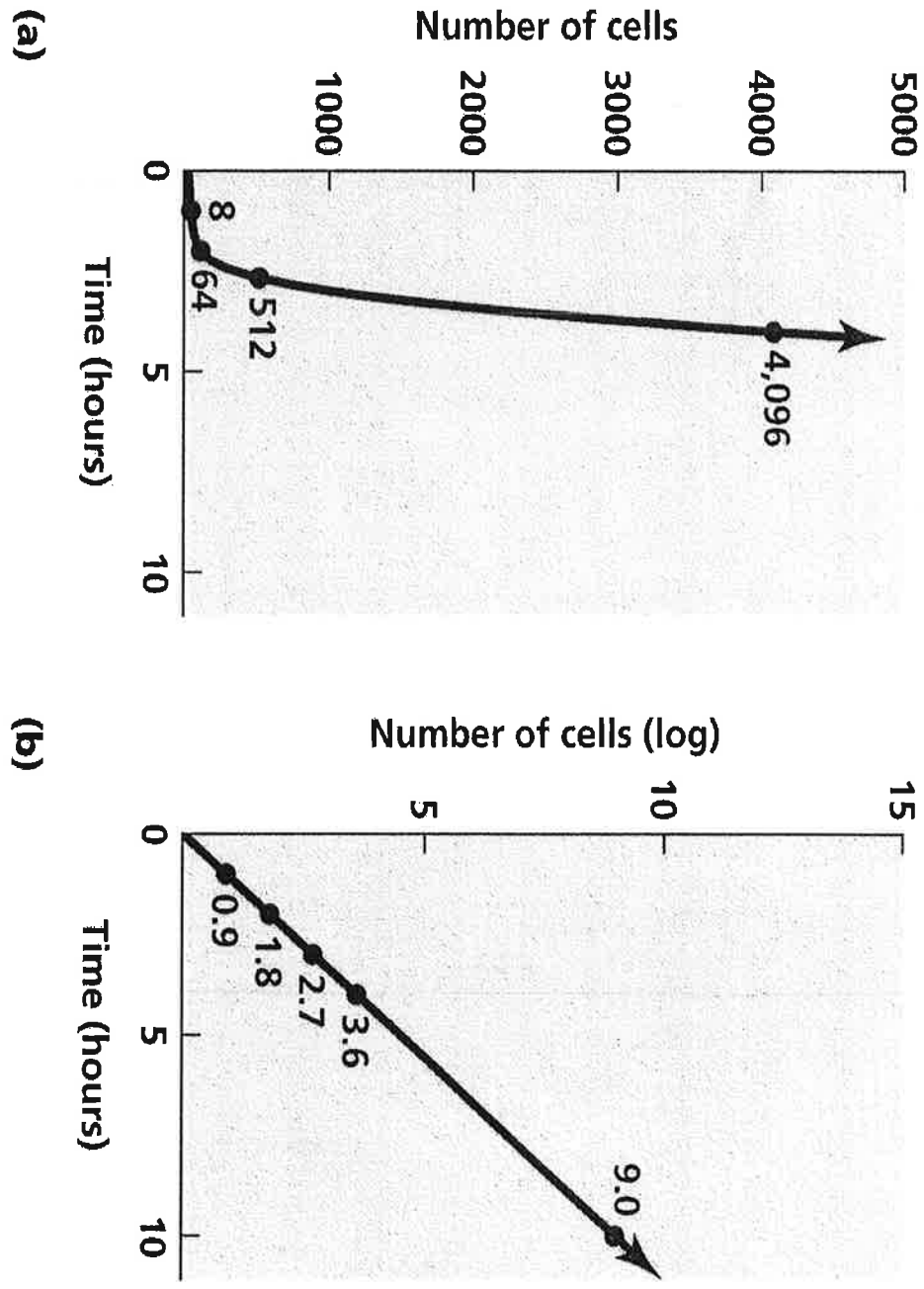


Figure 2.

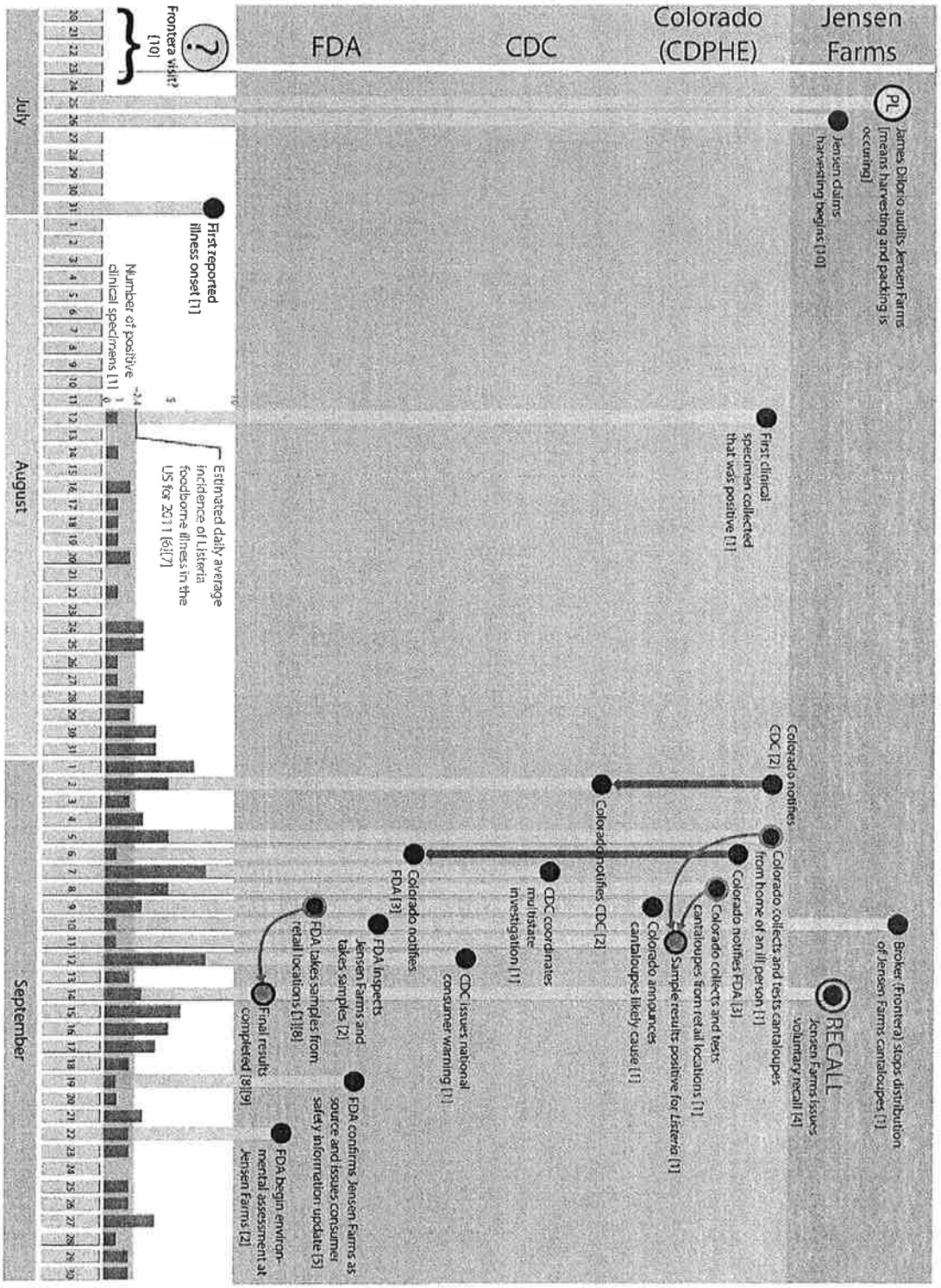

Timeline of Events
Privileged Information - Attorney Work Product
Jensen Farms
Colorado (CDPHE)
CDC
FDA
James Dilorio audits Jensen Farms [means harvesting and packing is occuring]
Jensen claims harvesting begins [10]
Broker (Frontera) stops distribution of Jensen Farms cantaloupes [1]
RECALL
Jensen Farms issues voluntary recall [4]
Colorado notifies CDC [2]
First clinical specimen collected that was positive [1]
Colorado collects and tests cantaloupes from home of an ill person [1]
Colorado notifies FDA [3]
Colorado collects and tests cantaloupes from retail locations [1]
Sample results positive for Listeria [1]
Colorado announces cantaloupes likely cause [1]
Colorado notifies CDC [2]
CDC coordinates multistate investigation [1]
CDC issues national consumer warning [1]
Colorado notifies FDA [3]
FDA inspects Jensen Farms and takes samples [2]
FDA takes samples from retail locations [1][8]
Final results completed [8][9]
FDA confirms Jensen Farms as source and issues consumer safety information update [5]
FDA begin environmental assessment at Jensen Farms [2]
First reported illness onset [1]
Frontera visit? [10]
Estimated daily average incidence of Listeria foodborne illness in the US for 2011 [6][7]
Number of positive clinical specimens [1]
July
August
September

Figure 2b - Timeline Citations.

Privileged Information - Attorney Work Product

Citations for Timeline of Events

1. Centers for Disease Control and Prevention (December 8, 2011). Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado. Retrieved March 26, 2014. http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/110211/timeline.html
2. Committee on Energy and Commerce (January 10, 2012). Report on the Investigation of the Outbreak of *Listeria monocytogenes* in Cantaloupe at Jensen Farms. Retrieved March 26, 2014. http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/20120110Listeria.pdf
3. Food and Drug Administration (October 19, 2011). Results of the FDA-Led Root Cause Investigation of the Multi-State Listeria Outbreak Related to Jensen Farms Cantaloupe. Retrieved March 26, 2014. http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM277070.pdf
4. Food and Drug Administration (September 14, 2011). Recall – Firm Press Release: Jensen Farms Recalls Cantaloupe Due to Possible Health Risk. Retrieved March 26, 2014. http://www.fda.gov/Safety/Recalls/ucm271879.htm
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9. Food and Drug Administration. Jensen Farms, Granada, CO Sample Records (Last Update: September 2, 2012). Retrieved April 2, 2014. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/ucm276709.htm

Figure 3.

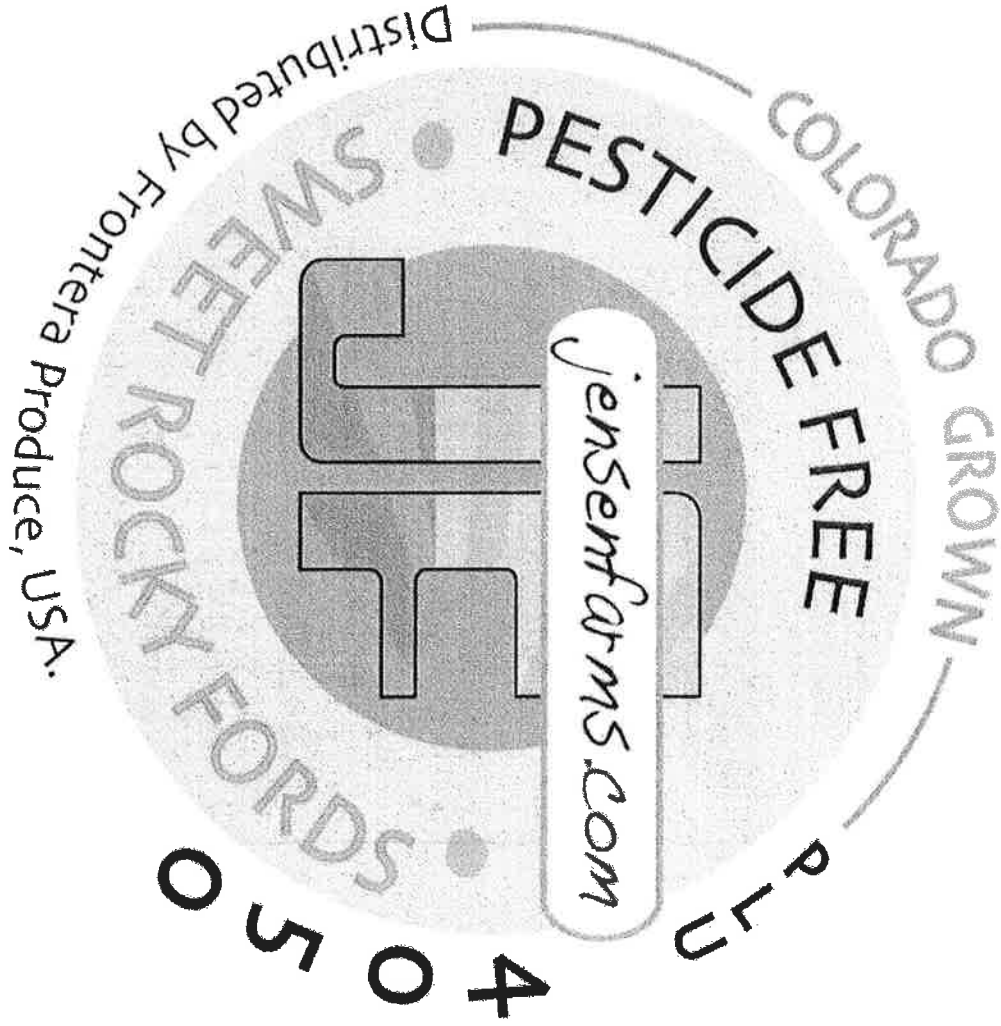

COLORADO GROWN
PESTICIDE FREE
PLU
5040
SWEET ROCKY FORDS
jensenfarms.com
Distributed by Frontera Produce, USA.

Figure 4.

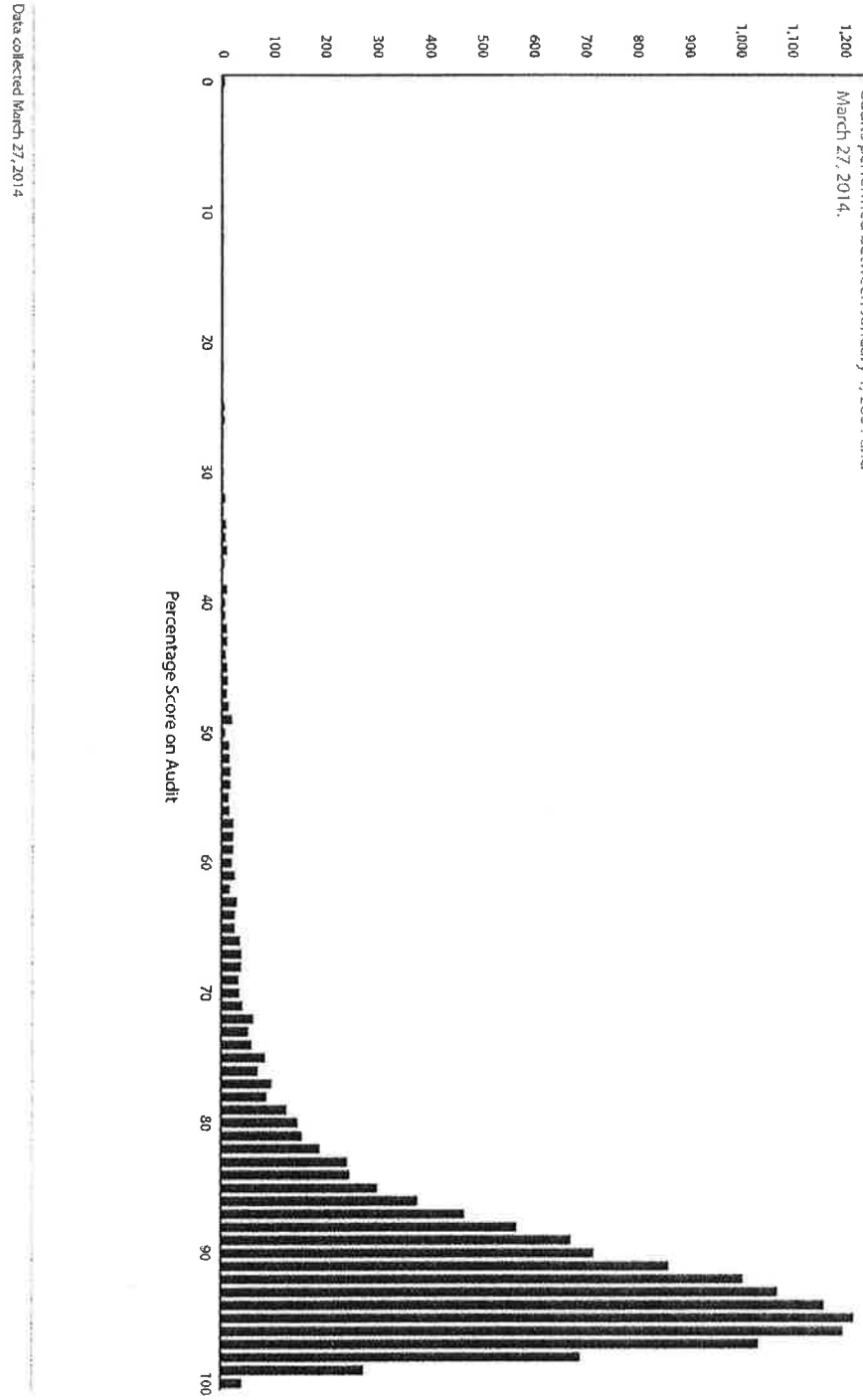
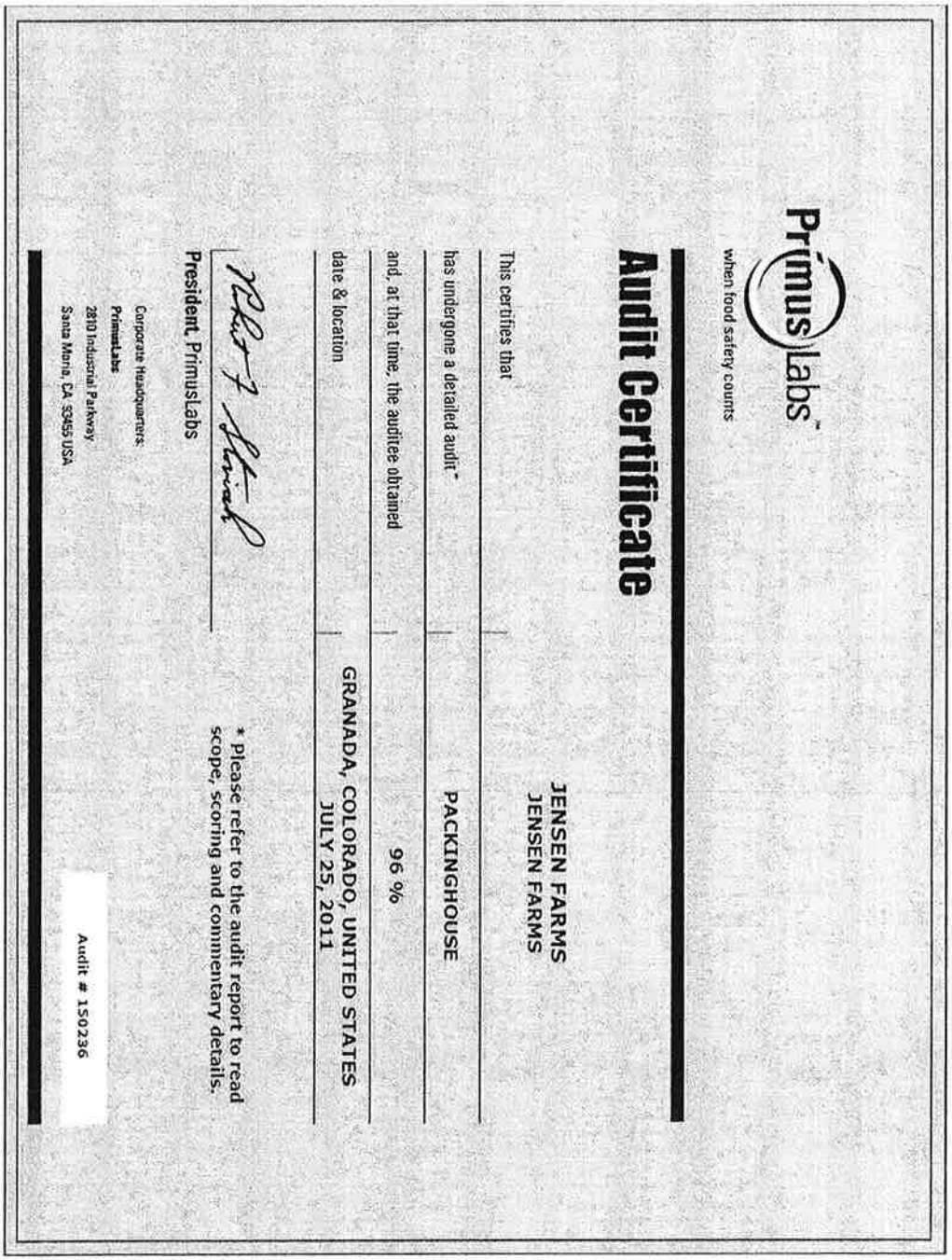

PrimusLabs Proprietary GMP audit scores from January 1, 2001 to March 27, 2014
Number of Audits for each Score
1,300
1,200
1,100
1,000
900
800
700
600
500
400
300
200
100
0
There were 14,112 PrimusLabs Proprietary GMP audits performed between January 1, 2001 and March 27, 2014.
0
10
20
30
40
50
60
70
80
90
100
Percentage Score on Audit
Data collected March 27, 2014

Figure 5.



PrimusLabs™

when food safety counts

Audit Certificate

This certifies that

JENSEN FARMS
JENSEN FARMS

has undergone a detailed audit*

PACKINGHOUSE

and, at that time, the auditee obtained

96 %

date & location

GRANADA, COLORADO, UNITED STATES
JULY 25, 2011

* Please refer to the audit report to read scope, scoring and commentary details.

President, PrimusLabs

Corporate Headquarters:
PrimusLabs
2810 Industrial Parkway
Santa Maria, CA 93455 USA

Audit # 150236

Figure 6.

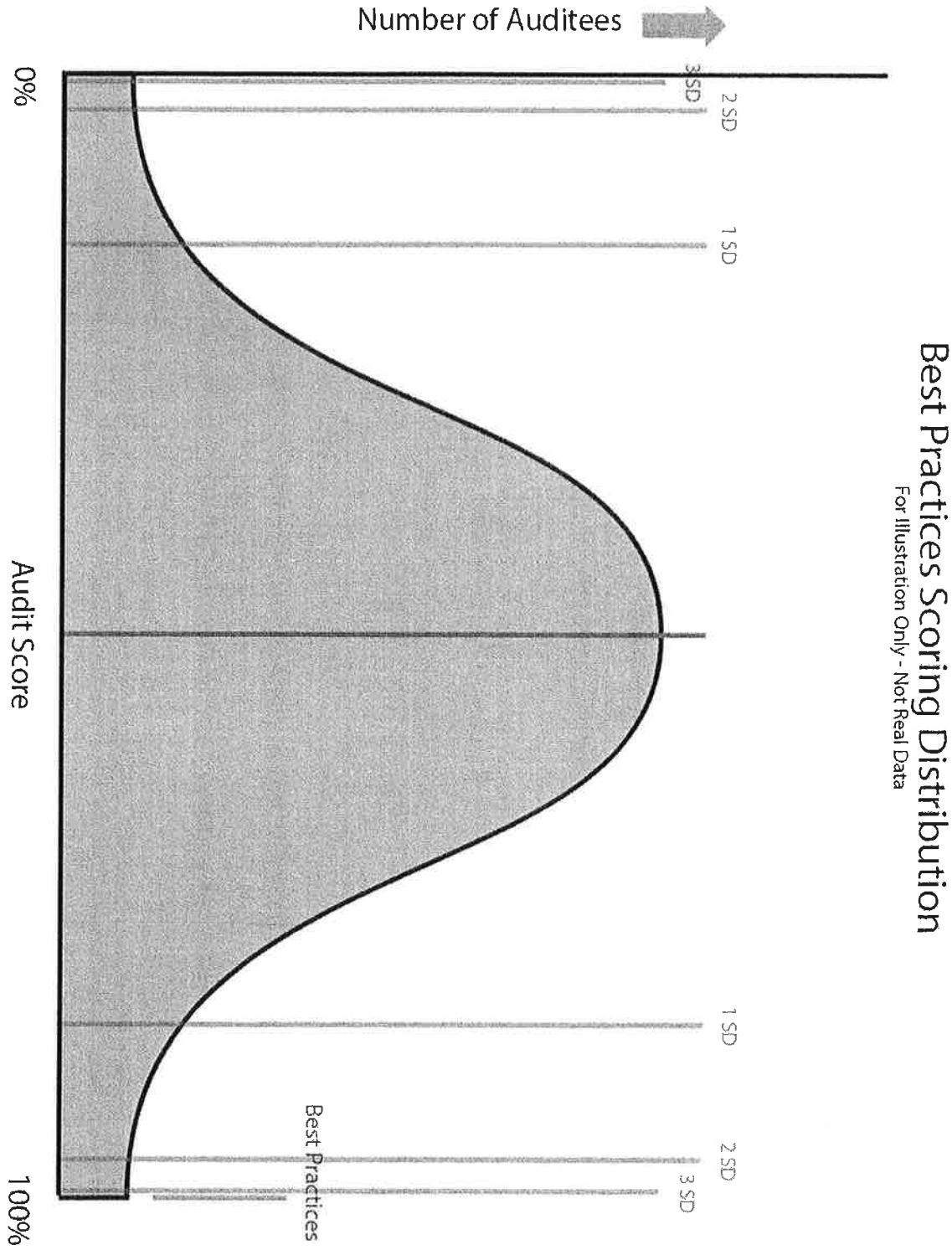

Best Practices Scoring Distribution
For Illustration Only - Not Real Data
Number of Auditees
0%
Audit Score
100%
3 SD
2 SD
1 SD
1 SD
2 SD
3 SD
Best Practices

Figure 7.

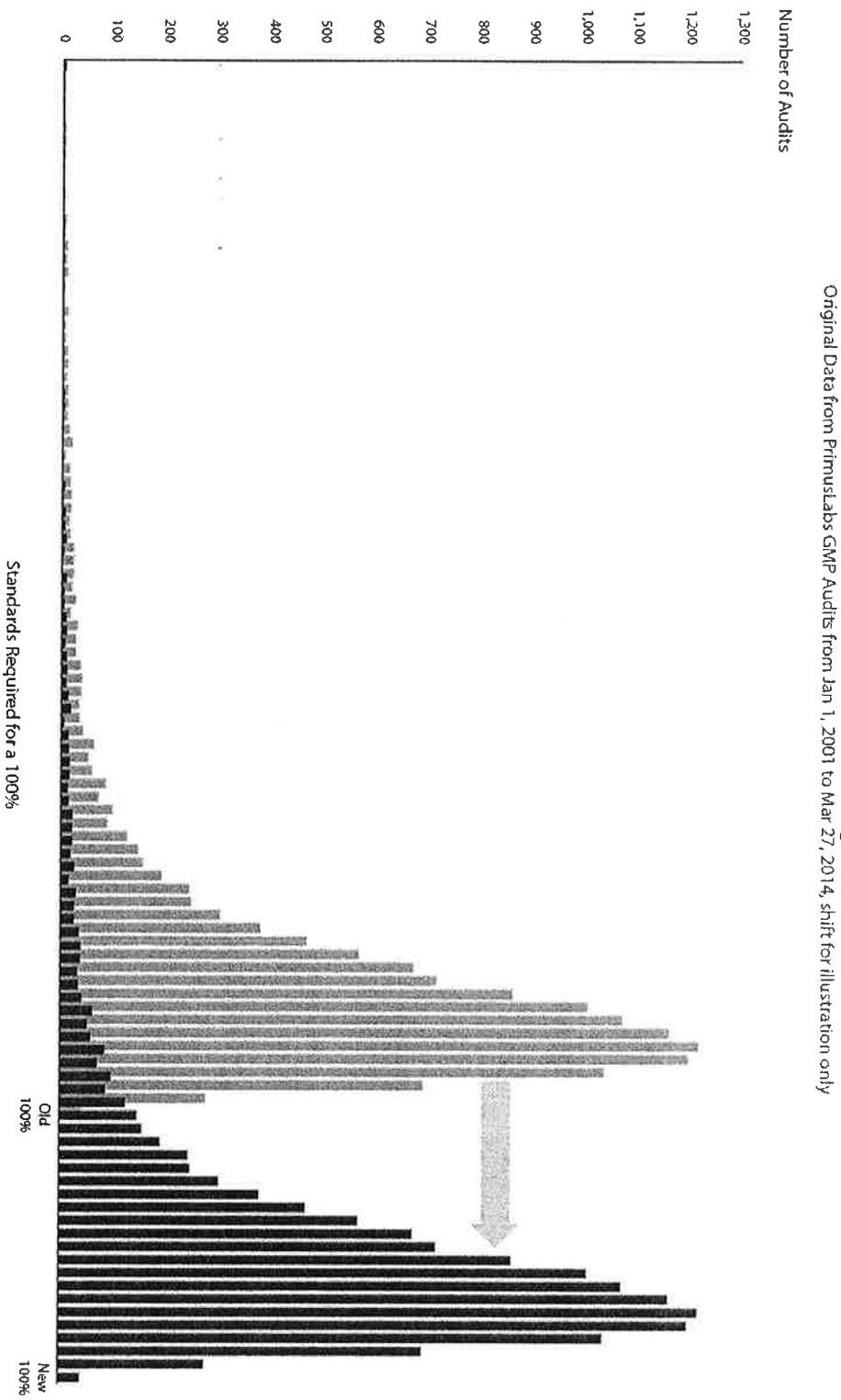

Impact of Raising Standards on Audit Scoring Distributions
Original Data from Primuslabs GMP Audits from Jan 1, 2001 to Mar 27, 2014, shift for illustration only
Number of Audits
1,300
1,200
1,100
1,000
900
800
700
600
500
400
300
200
100
0
Old
100%
New
100%
Standards Required for a 100%

Figure 8.

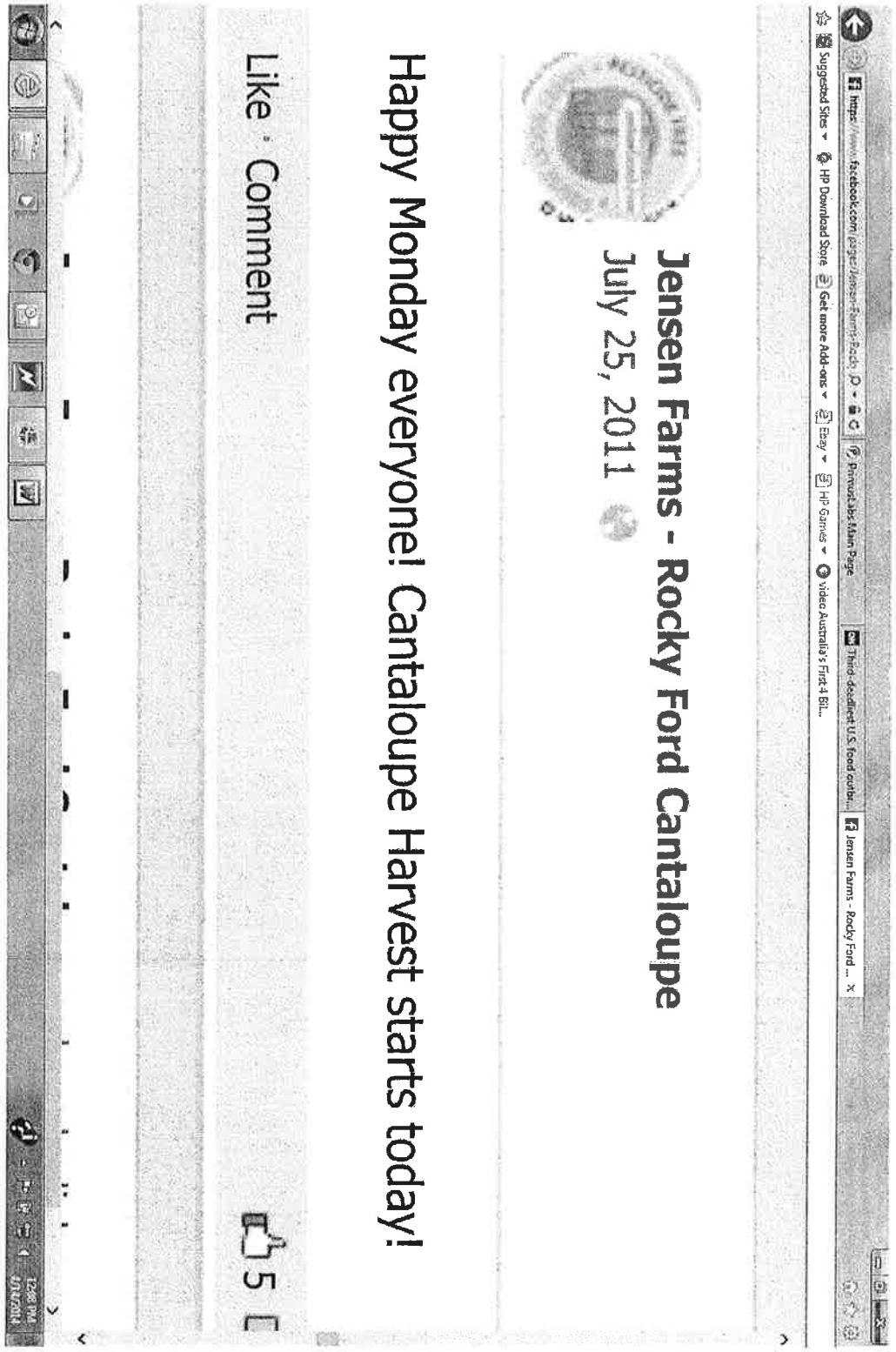

Jensen Farms - Rocky Ford Cantaloupe
July 25, 2011
Happy Monday everyone! Cantaloupe Harvest starts today!
Like · Comment
5

Figure 9.

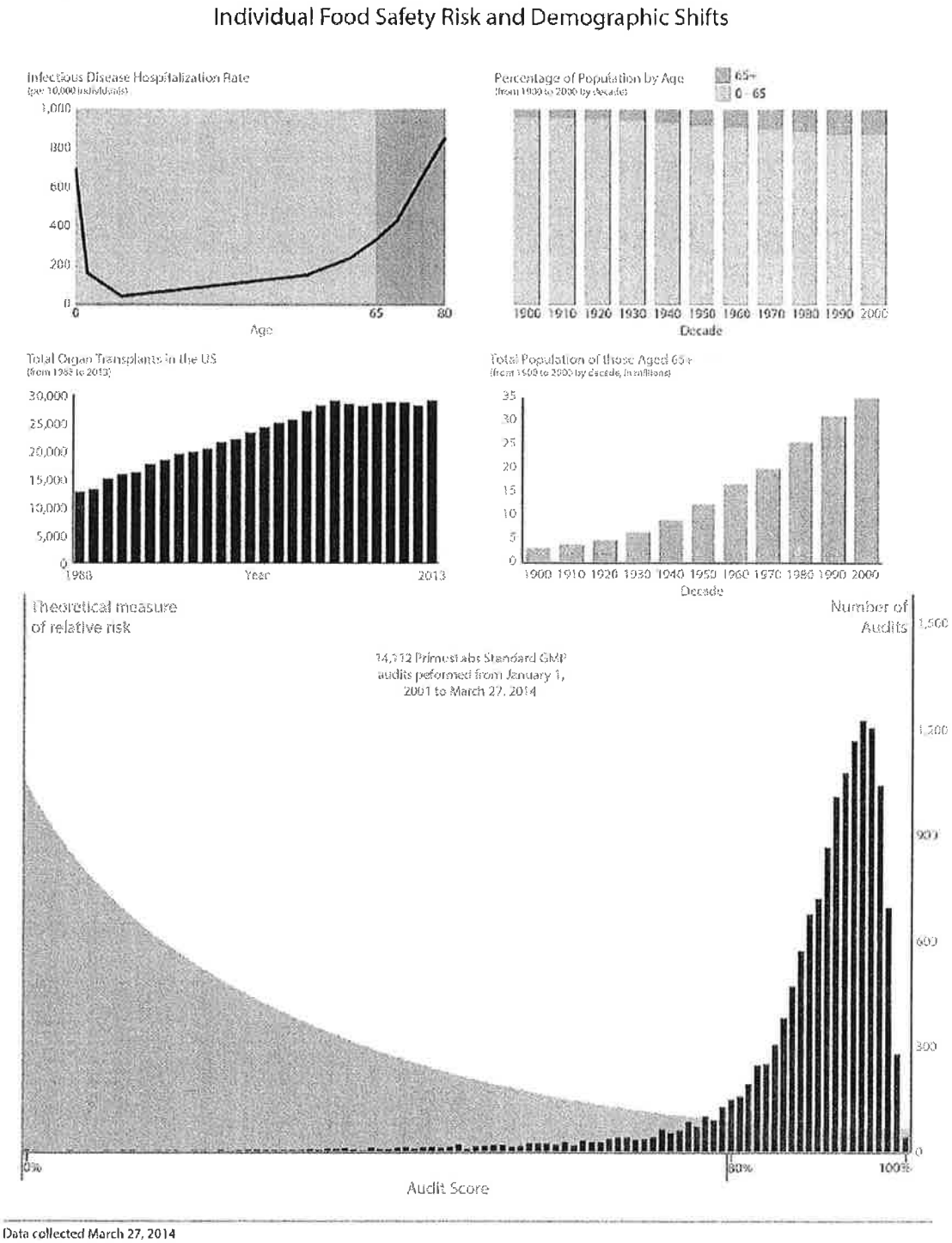


Figure 10

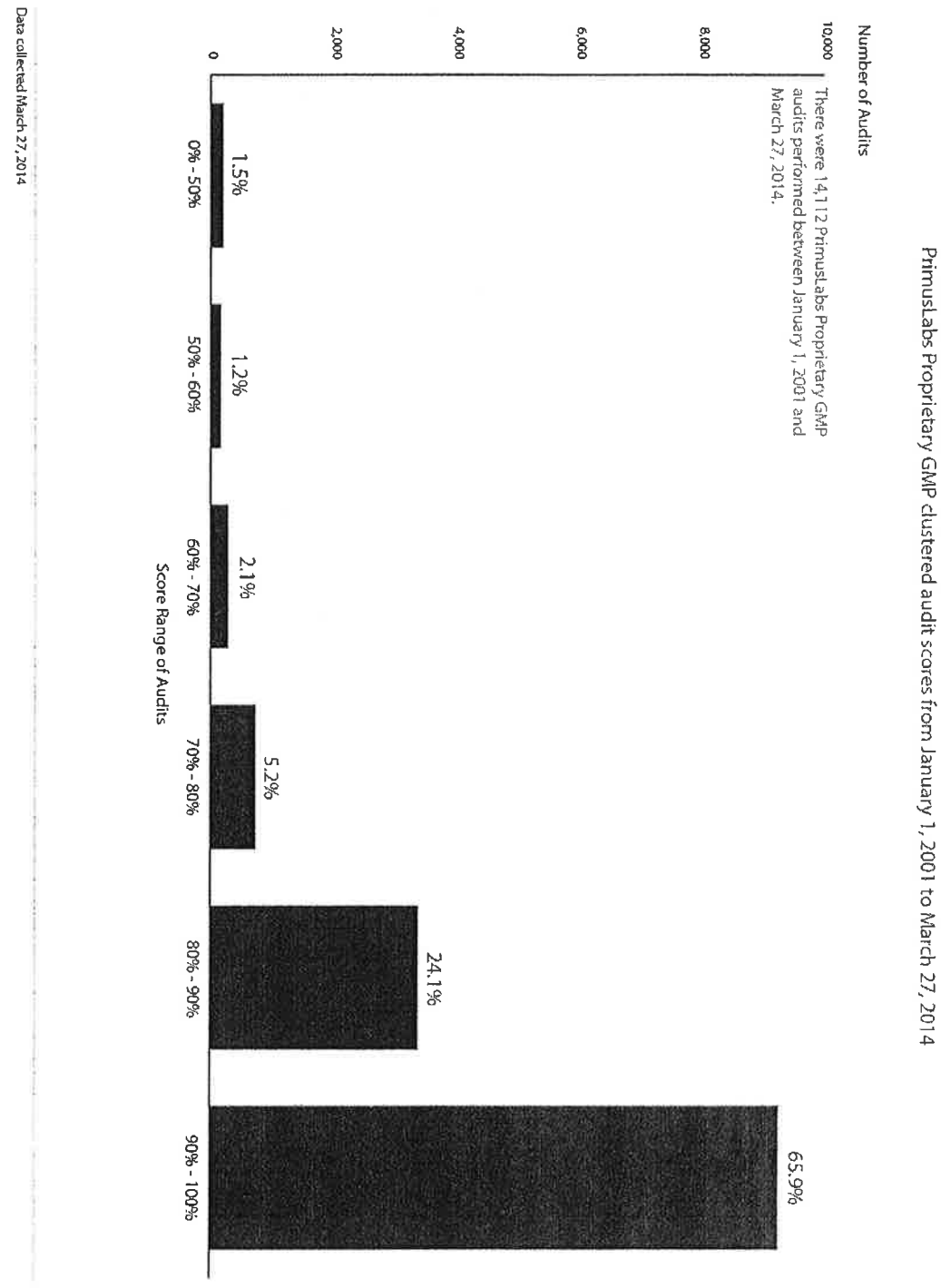
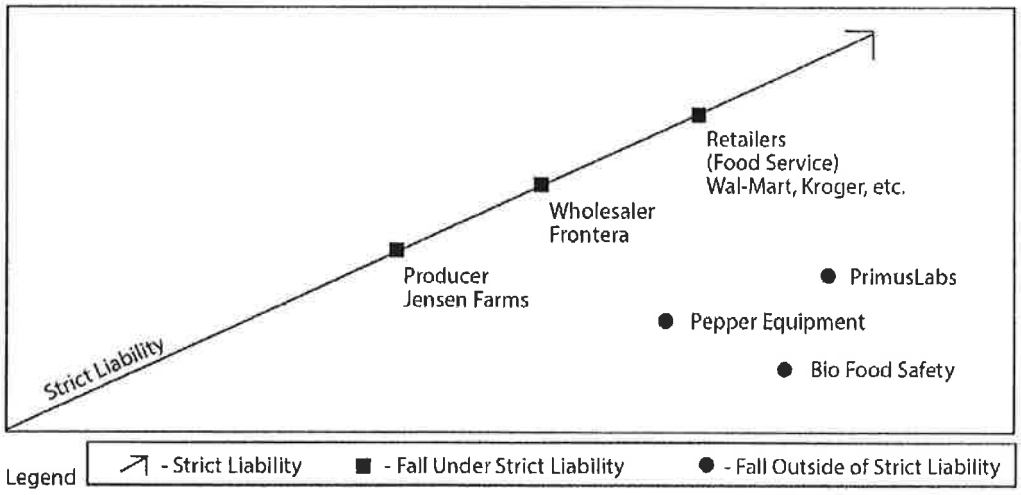
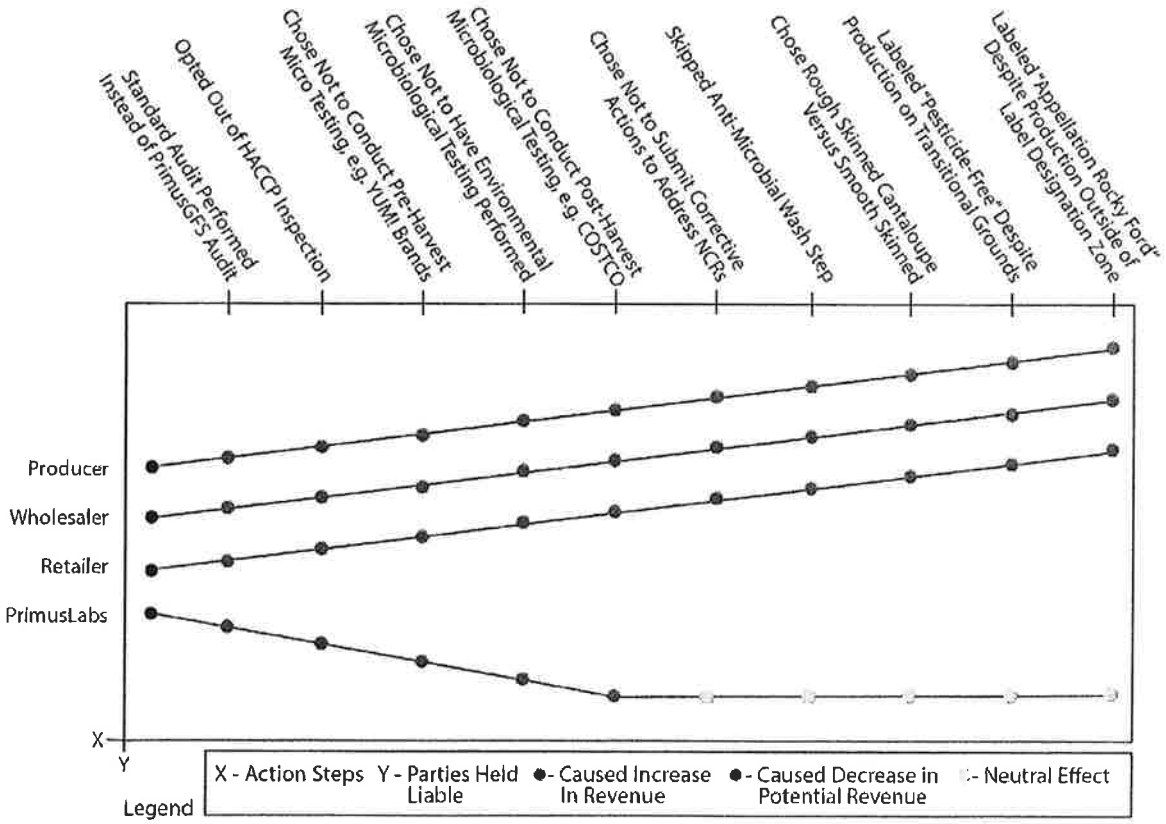

PrimusLabs Proprietary GMP clustered audit scores from January 1, 2001 to March 27, 2014
Number of Audits
10,000
8,000
6,000
4,000
2,000
0
There were 14,112 PrimusLabs Proprietary GMP audits performed between January 1, 2001 and March 27, 2014.
1.5%
1.2%
2.1%
5.2%
24.1%
65.9%
0% - 50%
50% - 60%
60% - 70%
70% - 80%
80% - 90%
90% - 100%
Score Range of Audits
Data collected March 27, 2014

Figure 11.

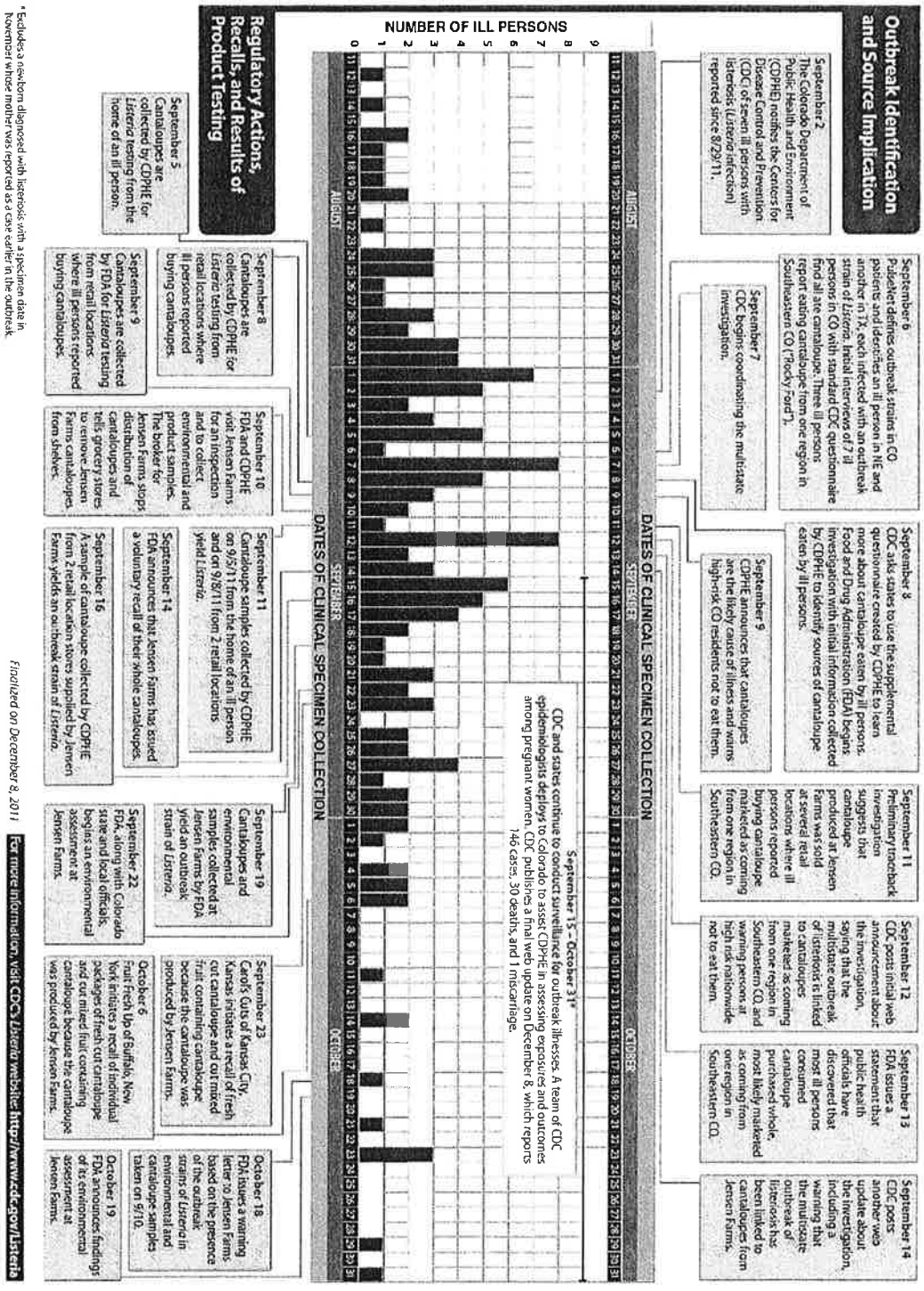
Strict Liability Graphics 1 and 2





Appendix 1 – "Timeline – Final CDC Report on Jensen Farms – 8 December, 2011

Timeline of Events: Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms in Colorado—United States, 2011



Appendix 2 – "The Walmart Letter" to Private Brand Suppliers

Walmart
Save money. Live better.

Food Safety & Health

702 SW 8th Street
Bentonville, AR 72716
Phone 479 204 8284
Fax 479 276 1911
www.walmart.com

November 29, 2010

Dear Produce Supplier:

At Walmart, our commitment to our customers is unparalleled and we strive relentlessly to provide safe, quality foods in our Stores and Clubs. As part of our commitment to continuous improvement, we go further than many U.S. retailers in requiring that harmonized, leading-edge food safety standards be adopted throughout the entire food production system. Below is an overview of these standards and expectations which impact our produce suppliers worldwide.

Alignment with GFSI

In December 2007, Walmart and Sam's Club became the first U.S. retailer to require our Private Brand suppliers to achieve prevention-based certification against one of the Global Food Safety Initiative (GFSI) internationally recognized food safety standards. As we transition beyond our Private Brands and enhance the requirements for other food groups, including produce, we are introducing updated Food Safety requirements to align our other programs to our commitment with GFSI.

As such, we have standardized our food safety requirements for all produce suppliers. The audits you will be required to complete are based on the commodities you provide to our Stores and Clubs and MUST cover ALL growing and packhouse operations that are used to provide product to us. Final audit results must be submitted to Walmart. If you are a broker or distributor or you source or pack product from multiple locations, your distribution or warehouse facility and every location that you source from to provide produce to our stores or clubs must be disclosed and meet the same audit and disclosure requirements.

iCiX

In addition, Walmart has partnered with iCiX (International Compliance Information Exchange) in order to implement an effective and efficient way to manage our Food Safety, Compliance and Quality Assurance programs. All food safety certification, audit and compliance documentation as well as all other required documents will be shared with Walmart through this system.

Walmart is committed to this system and participation by our produce suppliers is **Mandatory**. Every corporate location, broker/distributor and packhouse (cold storage for field pack items) facilty with its own pyhsical address used to provide product to our Stores or Clubs should be registered in the iCiX system individually. Once registered in iCiX, or if your operations are already registered, please upload a copy of your current GFSI certificate or final audit report (for non-GFSI benchmarked audits) and corrective action report into the iCiX system and grant viewer access rights to Walmart - Global Food.

If you do not currently meet our updated food safety audit requirements, upload a copy of your current pack house or cold storage food safety audit report and the associated corrective action report and grant viewer access rights to Walmart – Global Food. When you conduct your renewal audits in alignment with our enhanced requirements these should be uploaded in the facilties site. Field and ranch GAP audits should be uploaded into the site for the packhouse/cold storage operation they support.

Walmart

Attached with this letter is a document that provides information on the iCiX registration process and clearly outlines the updated audit requirements along with the timeline you will have to comply with these standards. You are free to choose any audit noted in the document you feel best fits your business model.

Walmart would like thank you for working with us towards a common goal of ***providing safe and affordable food, so people can live better.***

Sincerely,

Walmart Food Safety & Health

Appendix 3 – Walmart Requirements for Small Suppliers in Local Purchase Program

Small Produce Supplier Food Safety Audit Requirements

Supplier Type

- **Small Suppliers in the Local Produce Program providing ANY of the Following Products Associated with Foodborne Disease (including but not limited to):** [1]
  - Berries - Herbs - Melons - Nuts - Sprouts
  - Green Onions - Leafy Greens - Mushrooms - Peppers - Tomatoes

1. This list in not all inclusive and commodities can be added at any time

Field/Ranch and Pack House Audit Standard Requirements

Field Level [1,2,3]
Any GFSI Benchmarked Field Standard

one of the schemes listed below:
- GlobalGAP Primary Farm Assurance Intermediary Level Assessment
- PrimusLabs.com Standard Ranch, Greenhouse or Harvest Crew Audit[3]

Pack House or Distribution Center [1,2,3]
Any GFSI Benchmarked Standard

one of the schemes listed below:
- GlobalGAP Primary Farm Assurance Intermediary Level Assessment; Must Include (Produce Handling) - Section FV 5
- PrimusLabs.com Standard Packhouse Audit w/ HACCP[3]

1. Audits of both field and pack house (if applicable) operations (cold storage for field pack items) must be completed
2. Audits must be conducted when harvest and packing operations are being performed
3. Audits must be conducted annually PRIOR to the expiration of the current audit

Compliance Date

New Suppliers
- Must meet audit requirements PRIOR to supply

Current Suppliers
- Must audit against one of the approved standards for their next renewal audit

All Suppliers
- Must meet the requirement PRIOR to Nov 1, 2011

Small Produce Supplier Food Safety Audit Requirements

Supplier Type
Small Suppliers in the Local Purchase Program Providing all Other Produce Products not Listed on Page 1
Field/Ranch and Pack House Audit Standard Requirements
Field Level [1,2,3] **Any GFSI Benchmarked Field Standard** OR **one of the schemes listed below:** • GlobalGAP Primary Farm Assurance Foundation Level Assessment • Safe Quality Food 1000 Level I • PrimusLabs.com Basic Ranch, Greenhouse or Harvest Crew Audit[4] **Pack House or Distribution Center** [1,2,3] **Any GFSI Benchmarked Standard** OR **one of the schemes listed below:** • GlobalGAP Primary Farm Assurance Foundation Level Assessment; **Must Include (Produce Handling) - Section FV 5** • PrimusLabs.com Basic Packhouse Audit[3] • Safe Quality Food Level I 1. Audits of both field and pack house (if applicable) operations (cold storage for field pack items must be completed 2. Audits must be conducted when harvest and packing operations are being performed 3. Audits must be conducted annually PRIOR to the expiration of the current audit 4. Only verified PrimusLabs audits will be accepted. NOT affiliated audits using PrimusLabs software
Compliance Date
New Suppliers • Must meet audit requirements PRIOR to supply **Current Suppliers** • Must audit against one of the approved standards for their next renewal audit **All Suppliers** • Must meet the requirement PRIOR to **Nov. 1, 2011**

Small Produce Supplier Food Safety Audit Requirements

Audit Providers

Global Food Safety Initiative (GFSI) Benchmarked Certifications
Further information on any of the Global Food Safety Initiative (GFSI) Benchmarked Certifications can be found at:

- http://www.mygfsi.com/

A complete list of all certification bodies approved to conduct certifications against the individual recognized GFSI Benchmarked schemes can be found at:

- http://www.brcdirectory.com.uk/
- http://www.canadagap.ca/
- http://www.fssc22000.com/en/
- http://www.globalgap.org/
- http://www.ifs-certification.com/
- http://www.primusgfs.com/index.aspx
- http://www.sqfi.com/certificationbodies.html
- http://www.synergy22000-gss.com/

GlobalGAP Certifications & GlobalGAP Primary Farm Assurance (PFA) Assessments
The following companies can be contacted to conduct a GlobalGAP certification or PFA Assessment:

- Bureau Veritas
- CMI
- CPS
- Davis Fresh Technologies
- Det Norske Veritas
- DQS
- GFTC
- Inspectorate
- NCSI
- NSF
- SaiGlobal
- Scientific Certification Systems
- SGS
- Any other Certification Body approved by GlobalGAP

PrimusLabs.com (only verified PrimusLabs audits will be accepted. NOT affiliated audits using PrimusLabs software)

- For more information or to schedule an audit contact PrimusLabs directly at: **auditadmins@primuslabs.com**

Providing Audit Documents to Walmart

If you have not previously provided us with a copy of your current food safety audit documentation, please send a copy of the complete audit report and corrective action report to us at:

e-mail: supaudit@wal-mart.com
OR
Fax: 479-273-1911

If you do not meet our new enhanced audit requirements, please move to one of our approved formats for your next renewal audit. If you do not currently have a food safety audit in place one must be scheduled to occur at the start of your next harvest and packing season. Brokers or Distributors without a current audit in place must have one scheduled to occur wthin 70 days from the receipt of this letter. They should also provide copies of audit reports and corrective action reports from all sources that they supply from and provide product to Walmart or Sam's Club.

Appendix 4 – November 22, 2011, Meeting Minutes of United Fresh Harmonization Initiative Calibration Committee

Produce GAPs Harmonization Initiative
Calibration Committee
United Fresh headquarters, Washington DC
Tuesday, November 22, 2011

Committee Members Present:
- Reggie Brown, Florida Tomato Exchange
- LeAnn Chuboff, SQF Institute
- Charlie Cook, DRS/Subway
- Todd Cornelison, Idaho Potato*
- Milinda Dwyer, Costco Wholesale
- Wes Kline, Rutgers University
- Luke LaBorde, Penn State University
- Eva Lauve, Stemilt Growers
- Bob Mills, Misionero Vegetables
- Heena Patel, SCS
- Ken Petersen, USDA AMS*
- Susan Pheasant, GlobalG.A.P North America
- Rhiannon Woo, NSF Agriculture

Absent:
- Mike Aerts, Florida Fruit and Vegetable Association
- Brett Holman, NCSI Americas
- Larry Prentice, SGS
- Larry Robertson, Darden

Guests:
- Tim Amlaw, Sustainable Food Development LTD.*
- Tony Lotito, Sustainable Food Development LTD.*
- Kristian Moeller, GlobalG.A.P*
- Laura Dunn Nelson, Alchemy
- Dave Pompilio, USDA AMS*

United Fresh Staff:
- David Gombas*
- Erin Grether*

* Indicates attendance in person

Summary
The meeting was held in person and web conference format. Gombas welcomed the Committee members and briefed them on the progress of implementing the harmonized standards: the Field Operations and Harvesting standards have been completed and are on-line; the Post-harvest Operations standards are still draft, awaiting additional pilots before presenting to the Technical Working Group for finalization; volunteer operations are needed. He noted that a "U.S. national interpretation guideline", using the harmonized standards plus 14 "riders", has been submitted to GlobalG.A.P. The riders are audit items included in the GlobalG.A.P food safety standard but not in the harmonized standards. SQF is still considering whether to use the harmonized standards as their "module 7" standards for Growing and Production of Fresh Produce.

Training development

on the NSF slides (although trainers should emphasize where and what documents are required and should be reviewed). Amlaw expected to have a compiled deck for Committee review by mid-January. The Committee was again encouraged to send pictures and scenarios to Amlaw to include in the training deck, using the following format:

- Pictures should cover a multitude of commodities, large and small size operations, and examples of compliant and non-compliant practices, with comment as to why non-compliant. Pictures should be emailed to:
  - one picture per email;
  - the picture should be in jpg or similar format;
  - resolution should be at least good enough for a slide presentation; and
  - the email should include a name for the photo, location or region and season (if useful to understand the context of the picture), which item(s) in the harmonized standards that it relates to (i.e., the item number, and whether it is the pre-harvest or post-harvest standards), and text to explain the relevance of the picture to training (why it demonstrates compliance or non-compliance).

Submission of a picture implies that permission is given for its use in training; pictures for which permission is not given must not be submitted.

Scoring/ranking tool for audits using the harmonized standards

The Committee discussed ways to enable operations to be ranked or scored. While all agreed that the auditor's comments are the most important part of the report, there are efficiency and business benefits to have a rank or score for the audit. It was agreed that the word "fail" should not be used in the audit, except for immediate food safety risks, because of the implications in using a supplier that had been judged as "failed" in some aspect of the audit. One suggestion was to use the term "knockout" instead of failure.

Gombas presented an approach that had been used by the NFPA-SAFE audit program, which was also an unscored, non-weighted audit. In that program, customers were allowed to set their own weights (values) to all of the audit items. The auditor's "judgments" were also weighted: Fully Meets (full compliance) had the highest value, followed by slightly less value for Partially Meets (minor non-compliance), a significantly lower value for Does Not Meet (significant non-compliance but not an immediate food safety risk), and a large negative value for Immediate Action Required (imminent food safety risk).

Recognizing that different audit organizations may need to format the Harmonized Standards in their own way, the Committee recommended that a default audit report format be developed, using the auditor judgments developed for the Tomato Metrics audit; i.e., C (compliant), CAN (corrective action needed), IAR (immediate action required) and NA (not applicable). Then a scoring template could be developed with customer-specified values for each audit item; default values for C, CAN, IAR, NA; customer-specified knockouts, and a default algorithm equal to the value of each audit item times the value of the auditor judgment, minus knockouts, normalized for the total possible points. The Committee also recommended that the default audit report require auditor comments for all items rated CAN, IAR and NA, with optional comments for items rated C. Gombas proposed one approach during the meeting and agreed to work with Dwyer and Cook to develop an example scoring template, using this format, for the next meeting.

Other

The Committee discussed and agreed that there is a need for a licensing agreement and advantages to having an "auditor registry", which had already been recommended by the Operations Committee. The licensing agreement would be a no cost agreement by certification bodies/audit organizations to use the Harmonized Standards verbatim and to authorize auditors to do audits using the Harmonized Standards only after official Harmonized Standards training. One example format for the auditor registry would be a list of auditors (and their company and contact info) who have been through the Harmonized Standards training and are authorized to do audits using the Harmonized Standards, according to their parent company.

Gombas reminded the Committee members that the expectation for the training will be to calibrate auditors in how to use and interpret the intent of the harmonized standards, not how to audit – that is the responsibility of the audit organizations. The expectation is that official training materials will be ready for audit organizations to use by January.

Peterson and Pompilio described the agenda and training materials they used in training 300 USDA auditors to use the harmonized standards, in response to a request by a foodservice company to audit their produce suppliers using the harmonized standards. Their approach was to go line-by-line through the standard, using a review of the standards, photographs and scenarios to describe what is expected, as well as what is not the intent of the standards. Videos were not used in their training because of technological challenges, nor were sessions recorded. They minimized or skipped over audit items that their auditors were already familiar with, but the training duration was still 3 days, in roughly weekly sessions. The USDA training was performed live on-line, with "class" sizes of 30-100 trainees. There was an attempt to group trainees by experience (i.e., basic vs. intermediate experience). Training included "prework" and "homework" before and between sessions; part of each session was to review the homework. The on-line training was divided into approximately 30 minute chapters to avoid fatigue, and each chapter included a Question and Answer opportunity. Training concluded with a 25-30 question, one hour exam. Auditors who completed the training were still considered "new" and required one or two "shadow audits" before being considered ready to be a senior or sole auditor.

Gombas showed some of the NSF training slides, which were similar to the USDA training in that they went line-by-line through the standards. The NSF approach also included a manual, which was the same as the slides but with more detail of how auditors were to confirm compliance (e.g., inspection vs. records review vs. interview). A third harmonized standards training program, offered by TheAgBridge, was not available for review by the Committee.

Both USDA and NSF have offered their training materials as a beginning. Nelson described the services provided by Alchemy, and agreed to consider which services could potentially be useful for this training project.

The Committee deliberated on what was needed for the training and developed this list, in no particular order:

- Copies of the harmonized standards
- A model checklist, recognizing that each audit organization is at liberty to develop their own, as long as the wording of the standards is not altered
- A PowerPoint presentation deck, itemized to all of the items in the harmonized standards
- Lots of pictures (videos?) to provide context and opportunity for discussion of the expectations in the standards
- Scenarios that demonstrate compliant and non-compliant practices
- Teaching notes, to calibrate trainers in what to teach
- Learning objectives (overall vs specific items)
- A list of prerequisite core competencies (e.g., auditor being able to recognize whether a risk assessment is complete/adequate)
- Content resources; topic-specific modules to be reviewed by trainees prior to the harmonized standard training (e.g., as prework)
- Since the Verification column of the harmonized standards was developed as instructions to the auditor, the training should focus on those expectations
- Once developed, the training (and standards) must also be available in Spanish

offered to work with Gombas on developing a scoring/ranking tool that customers can use for their own purposes.

Dispute resolution
The second primary responsibility of the Calibration Committee is real-time resolution of audit disputes related to interpretation of the harmonized standards' intent. Gombas shared three questions that had been submitted to United Fresh. The Committee quickly came to consensus on interpretation of the audit items in question, demonstrating that they can undertake this responsibility. Further discussion on this (e.g., how disputes would be communicated to the Committee members, how they would be discussed and how consensus would be reached in real time) was tabled until later, since there can be no official audits using the harmonized standards until after auditors are officially trained.

Action Items
- Committee members should submit pictures for scenario building to Amlaw at ufphotos@susfd.com using the format described above.
- Gombas will notify the TWG members to likewise submit pictures for training purposes.
- Amlaw will collate submitted pictures for our next meeting.
- The Committee will begin developing the actual training presentation deck, beginning with the USDA, NSF and TheAgBridge materials and the submitted pictures, at our next meeting.
- The next meeting will be Thursday, December 8, 8 am - 2 pm PT, at Costco Headquarters (999 Lake Drive [building 1], Issaquah, WA 98027). Grether will send web conference information to those unable to attend in person.

Appendix 5 – December 8, 2011, Meeting Minutes of United Fresh Harmonization Initiative Calibration Committee

Produce GAPs Harmonization Initiative
Calibration Committee
Costco headquarters, Seattle WA
Thursday, December 8, 2011

Committee Members Present:
- Mike Aerts, Florida Fruit and Vegetable Association*
- Charlie Cook, DRS/Subway
- Milinda Dwyer, Costco Wholesale*
- Wes Kline, Rutgers University
- Pat Kole (for Todd Cornelison), Idaho Potato*
- Eva Lauve, Stemilt Growers*
- Ben Marchant (for Brett Holman), NCSI Americas*
- Kristian Moeller (for Susan Pheasant), GlobalG.A.P North America*
- Ken Petersen, USDA AMS*
- Larry Robertson, Darden
- Rhiannon Woo, NSF Agriculture

Absent:
- Reggie Brown, Florida Tomato Exchange
- LeAnn Chuboff, SQF Institute
- Luke LaBorde, Penn State University
- Bob Mills, Misionero Vegetables
- Heena Patel, SCS
- Larry Prentice, SGS

Guests:
- Tim Amlaw, Sustainable Food Development LTD.*
- Tony Lotito, Sustainable Food Development LTD.*

United Fresh Staff:
- David Gombas*
- Erin Grether

* indicates attendance in person

Summary
The meeting was held in person and web conference format. Gombas welcomed the Committee members and thanked Dwyer and Costco for hosting the meeting.

Training development
Gombas reminded the Committee members that the expectation for the training will be to calibrate auditors in how to use and interpret the intent of the harmonized standards, not how to audit – that is the responsibility of the audit organizations – but that the training will need to cover both the pre- and post-harvest standards and that the Committee had decided the training should be line-by-line through the standards and driven by scenarios, using pictures. The expectation is that official training materials will be ready for audit organizations to use by January. He also reminded the Committee that USDA, NSF and TheAgBridge have all offered their training materials as a beginning. Amlaw reminded the Committee that Sustainable Food Development had offered to develop a database collection point for pictures to be used for scenario teaching. He reported that, so far, only three pictures had been sent to him at ufphotos@susfd.com.

The Committee decided to use the NSF presentation slides as the basis of the training materials, to be merged with the pictures and scenario slides from USDA. Amlaw volunteered Sustainable Food Development's IT services to merge the two presentation decks. The Committee also decided to delete the "level" and "Type of Confirmation" entries

- United Fresh will develop an on-line forum or Q&A, including updates and interpretations to questions raised by anyone, and particularly decisions of interpretation from the Calibration Committee
- Where practical, decision trees should be developed to demonstrate the expected thought process on assessment of compliance
- Post-training verification scenarios, with training notes, should be available both as refresher and as for verification of adequacy of training (i.e., optional exam)

The Committee also deliberated on how the training should be structured:
- Primary source of training will be by the audit organizations, as part of their auditor training activities
- Training will cover both the Field Operations and Harvesting and the Post-harvest Operations standards; training should be developed for the Post-harvest Operations now, even though it is still draft, and adjusted when the standards are finalized
- The training should, at some point, be open to industry as well as auditors
- Training materials for auditor training should be developed first, then develop train-the-trainer and train-the-public materials
- Use of the authorized training material should be mandatory for audit organizations that want to perform audits using the harmonized standards
- Some evaluation of training effectiveness is recommended; a sample/example should be developed
- Actual training format should be left to the audit organization doing the training
- A registry of auditors who have been trained to the harmonized standards, with mailing list, should be developed, to enable United Fresh to push out ongoing communications/ updates on the harmonized standards;
- The Produce GAPs Harmonization Initiative website will need to be expanded and continuously updated
- Periodic re-training of auditors will be needed, but the course content and frequency of re-training may be best determined by each audit organization

Amlaw offered to develop a database collection point for pictures to be used for scenario teaching. Pictures should cover a multitude of commodities, large and small size operations, and examples of compliant and non-compliant practices, with comment as to why non-compliant. Pictures should be emailed to ufphotos@susfd.com:
- one picture per email;
- the picture should be in jpg or similar format;
- resolution should be at least good enough for a slide presentation; and
- the email should include a name for the photo, location or region and season (if useful to understand the context of the picture), which item(s) in the harmonized standards that it relates to (i.e., the item number, and whether it is the pre-harvest or post-harvest standards), and text to explain the relevance of the picture to training (why it demonstrates compliance or non-compliance).

Submission of a picture implies that permission is given for its use in training; pictures for which permission is not given must not be submitted.

Scoring/ranking tool for audits using the harmonized standards

During the development of the harmonized standards, the question of scoring and weighting of audit items was raised and discussed at length by the Technical Working Group. It quickly became apparent that there could be no consensus on weights or scores; every customer had their own opinion of what is important. However, several customers have indicated that the harmonized standards must have a scoring platform for them to use it. Patel and others noted the dangers in relying on scores, where a significant safety deficiency could be overlooked because of an otherwise high score. Dwyer and Cook have

Action Items

- Committee members should submit pictures for scenario building to Amlaw at ufphotos@susfd.com using the format described above.
- . Gombas will notify the TWG members to likewise submit pictures for training purposes.
- Amlaw will collate the submitted pictures with the NSF and USDA training deck, including the USDA teaching notes.
- The Committee will review the draft training presentation deck compiled by Amlaw.
- The Committee will be surveyed for the next meeting date/location.

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