FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Department of Health and Human Services

Memorandum

Date:	08/28/2020	**Firm:**	Thomson International Inc. 11220 S. Vineland Rd., Bakersfield, CA 93307-9489
From:	Daniel J Gorski Investigator ORA/OHAFO-W/DDHAFO/DPSB1		
Subject:	Outbreak Investigation	**FEI:**	3004391505
To:	Brandi McGrady Branch Chief ORA/OHAFO-W/DDHAFO/DPSB1		

Background

On 08/07/2020, I received an assignment (eNSpect Op ID #170668, FACTS ID 12055297) to conduct a foodborne illness outbreak investigation at Thomson International Inc., LLC as a continuation of a response to an outbreak of *Salmonella Newport*. Thomson International Inc. issued a recall on 07/31/2020 of red, yellow, white, and sweet yellow onions shipped from 05/01/2020 through present. The onions were distributed in 5 lbs. carton. 10 lbs. carton. 25 lbs. carton. 40 lbs. carton, 50 lbs. carton. bulk, 2 lb. mesh sacks, and 3 lb. mesh sacks, 5 lb. mesh sacks, 10 lb. mesh sacks 25 lbs. mesh sacks, 50 lbs. mesh sacks under the brand names Thomson Premium, TLC Thomson International, Tender Loving Care, El Competitor, Hartley's Best, Onions 52, Majestic, Imperial Fresh, Kroger, Utah Onions and Food Lion.

Endorsement **Date: 09/21/2020**

All samples collected as part of this investigation were negative for *Salmonella Newport*. The teams did not determine the source(s) or route(s) of contamination. No FDA-4056 (Produce Farm Inspectional Observations) was issued. 12 items were discussed with President Jack Thomson during the close out meeting regarding various sanitation, training, record-keeping concerns. (b) (5), (b) (7)(A) [redacted]

Distribution:
O: EI File
Cc: CFSAN OC Produce
Cc: CORE RESPONSE
Cc: HAFW5 ERC

Brandi N. Mcgrady -S
Digitally signed by Brandi N Mcgrady -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000368397, cn=Brandi N Mcgrady -S
Date: 2020.09.25 17:18:20 -04'00'

Brandi McGrady
Branch Chief
ORA Produce Safety Network, Branch 1

The epidemiological investigation suggests that illnesses could be associated with red onion consumption.

SUMMARY

This investigation was conducted at Thomson International Inc. (TII) as a continuation of a response to an outbreak of *Salmonella Newport* under eNSpect Op ID #170668, FACTS ID 12055297. TII has a packing house located at 11220 Vineland Road, Bakersfield, CA 93307 with (b) (4) packing lines, (b) (4), and a storage warehouse. The (b) (4) packing line is a traditional brick and mortar fully enclosed building with (b) (4) (b) (4) for onions. The (b) (4) packing line is (b) (4) (b) (4) (b) (4) with (b) (4) for packing onions. TII's Bakersfield packing facility also receives and packs watermelon, in a (b) (4) on the same property, on a dedicated watermelon packing line. The (b) (4) is (b) (4) ft², the (b) (4) is (b) (4) ft², and the onion storage warehouse is (b) (4) ft². TII has (b) (4) ranches and a "farm shop" (b) (4) (b) (4) (see associated attachments). All sites were visited during this investigation and an individual farm questionnaire was drafted for each. TII has (b) (4) ranches (b) (4) (b) (4)) in (b) (4). TII's packing facility, the farm shop, and (b) (4) (b) (4) ranches were visited by the investigation team to identify any potential sources/routes of contamination as well as collect samples. Environmental swabbing was conducted at TII's packing facility. Additionally, (b) (4) water samples, apparent scat, sediment, and product samples were also collected. A (b) (4) sample was collected for all (b) (4) (b) (4) sourced agricultural water used in TII's operation; (b) (4) sourced agricultural water was not sampled during this investigation. TII voluntarily ceased all harvesting, processing, and packing activities for all products prior to the start of this investigation. Because of this, neither team was able to observe harvesting, processing, or packing activities during this investigation. A Farm Intelligent Questionnaire was completed for TII and attached to the memorandum as **attachment 18**.

TII reported that they are in their normal cycle of (b) (4) (b) (4). The operation is preparing to till and prep the onion fields for the (b) (4). TII plans to prepare the fields (b) (4) (b) (4), but no tentative date was given. Mr. Thomson stated that the (b) (4) and has not confirmed with the onion growers for the start of 2021 season.

COMPLETE NARRATIVE REPORT

This investigation was conducted by two teams with participants from both FDA, CDFA, and CDPH. The investigation and sampling began on August 3rd, 2020 with the field investigation concluding on August 12th, 2020. Five additional onion product samples were collected at TII by HAWW5 CSO Joseph Willems on August 17th, 2020. The close-out meeting was conducted on August 27th, 2020 with only myself (Daniel Gorski) and Thomson International President Jack Thomson present.

Team one (Aug 03 – Aug 05):

Team Lead - Ismael Garibay (FDA, HAFW5)
Joseph Willems (FDA, HAFW5)
DeLarian Dyson (CDFA)
Cristina Jimenez (CDFA)
Julian Potier (CDFA)

Team Two (Aug 06 – Aug 12):

Team Lead – Daniel Gorski (FDA PSN)
Shane Teeter (FDA PSN)
Arturo De La Garza (FDA PSN)
Avery Cromwell (FDA PSN)
Shane Rainey (FDA PSN)
Joseph Willems (FDA, HAFW5)
Rodrigo Chipres (CDFA)
Christian Bond (CDPH)

Responsible Individuals / Administrative Information

Team One (Aug 03 – Aug 05)

On 08/03/2020, Team One met with the following individuals to begin the investigation:

Mr. Jack S. Thomson, President
Mr. Jose A. Perez, Operations Manager
(b) (6), (b) (7)(C), Admin/Food Safety
(b) (6), (b) (7)(C) Sales Assistant

An FDA-482 (Notice of Inspection – **Attachment** 1) was issued to Thomson International President Jack Thomson on August 03. All four individuals listed above were present during environmental sampling. Thomson International Inc (also referred to as "TII" in this memorandum) did not collect their own environmental sample but did photograph the environmental sampling locations.

Team Two (Aug 06 – Aug 12)

On 08/06/2020, Team Two met with the following individuals to begin the investigation:

Mr. Jack S. Thomson, President
Mr. Jose A. Perez, Operations Manager
(b) (6), (b) (7)(C), Admin/Food Safety
(b) (6), (b) (7)(C), Food Safety

An additional FDA-482 (Notice of Inspection – **Attachment** 3) was issued to Thomson International President Jack Thomson on August 06. A third FDA-482 (Notice of Inspection – **Attachment** 5) was issued to Thomson International President Jack Thomson on August 17th by CSO Joey Willems.

No refusals were encountered by either team during this investigation.

TII voluntarily ceased all harvesting, processing, and packing activities for all products prior to the start of this investigation. Because of this, neither team was able to observe harvesting, processing, or packing activities during this investigation.

TII's onion operation is seasonal and runs generally from (b) (4). The packing facility hours of operation are (b) (4).

TII's corporate office is located approximately one mile from the packing facility at 9852 Buena Vista Blvd. Bakersfield, CA 93307.

TII utilizes contact laborers for both harvest and packing activities. TII's contract laborers are provided through a 3rd party company: (b) (4) (b) (4)

Investigation – Day One (08/03/2020)

The investigation was initialized by Team One on 08/03/2020 and had a primary objective to conduct environmental sampling at TII's packing facility. TII's packing facility experienced a power outage in the morning of 08/03/2020 that also affected neighboring businesses. TII did not get power back until after 11am, and some parts of the facility like the outdoor (b) (4) Line did not regain electricity until the following day. This initially impacted the operation's ability to log into their computers/printers to access documents at the start of the investigation.
Prior to beginning environmental sampling, Team One conducted a walkthrough of the operation's onion processing/packaging areas on TII's grounds. TII's packing operation consists of:

- (b) (4) used for processing/packing red, white, and yellow onions as well as (b) (4) consumer bagger lines
- (b) (4) used for processing/packing red, white, and yellow onions
- (b) (4) and onion staging area
- (b) (4) ambient storage rooms

During the walkthrough and environmental sampling on 08/03/2020, Team One observed two instances of apparent mammal droppings, two live cats, and two birds in the (b) (4) .

On 08/03/2020, Team One collected 108 environmental swabs under sample **INV 1145759**. Environmental swabs were collected from Zones 1,2, and 3 from the (b) (4) line and consumer bagger line ((b) (4)). The sample was shipped via FedEx and delivered to the PSFFL Lab on Tuesday, August 04, 2020.

Investigation – Day Two (08/04/2020)

On 08/04/2020, Team One collected 100 environmental swabs under sample INV 1145760. Environmental swabs were collected from Zones 1,2, and 3 from the (b) (4) consumer bagging line ((b) (4)) and partially from the (b) (4) Line. The samples were shipped via FedEx First and delivered to the PSFFL Lab on Wednesday, August 05, 2020.

Additionally, on 08/04/2020, Team One collected two subsamples of apparent mammalian scat to be analyzed for Salmonella under sample INV 1141449. The sample was shipped via FedEx and delivered to the PSFFL Lab on Wednesday, August 05, 2020. One subsample was collected from the plants ground located approximately 60 feet from staged onions in plastic bins and in an area where there is forklift activity. One subsample was collected approximately 5 feet from dedicated employee portable toilet area and in an area where there is employee foot traffic. The operation's manager stated that the portable toilets are intended for employees working the (b) (4) (b) (4)

While environmental sampling on 08/04/2020, Team One observed one cat in the (b) (4) near the (b) (4) line, three birds in the (b) (4) , and an apparent bird's nest along the top corner of the north west (b) (4) of the (b) (4) Line. The apparent nest is approximately five feet from the (b) (4) Line. The surrounding equipment, walls, and floor located near the apparent nest was sampled during environmental sampling

Team One also observed apparent pigeon droppings on the (b) (4) line adjacent to the (b) (4) line inside the (b) (4) and on the surrounding surface of the hopper used in the (b) (4) (b) (4) Line. The (b) (4) line, adjacent lines, and floor areas were sampled during environmental sampling.

Team One collected the following documents that were requested in the HAF5W assignment:

Exhibit 1 - GPS coordinates and maps of ranches were onions are grown
Exhibit 2 - 2020 customers that received lots implicated in the outbreak
Exhibit 3 - 2020 Customer List
Exhibit 4 - Pallet Tag & Sticker Label Example
Exhibit 5 - Brands Sold May 2020 to Present
Exhibit 6 - Lot Information & Lot Chart

Investigation – Day Three (08/05/2020)

On 08/05/2020, Team One collected 71 environmental swabs under sample INV 1145761. Environmental swabs were collected from Zones 1, 2, and 3 from the (b) (4)

Line, loading dock, (b) (4) onion storage rooms, and adjacent equipment and areas. The sample was shipped via FedEx and delivered to the PSFFL Lab on Thursday, August 06, 2020.

After Team One had completed sampling on 08/05/2020, Team One and Team Two held a meeting to facilitate transitioning from Team One to Team Two. The meeting consisted of a review Team One's observations at the packing facility, the samples collected, and a review of documents collected.

Investigation – Day Four (08/06/2020)

The investigation teams transitioned from Team One to Team Two on 08/06/2020. An additional FDA-482 (Notice of Inspection – **Attachment** 3) was issued to Thomson International President Jack Thomson on August 06 (signed by members of Team Two).

Team Two had broader objectives that included using FDA's Produce Safety Rule to evaluate and consider additional environmental factors TII's packing facility an (b) (4) of TII's ranches in (b) (4) to identify any conditions or practices that could have potentially contributed to this *Salmonella Newport* outbreak. Team Two was also tasked with collecting product, sediment, soil, scat, and (b) (4) water samples.

Team Two conducted a walk-through of TII's packing facility including the (b) (4) Line and the (b) (4) line and observed sanitation and maintenance concerns (see General Discussion with Management). We also collected sanitation records for Thomson's packing lines, which included procedures/records generated by both Thomson International and their contract labor company, (b) (4) . Discrepancies between the documents were noted. Practices observed on (b) (4) packing lines did not reflect what was in Thomson's or (b) (4) (b) (4) documents (see General Discussion with Management). We conducted a walkthrough of Thomson International's "Farm Shop" to obtain an inventory of equipment stored there, focusing on any shared equipment used on other Thomson ranches that do not grow onions.

On 08/06/2020, Team Two collected 1 sample (11 subsamples) of (b) (4) red onions, lot 563A, grown on (b) (4) field (b) (4) under sample INV 1145947. The product was packed on Thomson's (b) (4) Line. Team Two also collected 1 sample (11 subsamples) of (b) (4) white onions, lot 522C, grown on (b) (4) , field " (b) (4) under sample INV 1145948. The samples were shipped via FedEx and delivered to the NFFL Lab on Friday, August 07, 2020. Both product samples were collected from TII's packing facility.

Investigation – Day Five (08/07/2020)

Team two split into two groups to concurrently visit separate ranches where TII had grown onions in 2020. CSO's Gorski, Teeter, De La Garza, and Rodrigo Chipres (CDFA) conducted a walkthrough of ranch (b) (4) An FDA-482 (Notice of Inspection – **Attachment 4**) issued to (b) (4), (b) (5), (b) (7)(C) (of (b) (4)) on 08/07/2020 All (b) (4) water is sourced from (b) (4) . No sampling opportunities were identified at this ranch. A ranch map for (b) (4) is included as Exhibit 1, page 10.

CSO's Willems, Rainey, Cromwell, and Christian Bond (CDPH) conducted a walkthrough of ranch (b) (4). Four samples were collected from this location on 08/07/2020 and sent via FedEx to NFFL for delivery on Saturday August 08:

INV 1145949 – 1 subsample of apparent animal scat
INV 1145950 – 3 subsamples of sediment from the (b) (4) on (b) (4)
INV 1145623 - 1 (b) (4) representing approximately 80 liters of water collected from (b) (4) on (b) (4) ranch.
(b) (4)
INV 1145624 - 1 (b) (4) used to (b) (4) approximately 100 liters of water from the (b) (4) of the (b) (4), a (b) (4) (b) (4) that (b) (4) (b) (4)

A ranch map for (b) (4) is included as Exhibit 1, page 4.

Investigation – Day Six (08/08/2020)

Team two split into two groups to concurrently visit separate ranches where TII had grown onions in 2020. CSO's Gorski, Teeter, and Rainey conducted a walkthrough of ranch (b) (4) (b) (4) All irrigation water is sourced from (b) (4). No sampling opportunities were identified at Ranch (b) (4) A ranch map for ranch (b) (4) is included as Exhibit 1, page 5.

CSO's Willems, De La Garza, and Cromwell conducted a walkthrough of TII's (b) (4) ranch. No sampling opportunities were identified at TII's (b) (4) ranch. A ranch map for (b) (4) is included as Exhibit 1, page 9.

Investigation – Day Seven (08/10/2020)

On 08/10/2020, CSO's Willems, Cromwell, and De La Garza and Christian Bond (CDPH) visited TII's two (b) (4) ranches ((b) (4) (b) (4) Prior to starting the walkthrough, the team met with (b) (4), (b) (6), (b) (7)(C) (Supervisor) of (b) (4) and issued an FDA-482 (Notice of Inspection – **Attachment 19**). (b) (4) (b) (4) each have (b) (4) on site that feeds an (b) (4), which is ultimately used for irrigation. The (b) (4) on (b) (4) (b) (4) are (b) (4). 1 DEUF water sample and a corresponding sediment sample was collected from each (b) (4)

(b) (4) acres. No apparent environmental concerns and no significant wildlife concerns were observed by investigators or stated by (b) (6), (b) (7)(C). Yellow onions were planted in (b) (4) and harvested on (b) (4) 2020. Harvesting was contracted by Thomson International. (b) (6), (b) (7)(C) stated he does not have information on pesticide applications and fertilizer applications. The land is (b) (4) from (b) (6), (b) (7)(C). A ranch map for

(b) (4) is included as Exhibit 1, page 8. The following two samples were collected from (b) (4) (b) (4) on 08/10/2020:

INV 1145951 – (b) (4) 100 liters from the (b) (4) (b) (4). (b) (4)
INV 1145952 –4 subsamples of sediment from the same (b) (4) (same GPS as the (b) (4) sample above)

(b) (4) acres for red and white onions. The land (b) (4) are owned by (b) (4) The water (b) (4) measures approximately (b) (4) '. The water is sourced (b) (4) % from (b) (4) and (b) (4) % from (b) (4), according to (b) (6), (b) (7)(C). Thomson is in charge of the harvest. Onions were planted at this ranch around (b) (4) and were harvested in late (b) (4). A ranch map for (b) (4) is included as Exhibit 1, page 7.
The following two samples were collected from (b) (4) on 08/10/2020:

INV 1145953 - 1(b) (4) 100 liters from the (b) (4) (b) (4) (b) (4)
INV 1145954 - 4 subsamples of sediment from the same (b) (4) (same GPS as the (b) (4) sample)

Also, on 08/10/2020, CSOs Gorski and Teeter collected onion product samples from TII's packing facility. The following product samples were collected on 08/10/2020:

INV1145625 Lot 543C Field: (b) (4) 11 subs	Bagged onions. Returned from customer as part of the recall	Red onion "(b) (4) " varietal	NFFL
INV1145626 Lot 543A Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	Red onion "(b) (4) varietal	NFFL
INV1145627 Lot 571 A Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	(b) (4) White	NFFL
INV1145628 Lot 522 Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	(b) (4)	NFFL
INV1145629 Lot 581/591 Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	Yellow onion "(b) (4)" varietal Jack Thomson stated lot was 581, bins were labeled "591"	NFFL

INV1145955 Lot 561 Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	Yellow onion	NFFL
INV1145956 Lot 563 Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	Red onion "(b) (4) " varietal	NFFL

Investigation – Day Eight (08/11/2020)

No samples collected. Document review at TII's packing facility and additional information was collected. At this time, I contacted my supervisor to schedule a meeting to discuss the concerns the team had seen and schedule the close-out meeting.

According to Jack Thomson, no product was shipped to (b) (4) from Thomson International in July 2020. The two most recent shipments were both in June:

- Order #10272: (b) (4) – 50lb sacks of Jumbo Yellow onions and (b) (4) – 50lb sacks of Colossal Yellow onions, both lot 531, grown on (b) (4) , branded "Thomson Premium". Harvested (b) (4) ; shipped 06/12/2020

- Order #10275: (b) (4) – 40lb cartons of Sweet Jumbo Yellow onions were rejected by TII customer (b) (4) so TII directed (b) (4) to send the (b) (4) rejected cartons to (b) (4) . Lot 571, grown on TII (b) (4) branded "TLC Thomson International". Shipped 6/1520, arriving at (b) (4) ~06/16/2020

Order # 10209 was a shipment of 50lb Colossal Yellow onions from TII via Onions 52 to (b) (4) (b) (4)). The onions used to supply this order were lot 531A, grown on (b) (4) consisting of (b) (4) – 50lb bags harvested on (b) (4) , shipped on 06/06/2020.

Investigation – Day Nine (08/17/2020)

CSOs Joey Willems and Nicolas Tolosa collected 5 additional product samples. An FDA-482 (Notice of Inspection – **Attachment 5**) was issued to President Jack Thomson on 08/17/2020 by CSO Willems. CSO Willems also obtained more information regarding TII's (b) (4) field on (b) (4) that (b) (4) . Mr. Thomson stated that no biological soil amendments were used on the (b) (4) field. He stated that (b) (4) fertilizers were added only, although he could not immediately provide the names/dates applied. Mr. Thomson also stated that the (b) (4) field covers (b) (4) on the (b) (4) of the (b) (4) field. The remaining (b) (4) was used to grow onions. Th (b) (4) field yielded an estimated (b) (4) tons per acre. It was planted on or about (b) (4) , and harvested on or about (b) (4) . Mr. Thomson stated the onions were harvested from (b) (4) , depending on whether or not

that portion of the field was ready. Mr. Thomson also stated that no toilet facilities were present on (b) (4) at the time the (b) (4). Mr. Thomson again clarified that using the water from (b) (4) on (b) (4) to irrigate onions is not normal practice and has never happened before. He explained that (b) (4) statement summarizing the incident was drafted by Mr. Thomson and included as Exhibit 9. A diagram showing the flow of water from (b) (4) (b) (4) to the onion fields on (b) (4) is included as Exhibit 8.

The following product (onion) samples were collected by CSOs Joey Willems and Nicolas Tolosa on 08/17/2020 at TII's packing facility:

INV1146412 Lot 533A Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	Red onion "(b) (4)" varietal	NFFL
INV1146413 Lot 532A Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	Red onion "(b) (4)" varietal	NFFL
INV1146414 Lot 522A Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	White onion "(b) (4) (b) (4)" varietal	NFFL
INV1146415 Lot 551E Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	Yellow onion "(b) (4)" varietal	NFFL
INV1146416 Lot 553A Field: (b) (4) 11 subs	Bulk bin onions that were not run through Thomson packing lines	Red onion "(b) (4)" varietal	NFFL

Investigation – Day Ten, Close-out Meeting (08/27/2020)

On 08/27/2020, I (CSO Gorski) met with President Jack Thomson for the close-out meeting. Only Mr. Thomson and I were present for this meeting. During this meeting, we went over 11 discussion items identified over the course of the investigation. An FDA-484 was issued at the conclusion of the meeting. Mr. Thomson promised correction of all 11 verbal discussion items. He stated he would respond in writing to the discussion items, which I expressed is voluntary. As Mr. Thomson wanted to ensure he captured everything accurately, he and I went over his notes prior to concluding the investigation and issuing the FDA-484.

Sample Summary for Entire Investigation

Sample #	Collection Date	Sample Description	FDA Lab	Results
INV 1145759	08/03/2020	108 environmental swabs from Zones 1,2, and 3 from the (b) (4) line and consumer bagger line ((b) (4) bagger)	PSFFL Lab	Negative

INV 1145760	08/04/2020	100 environmental swabs from Zones 1, 2, and 3 from the (b) (4) consumer bagging line ((b) (4)) and partially from the (b) (4) line	PSFFL Lab	Negative
INV 1141449	08/04/2020	2 subsamples of apparent mammalian scat o Sub 1: Scat from the plants ground, approx. 60 ft from staged onions in plastic bins o Sub 2: Scat, approx. 5 ft from dedicated employee portable toilet area	PSFFL Lab	Negative
INV 1145761	08/05/2020	71 environmental swabs from Zones 1-3 from the outdoor (b) (4) line, loading dock, (b) (4) onion storage rooms, and adjacent equipment and areas	PSFFL Lab	Negative
INV 1145947	08/06/2020	11 subs of (b) (4) red onions, lot 563A, grown on (b) (4) field (b) (4) Product was packed on Thomson's (b) (4) (b) (4) line.	NFFL	Negative
INV 1145948	08/06/2020	11 subs of (b) (4) white onions, lot 522C, grown on Thomson Ranch, (b) (4) (b) (4)	NFFL	Negative
INV 1145949	08/07/2020	1 sub of apparent animal scat ((b) (4) field area)	NFFL	Negative
INV 1145950	08/07/2020	3 subs of (b) (4) (between (b) (4))	NFFL	Negative
INV 1145623	08/07/2020	(b) (4) ~80L of water from a (b) (4) on (b) (4)	NFFL	Negative
INV 1145624	08/07/2020	(b) (4) ~100L of (b) (4) water (b) (4)	NFFL	Negative
INV1145625	8/10/2020	Bagged onions. Returned from customer as part of the recall; Red onion "(b) (4) " varietal; Lot 543C Field: (b) (4) ; 11 subs	NFFL	Negative
INV1145626	8/10/2020	Bulk bin onions that were not run through Thomson packing lines; Red onion "(b) (4) (b) (4) varietal; Lot 543A Field: (b) (4) ; 11 subs	NFFL	Negative
INV1145627	8/10/2020	Bulk bin onions that were not run through Thomson packing lines; (b) (4) White; Lot 571 A Field (b) (4) 11 subs	NFFL	Negative
INV1145628	8/10/2020	Bulk bin onions that were not run through Thomson packing lines; (b) (4) ; Lot 522 Field: (b) (4) 11 subs	NFFL	Negative
INV1145629	8/10/2020	Bulk bin onions that were not run through Thomson packing lines; Yellow onion "(b) (4) " varietal Jack Thomson stated lot was 581, bins were labeled "591" Lot 581/591; Field: (b) (4) 11 subs	NFFL	Negative
INV1145955	8/10/2020	Bulk bin onions that were not run through Thomson packing lines; Yellow onion; Lot 561	NFFL	Negative

		Field: (b) (4) ; 11 subs		
INV1145956	8/10/2020	Bulk bin onions that were not run through Thomson packing lines; Red onion "(b) (4) (b) (4) varietal; Lot 563 Field: (b) (4) ; 11 subs	NFFL	Negative
INV 1145951	8/10/2020	(b) (4) water; 1 sub; (b) (4) approximately 100 liters	NFFL	Negative
INV 1145952	8/10/2020	Sediment collected from (b) (4) (b) (4) ; 4 subs	NFFL	Negative
INV 1145953	8/10/2020	(b) (4) water 1 sub; (b) (4) approximately 100 liters	NFFL	Negative
INV 1145954	8/10/2020	Sediment collected from the (b) (4) (b) (4) ; 4 subs	NFFL	Negative
INV 1146412	8/17/20	Lot 533A; Field (b) (4) red onion "(b) (4) " varietal	NFFL	Negative
INV 1146413	8/17/20	Lot 532A; Field (b) (4) ; white onion "(b) (4) " varietal	NFFL	Negative
INV 1146414	8/17/20	Lot 522A; Field (b) (4) white onion "(b) (4) (b) (4) " varietal	NFFL	Negative
INV 1146415	8/17/20	Lot 551E; Field: (b) (4) ; Yellow onion "(b) (4) " varietal	NFFL	Negative
INV 1146416	8/17/20	Lot 553A; Field (b) (4) ; Red onion "(b) (4) " varietal	NFFL	Negative

General Discussion with Management

As this was a directed outbreak investigation and not a produce safety inspection, no FDA-4056 was issued. No egregious conditions were observed. Prior to the conclusion of this inspection, the following items were discussed with Thomson International President Jack Thomson:

- **Verbal discussion items 1 – 7 are concerns that were discussed that directly relate to a specific cite within the PSR currently being enforced.**

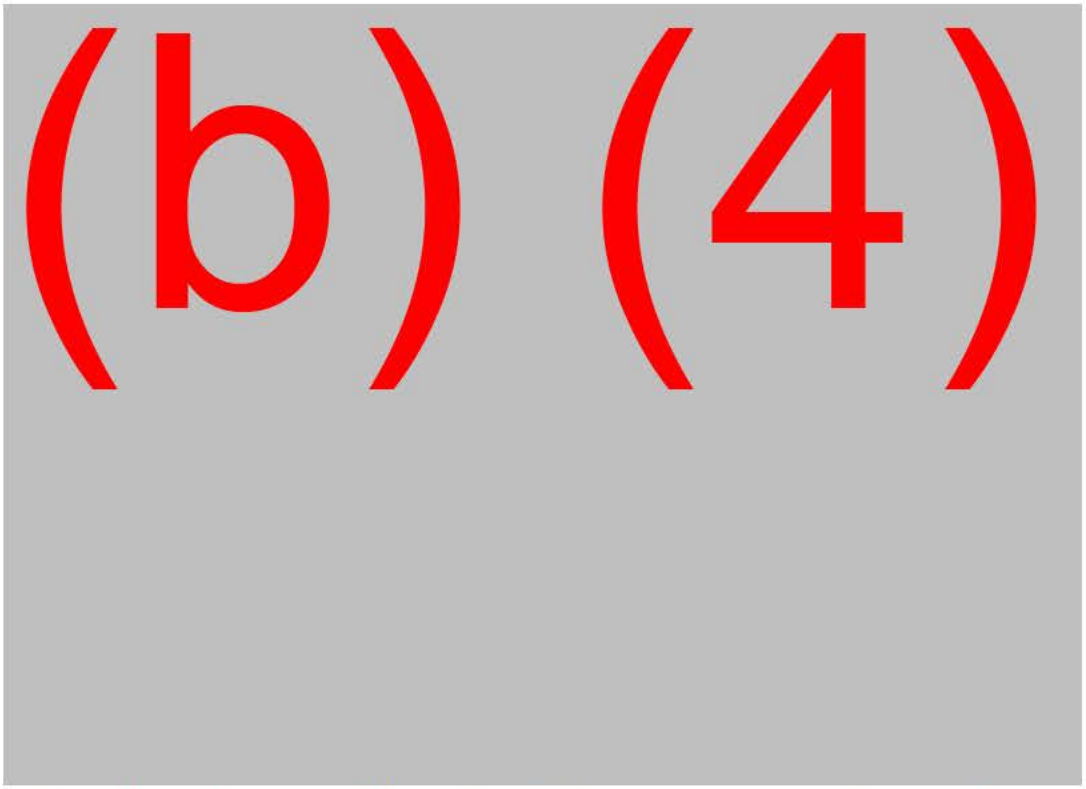
(1)
You did not take adequate measures to exclude pests from your (b) (4) buildings.

21 CFR 112.128(b)

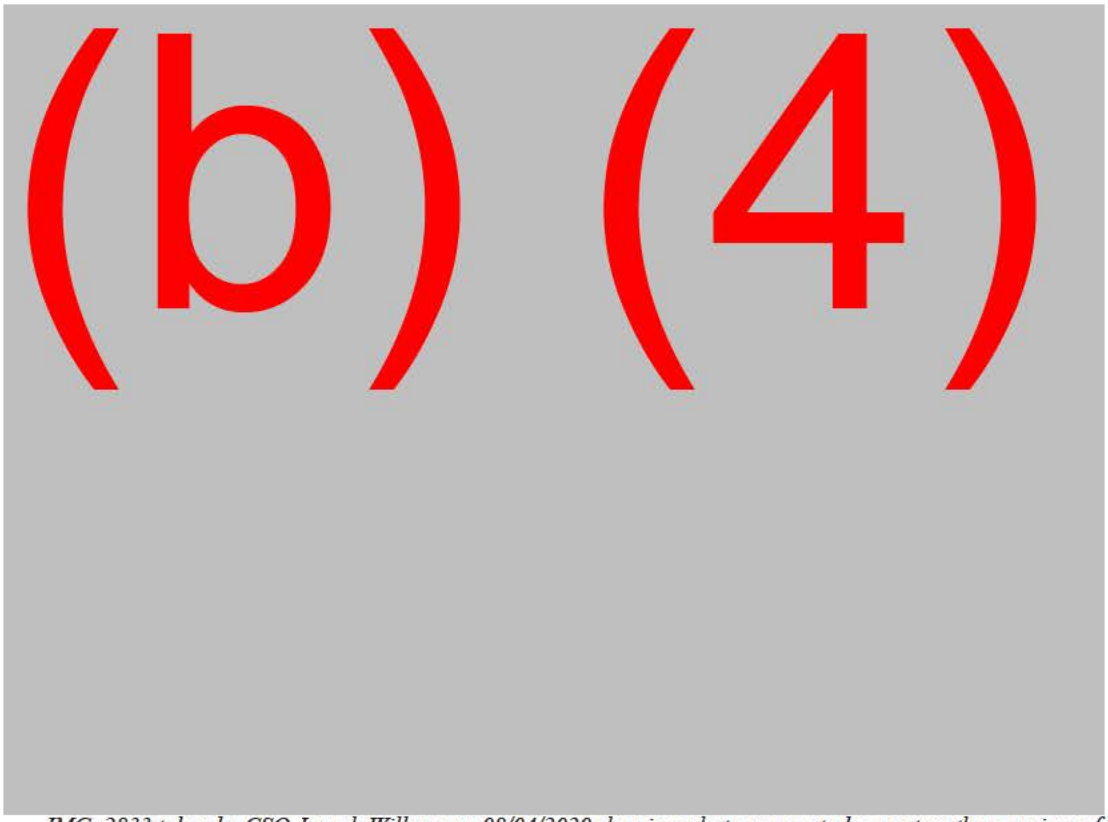
Specifically,

a. On 08/03/20, CSO JW observed two cats in the (b) (4) where onion packing occurs.
b. On 08/04/20, CSO JW observed one cat in the (b) (4) near the (b) (4) line used for packing onions.
c. On 08/04/20, CSO JW observed three pigeons in the (b) (4) above your (b) (4) (b) (4) line.
d. On 08/11/2020, CSOs (DG, AD, SR, AC, ST, JW) observed two pigeons on the support beams near the ceiling, above the (b) (4) line in the (b) (4)

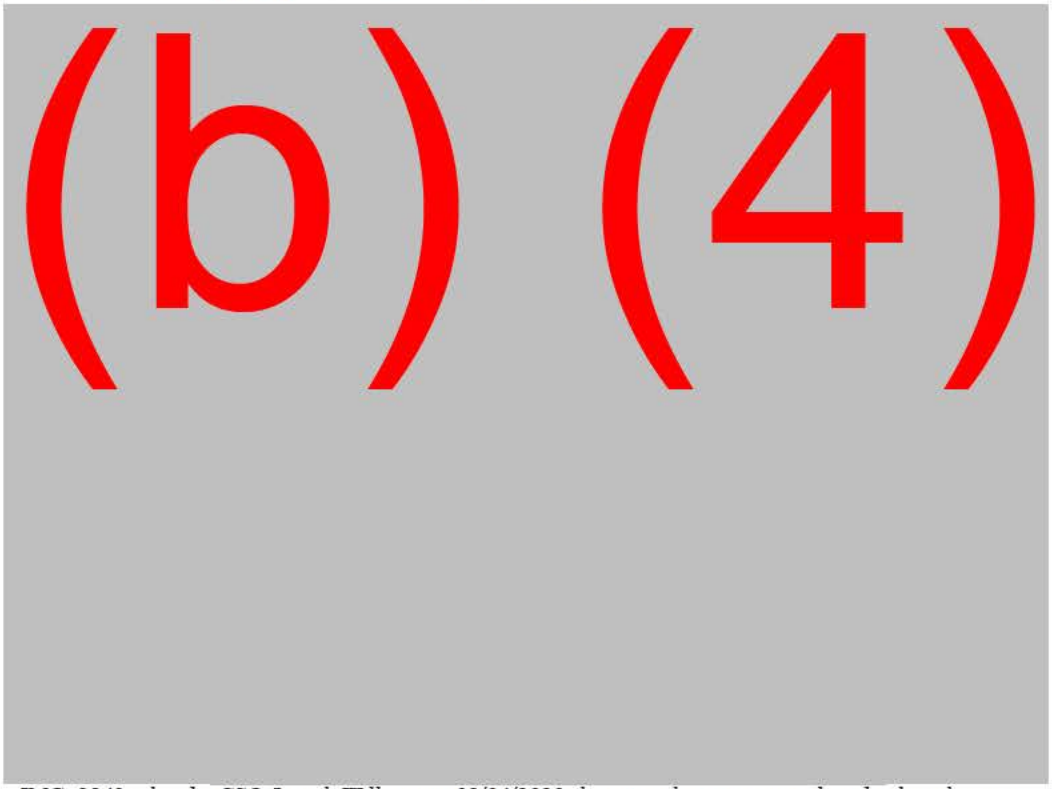
Supporting Evidence and Relevance:



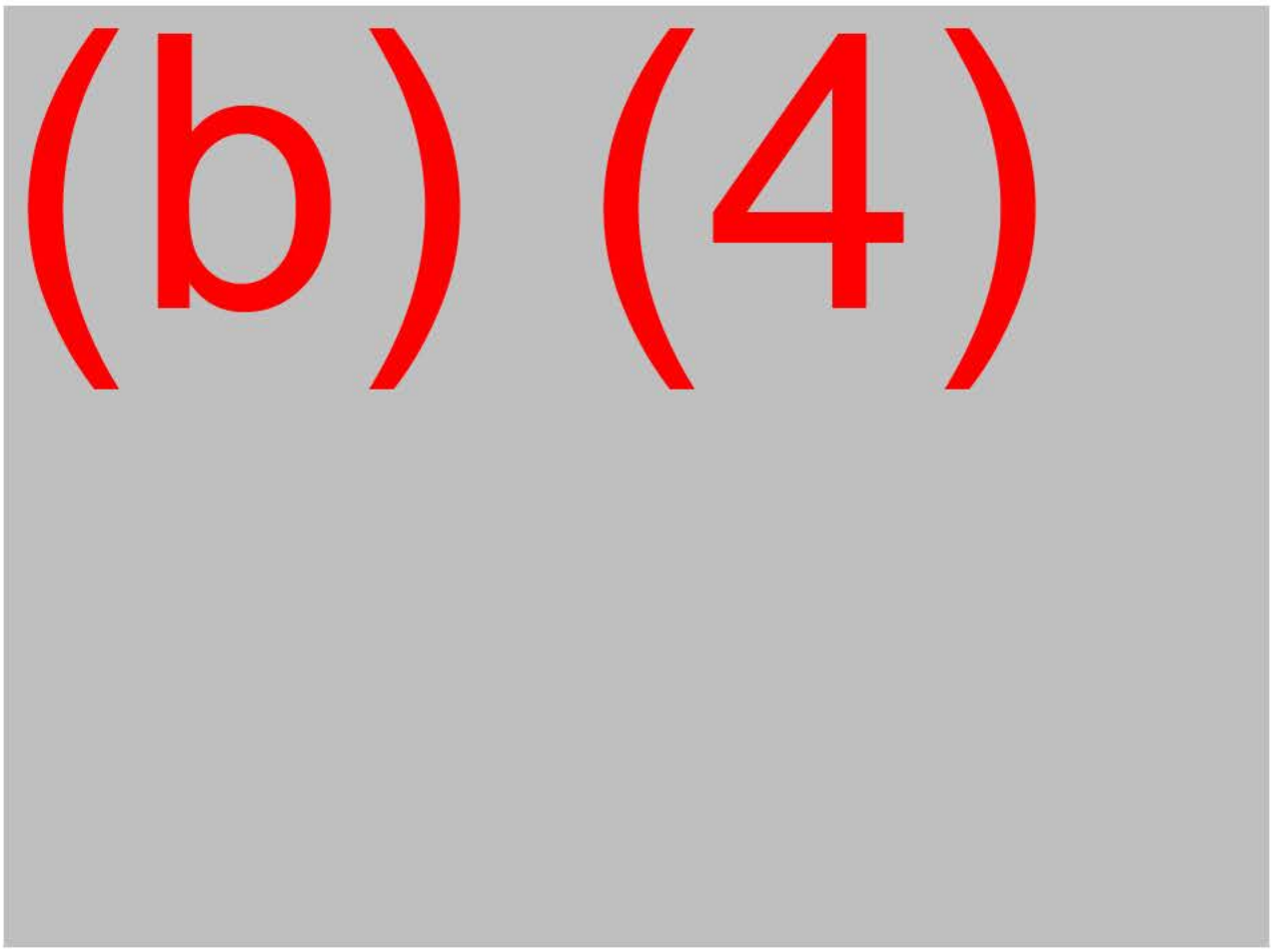
IMG_2711 taken by CSO Joseph Willems on 08/03/2020 showing an apparent cat at TII's packing facility, approximately 5 feet from watermelons stored in bins.



IMG_2833 taken by CSO Joseph Willems on 08/04/2020 showing what appears to be a cat on the premises of Thomson International, in the (b) (4) *near the Northwest roll-up door.*



IMG_2841 taken by CSO Joseph Willems on 08/04/2020 showing what appears to be a bird on the premises of Thomson International, directly above the onion (b) (4) *line.*



IMG_2840 taken by CSO Joseph Willems on 08/04/2020 showing closeup image of what appears to be a bird on the premises of Thomson International, directly above the onion (b) (4) line.

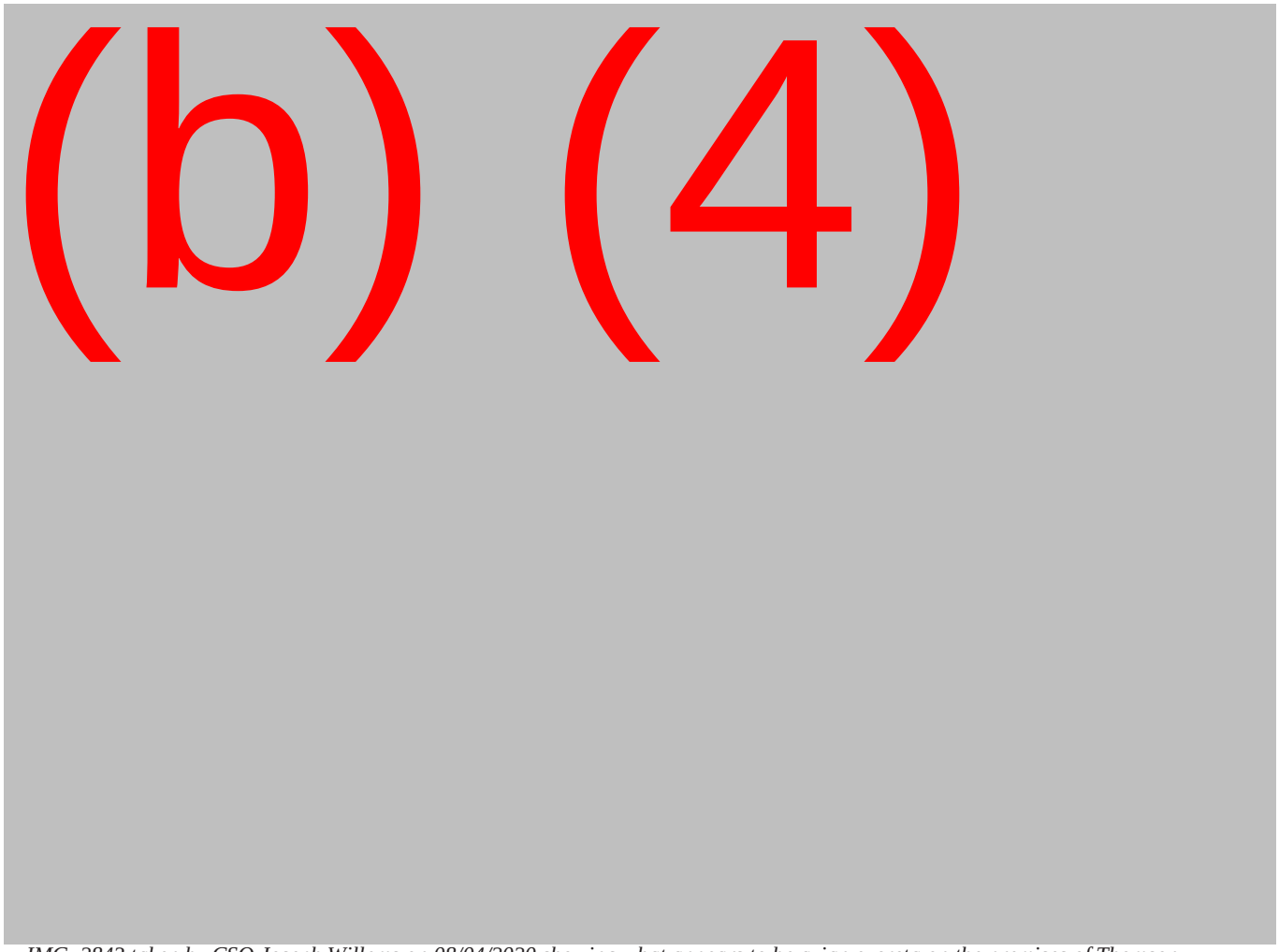
(2)
You did not take necessary measures to protect against contamination by pests in buildings.

21 CFR 112.128(a)

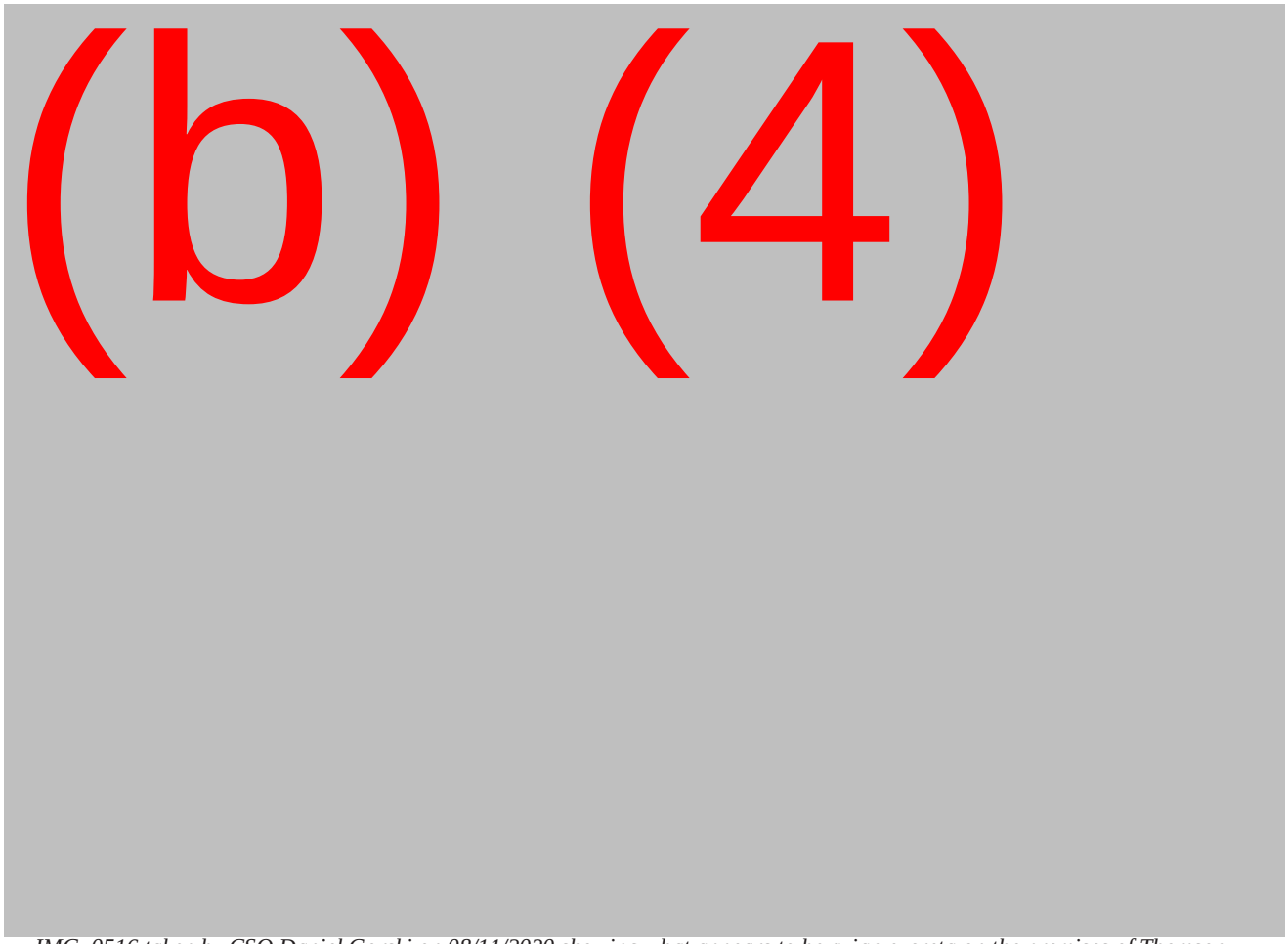
Specifically,

a. On 08/04/20, CSO JW observed apparent bird droppings on the onion (b) (4) line adjacent to the (b) (4) inside the (b) (4) line and apparent bird droppings on the surrounding surface of the onion loading hopper, a food contact surface, in the (b) (4) line.
b. On 08/11/20, CSOs (DG, SR, ST, AD) observed apparent bird droppings on a metal chute at the end of a conveyor on the (b) (4) in the (b) (4) . This chute is a direct food contact surface. Apparent bird droppings were also observed on a metal beam on the (b) (4) line, adjacent to this chute.

Supporting Evidence and Relevance:



IMG_2843 taken by CSO Joseph Willems on 08/04/2020 showing what appears to be avian excreta on the premises of Thomson International, on the (b) (4) *line directly below where the apparent bird was observed.*



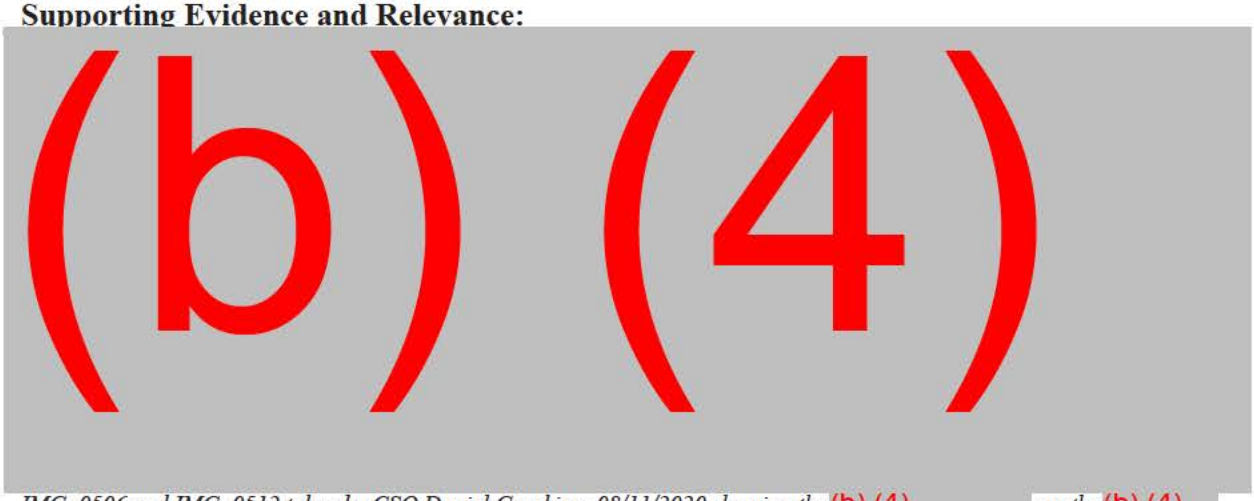
IMG_0516 taken by CSO Daniel Gorski on 08/11/2020 showing what appears to be avian excreta on the premises of Thomson International, on the (b) (4) *line*

(3)
You did not inspect, maintain, clean, and sanitize food contact surfaces as frequently as necessary to protect against the contamination of produce.

21 CFR 112.123(d)(1)

Specifically, (b) (4) brush rollers on the (b) (4) packing line were observed to have a thick build-up of dirt and soil that directly contacts onions. Onions pass through these (b) (4) (b) (4) brush rollers after they are conveyed from the hopper, immediately before the (b) (4) line. This build-up was not removed though TII's last regular cleaning/sanitizing activities, occurring prior to 08/03/20.

Supporting Evidence and Relevance:



IMG_0506 and IMG_0512 taken by CSO Daniel Gorski on 08/11/2020 showing the (b) (4) *on the* (b) (4) (b) (4) *Line*

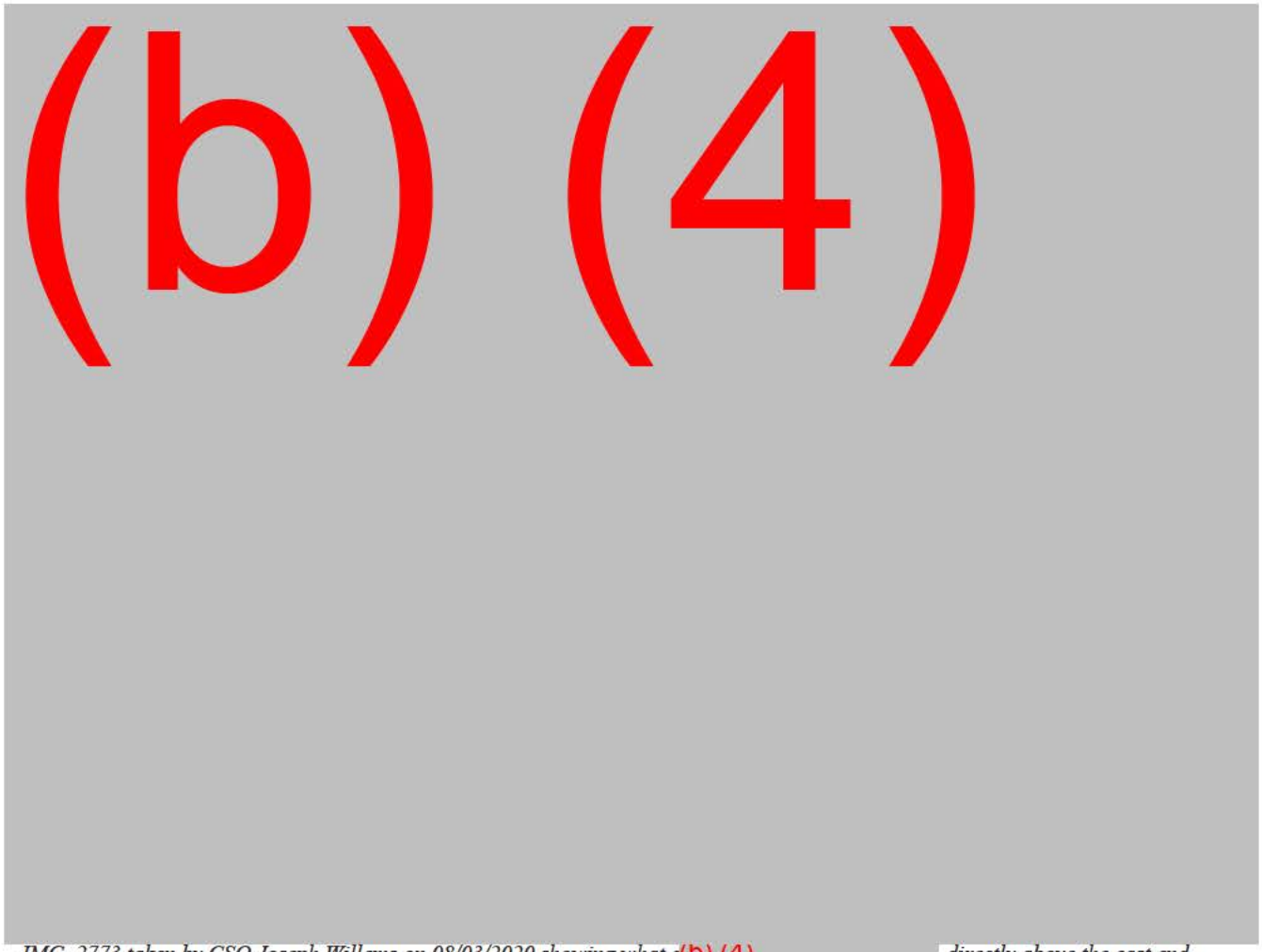
(4)

You did not install and maintain equipment to facilitate cleaning of the equipment and adjacent area.

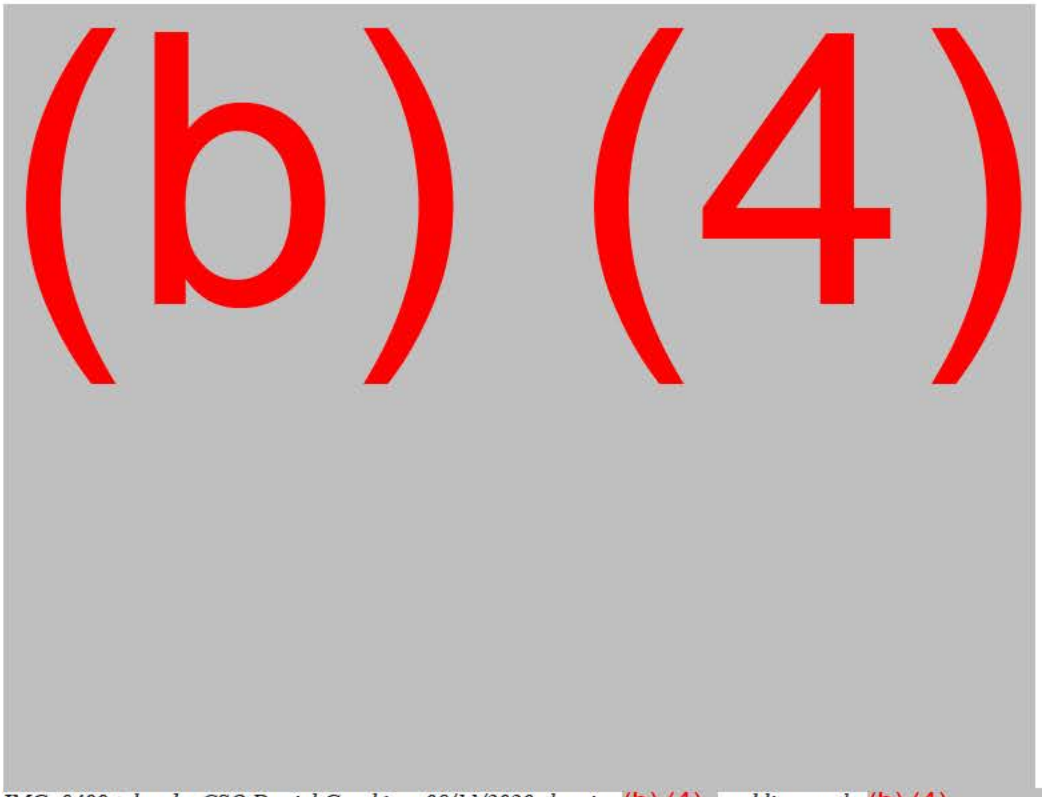
21 CFR 112.123(b)(1)

Specifically, (b) (4) brush rollers on the (b) (4) line were observed in disrepair. The rollers are used to remove soil from onions after being loaded onto the line from the hopper, before the sorting line. The bristles on the brush rollers showed substantial degradation with a thick build-up of dirt and soil. Some (b) (4) brush rollers had degraded to the point where the bristles on the rollers had worn down completely and only the base plastic remained. Additionally, the (b) (4) padding on the (b) (4) hopper was observed peeling off the lip of the hopper with significant soil and dirt build-up trapped underneath. Rough, dirty weld points were observed at the output of the (b) (4) hopper. The (b) (4) padding near the output end of the (b) (4) Line (b) (4) line was observed to have been installed in a manner that collects significant dirt and soil.

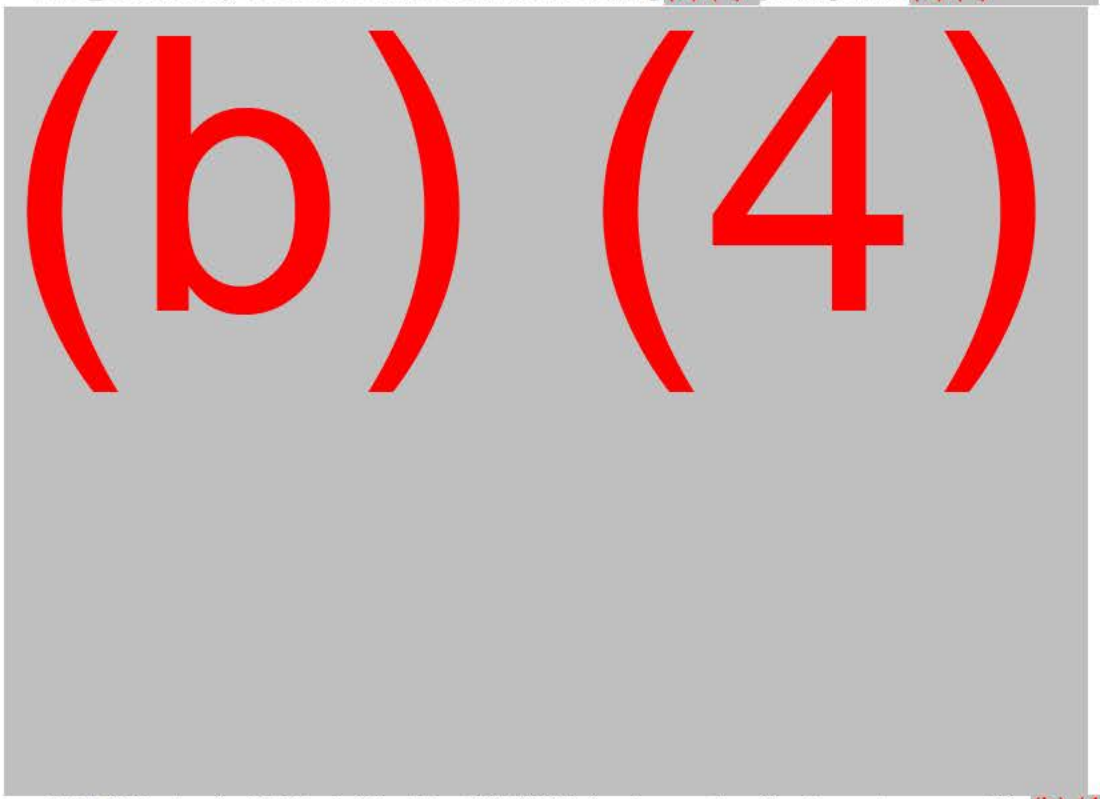
Supporting Evidence and Relevance:



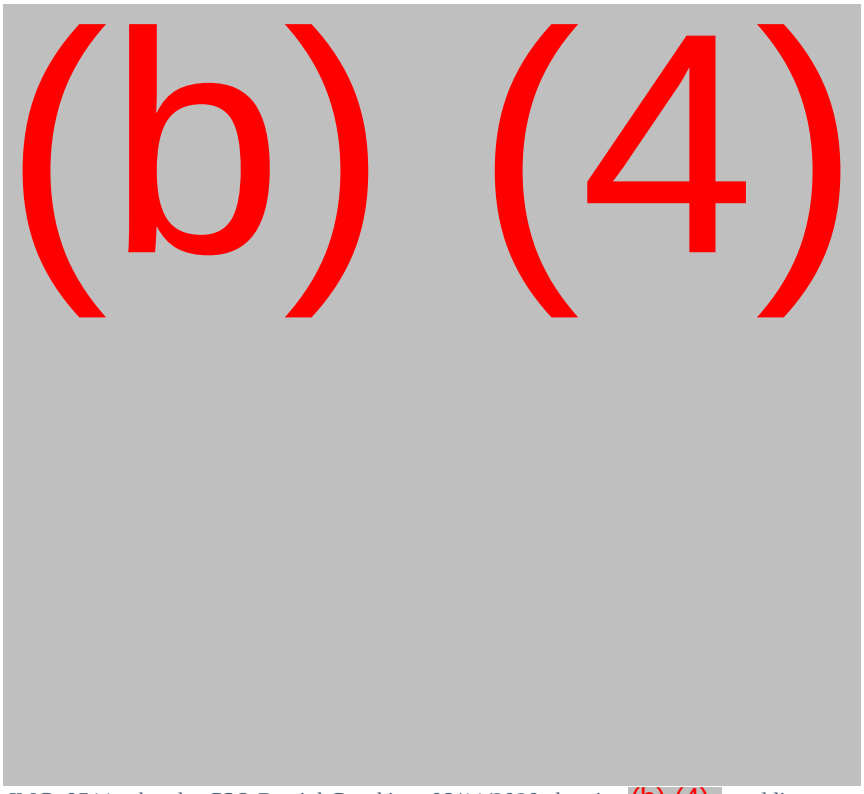
IMG_2773 taken by CSO Joseph Willems on 08/03/2020 showing what a (b) (4) *directly above the east end of the* (b) (4) *in the* (b) (4) *Line.*



IMG_0499 taken by CSO Daniel Gorski on 08/11/2020 showing (b) (4) *padding on the* (b) (4)



IMG_0500 taken by CSO Daniel Gorski on 08/11/2020 showing rough weld points at the output of the (b) (4) *hopper*



IMG_0511 taken by CSO Daniel Gorski on 08/11/2020 showing (b) (4) *padding near the output end of the* (b) (4) *Line* (b) (4) *line*

(5)
You did not establish and keep documentation of the date and method of cleaning and sanitizing of equipment.

21 CFR 112.140(b)

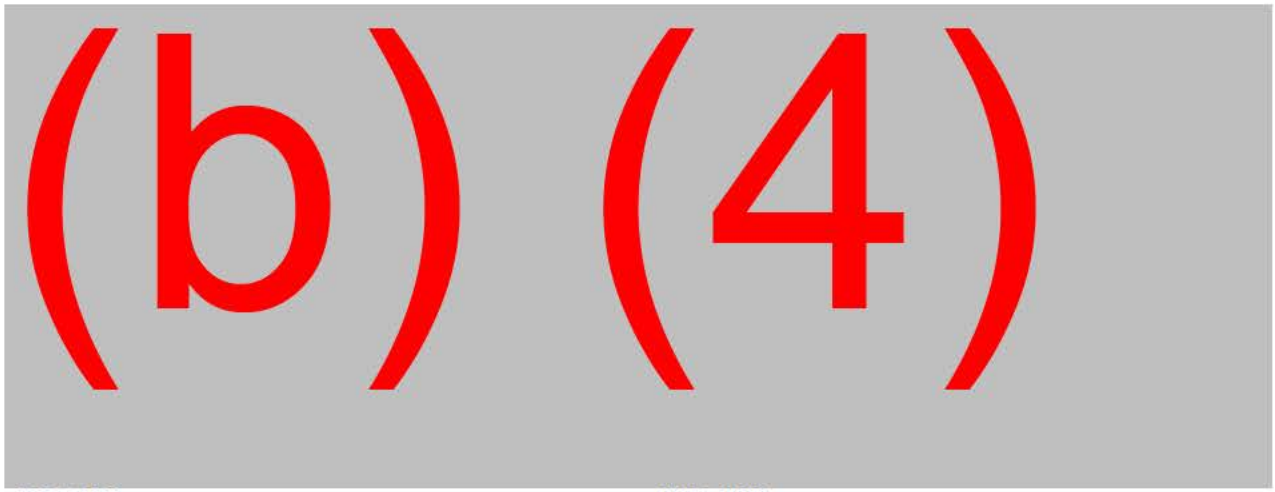
Specifically, you do not maintain any records of harvest container inspection or harvest container cleaning activities during this growing season, which occurred approximately (b) (4)(b) (4) to (b) (4)(b) (4) nd you harvested approximately (b) (4) acres of onions.

Additionally, you do not maintain any records of harvest equipment inspection or harvest equipment cleaning activities for (b) (4) and (b) (4) stored at TII's Farm Shop used during your (b) (4) onion growing season.

Supporting Evidence and Relevance:

According to Mr. Thomson, if an employee determines a harvest container must be cleaned during the season, it is brought to a designated area (IMG_0497 & IMG_0498) at the packing facility and cleaned using (b) (4) . Mr. Thomson was unable to provide records or give details as to what employees are trained to look for when determining if a harvest container necessitates cleaning throughout the season. Harvest container cleaning is conducted

by (b) (4) laborers; harvest container inspection can be conducted by TII or (b) (4) (b) (4) employees.



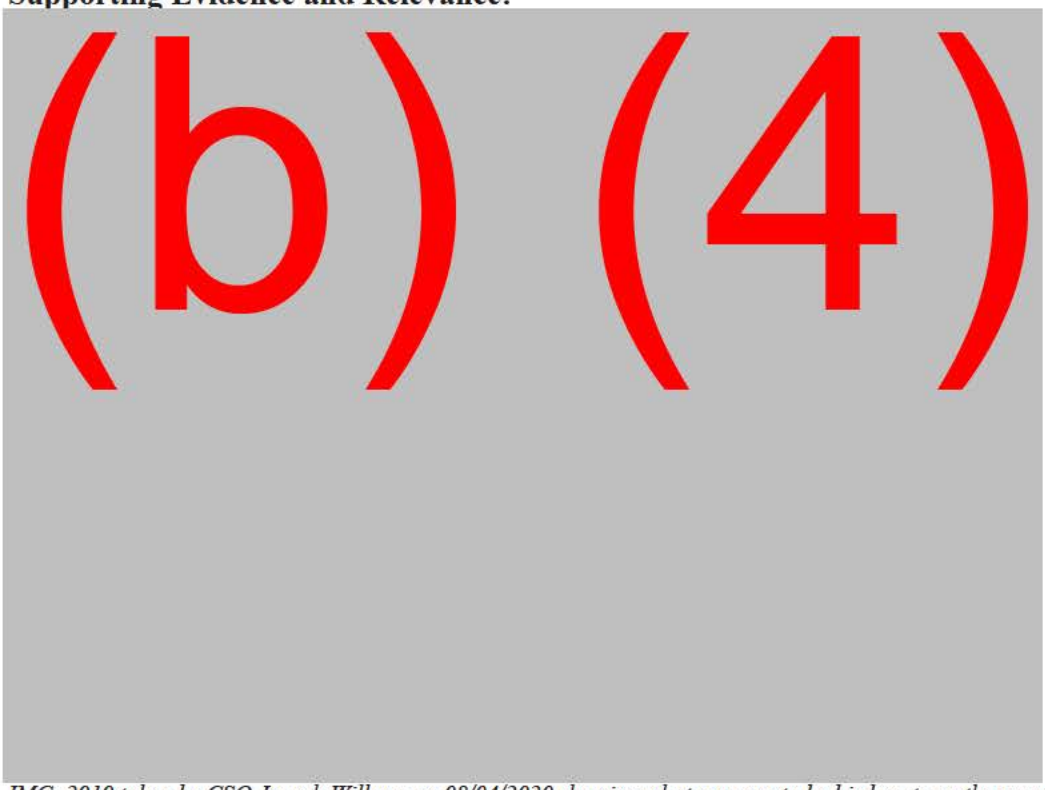
IMG_0497 *IMG_0498*

(6)
You did not take adequate measures to prevent pests from becoming established in your (b) (4) (b) (4) buildings.

21 CFR 112.128(c)

Specifically, during the investigation, we observed apparent swallow nests along the top corner of the north west (b) (4) , approximately five feet from the (b) (4) (b) (4) line which you used to pack onions.

Supporting Evidence and Relevance:



IMG_2919 taken by CSO Joseph Willems on 08/04/2020 showing what appears to be bird nests on the premises of TII's packing facility, at the top of (b) (4) *on the Northwest side of the* (b) (4) *line.*

(7)

You did not provide training to persons who conduct harvest activities that includes inspecting harvest containers and equipment so they are not a source of contamination and correcting or reporting problems with harvest containers or equipment.

21 CFR 112.22(b)

Specifically, we reviewed your employee training records for your 2020 harvest season, and they did not include training on inspecting harvest containers and equipment.

Supporting Evidence and Relevance:

Exhibit 16 is the training material presented to TII contract laborers before they are allowed to work at TII's packing facility. Exhibit 16, page 1 is the food safety and hygiene training that packing facility employees receive. TII's food safety and hygiene training document does not include training on inspecting harvest containers and equipment. TII has a document titled, "Personnel Food Safety Training SOP" (exhibit 21) that was created, signed, and reviewed by (b) (6), (b) (7)(C) on 03/13/2020. TII also has a document titled, "Food Safety Hygiene and Health Policy" (exhibit 22) that was updated and signed by (b) (6), (b) (7)(C) on 03/13/2020. TII did not provide any corresponding logs or other documentation showing that these trainings had been administered to either TII or contract employees. Mr. Thomson stated that contract laborer

training is provided and recorded by (b) (4) and the documentation in exhibit 16 is all of the training records for TII contract employees.

- **Verbal discussion items 8 – 12 are concerns that were discussed that do not directly relate to a specific cite within the PSR currently being enforced.**

(8)
Thomson International has 2 separate and apparently unrelated cleaning/sanitation SOPs that apply to their packing line. One drafted by (b) (4) and one drafted by Thomson International:

1.) TII's "Master Sanitation SOP – TII0008" (exhibit 17) states that cleaning frequency for their packing lines is "(b) (4) (b) (4) The (b) (4) Cleaning Procedure (Written In Instruction Format)" indicated the following steps: equipment must be free of raw material/packing material/finished goods, removal of debris, (b) (4) rinsing with hose, scrubbing with soap (b) (4), rinsing with hose, visual inspection of equipment, clean/rinse floor drains, and lastly allow to air dry. Within this same SOP, the "(b) (4) Sanitizing Procedure (Written In Instruction Format)" the same steps in the (b) (4) Cleaning Procedure should be followed, but in addition, sanitizer should be applied after the equipment is cleaned. TII generates a "(b) (4) Production Cleaning Log" and a "(b) (4) Sanitation Log" (exhibit 18) that documents (b) (4) cleaning and (b) (4) sanitation activities take place. However, we were explicitly told by Jack Thomson and (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) that the (b) (4) cleaning of the packing line is not a wet clean and no water or other liquid is used (b) (4)

2.) An additional sanitation SOP titled "SSOP Standard Operation Procedure #08 (To clean (b) (4)) drafted by (b) (4) was also provided by TII management. Mr. Thomson initially stated that "SSOP Standard Operation Procedure #08" (exhibit 19) was the SOP followed for cleaning activities at TII's packing facility and that (b) (4) procedures supersede any internal TII procedures. "SSOP Standard Operation Procedure #08" includes the following steps: (b) (4) washing, foam soap cleaner, scrubbing, and sanitizing with (b) (4) and left to dry ((b) (4)), with a (b) (4) frequency of (b) (4) ". The corresponding (b) (4) Machine Cleaning and Sanitizing Log" (exhibit 20) documents indicate that these cleaning procedures are followed (b) (4) documented a (b) (4) wet clean. TII management stated the (b) (4) Machine Cleaning and Sanitizing Logs were inaccurate and a (b) (4) does not happen (b) (4)

(9)
(b) (4) provided TII with records documenting the cleaning of toilets used by (b) (4) (b) (4) harvest crews while on TII fields. The records do not include the method of

cleaning. According to TII management, the physical toilets are provided by (b) (4) (b) (4) and the cleaning activities are performed by (b) (4). Mr. Thomson was unable to provide a description of how and where the toilets are cleaned, but provided a document summarizing (b) (4) sanitation services (exhibit 14). The records provided by (b) (4) (exhibit 13) lis (b) (4) services (b) (4) for the harvest crew toilets (b) (4) (b) (4) Mr. Thomson described the (b) (4) services on (b) (4) " as (b) (4) . Mr. Thomson could not clarify why the (b) (4) are cleaned (b) (4) but the (b) (4) is not.

(10)
A (b) (4) was used as a source for irrigation water on onions growing on (b) (4) in (b) (4) (b) (4) . Mr. Thomson was not able to provide an exact date of the event. Mr. Thomson clarified that using the water from the (b) (4) on (b) (4) to irrigate onions is not normal practice and has never happened before. He explained that the (b) (4) A statement summarizing the incident was drafted by Mr. Thomson and included as Exhibit 9. A diagram showing the flow of water from the (b) (4) to the onion fields on (b) (4) is included as Exhibit 8.

(11)
Agricultural water is sometimes tested for the presence or absence of total coliforms and E. coli, and sometimes quantified as (b) (4) Mr. Thomson was unable to provide rationale as to why TII is not having these results quantified. He was also unable to provide critical limits, actionable limits, or corrective actions as they would pertain to the results TII receives. Exhibit 15 shows TII's lab results for their 2020 microbiological water samples.

(12)
While reviewing TII's "(b) (4) Inspection Checklists" we observed 6 postdated (10/23-24/2020) and requested copies of all (b) (4) Inspection Checklists forms from 2019 to present (noting the dates of postdated documents prior the request). The copies and originals returned did not include the six postdated documents.

Management Response to Discussion Items
TII President Jack Thomson made no objection to these discussion items, promised corrections, and stated that he will respond in writing to FDA compliance with more details. I informed Mr. Thomson that responding in writing is not required, but it is in TII's best interest. Prior to starting the close-out discussion, I told Mr. Thomson that he would not be receiving written observations and should take thorough notes if TII wishes to respond to the discussion items in writing within 15 business days. During the close-out meeting, I paused and checked in several times to make sure Mr. Thomson's was not getting overwhelmed and taking accurate notes. Lastly, before issuing the FDA-484 and closing out the investigation, I had Mr. Thomson go over his notes with me to ensure he had captured everything we had discussed.

Exhibits

Exhibit 1 - GPS coordinates and maps of ranches where onions are grown (10 pages)
Exhibit 2 - 2020 customers that received onions from lots implicated in the outbreak (25 pages)
Exhibit 3 – List of all customers that received onions from TII in 2020 (1 page)
Exhibit 4 - Pallet Tag & Sticker Label Example (1 page)
Exhibit 5 - Brands Sold May 2020 to Present (2 pages)
Exhibit 6 - Lot Information & Lot Chart (2 pages)
Exhibit 7 – TII onions to Sysco spreadsheet (6 pages)
Exhibit 8 - (b) (4) water flow diagram (1 page)
Exhibit 9 - statement summarizing the (b) (4) incident, drafted by Mr. Thomson (1 page)
Exhibit 10 - TII Microbiological Swabbing SOP (3 pages)
Exhibit 11 – TII Microbiological Swab Results (1 page)
Exhibit 12 - TII Product Microbiological Testing Sample Results (5 pages)
Exhibit 13 - (b) (4) Restroom Service Record (19 pages)
Exhibit 14 - (b) (4) Sanitation Service Statement (1 page)
Exhibit 15 - TII Water Testing Lab Results – Micro (13 pages)
Exhibit 16 - Food Safety Tailgating Meeting and Hygiene Training plus 4 Non-PSR Training Topics and corresponding attendee logs (10 pages)
Exhibit 17 – TII's Master Sanitation SOP – TII0008 (5 pages)
Exhibit 18 – TII's (b) (4) Production Cleaning Log and (b) (4) Sanitation Log (2 pages)
Exhibit 19 – (b) (4) SSOP Standard Operation Procedure #08 (2 pages)
Exhibit 20 - (b) (4) Machine Cleaning and Sanitizing Log (1 page)
Exhibit 21 – TII's Personnel Food Safety Training SOP (6 pages)
Exhibit 22 – TII's Food Safety Hygiene and Health Policy (3 pages)

Attachments

Attachment 1 - FDA-482 (Notice of Inspection) issued to President Jack Thomson on 08/03/2020 (2 pages)
Attachment 2 - FDA-484 (Receipt for Samples) issued to President Jack Thomson on 08/05/2020 for environmental samples INV1145759; INV1145760; INV1145761 and apparent scat sample INV141449 by CSO Garibay (3 pages)
Attachment 3 - FDA-482 (Notice of Inspection) issued to President Jack Thomson on 08/06/2020 (1 page)
Attachment 4 - FDA-482 (Notice of Inspection) issued to (b) (6), (b) (7)(C) (of (b) (4)) on 08/07/2020 (1 pages)
Attachment 5 - FDA-482 (Notice of Inspection) issued to President Jack Thomson on 08/17/2020 by CSO Willems (3 pages)
Attachment 6 - FDA-484 (Receipt for Samples) issued to President Jack Thomson on 08/17/2020 by CSO Willems (2 pages)
Attachment 7 - FDA-484 (Receipt for Samples) issued to President Jack Thomson on 08/27/2020 (2 pages)
Attachment 8 – Investigation Assignment Questions – TII's packing facility (13 pages)
Attachment 9 – Investigation Assignment Questions - (b) (4) (9 pages)

Attachment 10 – Investigation assignment questions – (b) (4) (9 pages)
Attachment 11 – Investigation assignment questions – (b) (4) (8 pages)
Attachment 12 – Investigation assignment questions – (b) (4) (8 pages)
Attachment 13 – Investigation assignment questions – (b) (4) (6 pages)
Attachment 14 – Investigation team personal safety plan (5 pages)
Attachment 15 – TII's Farm shop summary and photos (4 pages)
Attachment 16 – TII Investigation Memorandum (26 pages)
Attachment 17 - (b) (4) Field Questions (2 pages)
Attachment 18 – Farm Intelligent Questionnaire (34 pages)
Attachment 19 – FDA-482 (Notice of Inspection) issued to (b) (6), (b) (7)(C) (supervisor at (b) (4)) on 08/10/2020 (2 pages)

Daniel J. Gorski -S

Digitally signed by Daniel J. Gorski -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000367476, cn=Daniel J. Gorski -S
Date: 2020.09.25 13:36:18 -06'00'

Daniel J Gorski
Investigator
ORA Produce Safety Network