

The Primus Audit Failures and Victims' Allegations

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

2. **Packing Machinery:** As is detailed below, Pepper Equipment Company sold Jensen Farms packing equipment that was not in adequate repair, and was not properly designed for the safe processing of cantaloupe. The equipment was made for processing potatoes, a different agricultural commodity requiring different packing equipment. The equipment could have been updated to include new brushes designed for cantaloupes¹ (clearly a different size and shape than potatoes, requiring different equipment to clean them), an injections system designed for microbiological chemicals, dryers to eliminate microbiological contamination, and the addition of stainless steel parts in place of wood, which would have allowed this machine to be effectively and regularly sterilized. This equipment implicated section 1.6.3, which asked whether "equipment design and condition (e.g. smooth surfaces, smooth weld seams, non-toxic materials, and no wood) facilitate effective cleaning and maintenance?" Clearly, as the FDA's environmental assessment showed, the design of Jensen Farms' equipment in place at the time of Primus audit did not allow for this—a critical failure that was, admittedly, exacerbated by Jensen Farms' inattention to the condition of its facility. Nevertheless,

¹ Pepper Equipment Company did sell Jensen Farms "½ share of brushes for washer," so the exact configuration of this equipment is not yet fully known.

Mr. Dilorio noted that, with regard to section 1.6.3, Jensen Farms' facility was in total compliance.

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

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

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

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

Jensen Farms for creating an unsatisfactory condition under USDA audit guidelines.

7. No Routine Environmental or Water Microbiological Testing:

Jensen Farms did not routinely conduct microbiological testing of environmental, water, or finished product samples. This is in violation of section 1.4.8 of Primus audit manual at page 26, where the “major deficiency” categories all assume that an antimicrobial is being used in the first place. The tests contemplated in that sections are to ensure that antimicrobial concentration is correct. Clearly, the lack of an antimicrobial anywhere in the facility, and the corresponding lack of microbiological testing to ensure that the equipment and water are not a source, or potential source, of contamination, must also be a major violation. Again, Primus auditors are cautioned in their audit manual to have “food safety and risk minimization” as their “key concerns.”

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

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

The following allegations are taken from victims’ various complaints, and relate equally to Primus’s duties and actions in breach of those duties:

- As part of its 2011 contract with Jensen Farms, Primus agreed, pursuant to its own guidelines, to assess and determine if Jensen Farms’ packinghouse facilities, premises, and food safety procedures met or exceeded the applicable good agricultural and manufacturing practices, industry standards, and relevant FDA industry guidance standards of care incumbent upon Jensen Farms as a manufacturer of cantaloupes for human

consumption. As part of its 2011 contract with Jensen Farms, Primus agreed, pursuant to its own guidelines, that its auditors should interpret its audit guidelines with food safety and risk minimization being the key concerns.

- The Primus Point Assignment Guidelines for the Jensen Farms audit contained a section captioned “Good Manufacturing Practices (The Facility Tour)”. That section contained questions regarding, amongst other issues, general food safety, operational practices, equipment, equipment cleaning, and general cleaning practices and procedures observed during the tour of the facility. The auditor was to utilize four separate conformance categories in assessing compliance with the audit guidelines, with related relative scoring levels and points: full conformance; minor deficiency; major deficiency; and non-conformance. The Primus Point Assignment Guidelines for the Jensen Farms audit contained a section captioned “Food Safety File”. That section contained questions regarding, amongst other issues, general food safety file requirements, self-inspection records; maintenance and sanitation records, and microbial testing records. The auditor was to utilize four separate conformance categories in assessing compliance with the related audit guidelines, with related relative scoring levels and points: full conformance; minor deficiency; major deficiency; and non-conformance.
- As part of its 2011 contract with Jensen Farms, Primus had the unilateral capability to determine if the Jensen Farms facility failed to meet critical food safety requirements, and if so it would then automatically fail the facility’s audit. Primus would then immediately inform Jensen Farms of the automatic failure.
- Initially, as part of its 2011 contract with Jensen Farms, Primus required that the Jensen Farms facility needed to be engaged in whatever functions would usually occur at the facility on a normal day, and that a normal complement of personnel be on site, at the time the audit was to be conducted, in order for the auditor to obtain a valid assessment. If the facility were not running product in a normal way, the audit would have to be terminated. The Primus audit failed to note that on July 25, 2011, the day of the audit, the Jensen Farms packinghouse was not operating in its normal fashion. The Jensen Farms harvest did not start until a few days later, and at the time of the audit the packinghouse was not operating in its usual fashion, i.e., it was not processing melons. Pursuant to its own guidelines, the audit was to be immediately terminated at that time, as a valid assessment could not be made at that time.
- The 2011 auditor, Mr. Dilorio, failed to observe, or properly downscore or consider, multiple conditions or practices that were in violation of

Primus's own audit standards applicable to cantaloupe packing houses, industry standards, and relevant FDA industry guidance. The Primus audit failed to note, and to down-score, that the facility floor was constructed in a manner that was not easily cleanable, a factor that likely contributed to the introduction, growth, or spread of *Listeria monocytogenes*.

- The Primus audit failed to note, and to down-score, that certain pieces of Jensen Farms equipment in the packinghouse were designed to process a different agricultural commodity, *i.e.* potatoes, a factor that likely contributed to the introduction, growth, or spread of *Listeria monocytogenes*. The Primus audit failed to note, and to down-score, that the design of the packing facility equipment, including equipment used to wash and dry the cantaloupe, did not lend itself to be easily or routinely cleaned and sanitized. Several areas appeared to be un-cleanable, and dirt and product buildup was visible. Corrosion was also visible. Further, because the equipment was not easily cleanable and was previously used for handling another raw agricultural commodity with different washing and drying requirements, *Listeria monocytogenes* could have been introduced as a result of past use of the equipment.
- The Primus audit failed to note, and to down-score, that Jensen Farms did not use an antimicrobial solution, such as chlorine, in the water used to wash cantaloupes, a factor that likely contributed to the introduction, growth, or spread of *Listeria monocytogenes*. The Primus audit failed to note, and to down-score, that Jensen Farms did not properly sanitize its facilities and equipment, a factor that likely contributed to the introduction, growth, or spread of *Listeria monocytogenes*.
- The Primus audit failed to note, and to down-score, that Jensen Farms did not have adequate and appropriate food safety policies and procedures, a factor that likely contributed to the introduction, growth, or spread of *Listeria monocytogenes*. The Primus audit failed to note, and to down-score, that Jensen Farms did not maintain the required food safety program records, documenting the implementation of its food safety program, a factor that likely contributed to the introduction, growth, or spread of *Listeria monocytogenes*.
- Mr. DiIorio, by improperly giving the Jensen facilities and procedures a “superior” rating in his audit, erroneously represented to Jensen that Jensen Farms’ packinghouse facilities, premises, and food safety procedures met or exceeded the applicable good agricultural and manufacturing practices, industry standards, and relevant FDA industry guidance standards of care incumbent upon Jensen Farms as a manufacturer of cantaloupes for human consumption. Mr. DiIorio, by improperly giving the Jensen facilities and procedures a “superior” rating in his audit, erroneously represented to Jensen that during the audit he had

interpreted the Primus guidelines with food safety and risk minimization being the key concerns.

- Mr. DiIorio, by improperly giving the Jensen facilities and procedures a “superior” rating in his audit, erroneously represented to Jensen and to others that the Jensen cantaloupes had been processed in facilities and with food safety procedures that met or exceeded the applicable good agricultural and manufacturing practices, industry standards, and relevant FDA industry guidance standards, and that thus the melons met the standards required to be “Primus Certified”. Mr. DiIorio, by improperly giving the Jensen facilities and procedures a “superior” rating in his audit, negligently gave Jensen false information, on which Jensen reasonably relied in Jensen’s evaluation of the safety and quality of its facilities and procedures and cantaloupes. Jensen Farms reasonably relied on the representation that its facilities and food safety procedures met or exceeded the applicable good agricultural and manufacturing practices, industry standards, and relevant FDA industry guidance standards.