

Department of Health and Human Services

Memorandum

Date: 9/10/2020
From: Jacob W Reynolds
Consumer Safety Officer
ORA/OHAFO-W/DDHAFO/DPSB2
Subject: Outbreak Investigation
To: Brittany Nork
Branch Chief
ORA/OHAFO-W/DDHAFO/DPSB2
Firm: Thomson International, Inc.
(Holtville)
444 Maple Ave
Holtville, CA 92250
FEI: 3017219425

Background

On 08/18/2020, I received an assignment, **Attachment 1**, (eNSpect OpID#171926 and FACTS Assignment #12060391) to conduct an investigation at Thomson International, Inc. (Holtville) as a continuation of an evaluation of the operations of Thomson International, Inc. (FEI:3004391505). The assignment requested a root cause investigation (note: this was not an official root cause investigation, per FDA SOPs, but was a foodborne illness outbreak investigation) with record collection and environmental, water, and product sample collection related to a foodborne illness outbreak of *Salmonella Newport* associated with onions. This Investigation covered the growing, harvesting and holding operations conducted in the Holtville, CA area by Thomson International, Inc. An Investigation was conducted of the packing facility (FEI:3004391505) located at 11220 S. Vineland Rd, Bakersfield, CA 93307 and the growing areas (b) (4) under FACTS Assignments #12055297 and #12055268.

To: EI File, FEI 3017219425

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The investigation was limited to a review of equipment, the field, and holding locations of onions. The farm was not currently in production at the time. Two items were discussed with management during this Investigation related to the potential of equipment maintenance and environmental factors contributing to factors which increase the risk of pathogen inclusion on their products. (b) (5), (b) (7)

Distribution:

O: EI File
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Brittany R. Nork -S4

Brittany Nork
Branch Chief
ORA Produce Safety Network, Branch 2

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
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Date: 2020.11.09 10:34:17 -0700

Upon issuance of the assignment, FDA reached out to state partners including the California Department of Food and Agriculture (CDFA) and California Department of Public Health (CDPH) to solicit their involvement, as able. CDPH and CDFA did not participate in the Investigation. The team consisted Investigators from the U.S. Food and Drug Administration.

The Investigation focused on the (b) (4) ranch utilized to grow lot 523 of red onions for Thomson International, Inc. in Holtville, CA. The approximately (b) (4) field is encompassed by the following GPS coordinates taken during this investigation:

- Northeast corner:
- Northwest corner:
- Southeast corner:
- Southwest corner:

(b) (4)

Further, Thomson International, Inc contracts with (b) (4) for the harvest and packing/packaging of onions in both the (b) (4) growing areas. The field packing/packaging equipment was sampled at the equipment yard located at (b) (4), (b) (4). This firm is contracted to conduct harvesting and packing for Thomson International, and were directly managed by Thomson International, Inc.

Mr. Thomson explained that products may be stored at (b) (4) located at (b) (4). Products stored at this location are pre-packaged and palletized and are shipped directly to customers. Samples of the storage environments and associated equipment were sampled as INV 1137803. Operations at this facility are not managed by Thomson International, Inc., according to Mr. Thomson. Additionally, the team worked with the (b) (4) (b) (4) to sample sediment, water, and apparent scat from areas around (b) (4). This includes the (b) (4) (b) (4) water service map for the (b) (4) can be found at (b) (4) (b) (4) (b) (4) is a private operation, and is not managed by Thomson International, Inc. As both of these operations are not managed by Thomson International, Inc. the team solely conducted sampling and did not include them in Investigational operations. A GIS map of locations sampled on (b) (4) property can be found at

(b) (4)

Between each day of this investigation, the team provided an update that included a summary of the investigation and sample collections to Brittany Nork, Branch Chief to ensure appropriate offices in FDA maintained awareness and could advise/ask questions throughout the assignment.

On 8/17/2020, Nicole Yuen, HAFW5 Emergency Response Coordinator, called Jack S. Thomson, President/CEO and notified him of our intention to beginning an Investigation in the (b) (4) region on 8/20/2020. During this call she notified him of our modified operational status based on the ongoing COVID-19 pandemic; a copy of the team's personal safety plan is included as **Attachment 2**.

Onsite Investigation – Day One

Investigation Team

US Food and Drug Administration: Jacob W. Reynolds, ORA PSN (Lead Investigator); Arturo De La Garza, ORA PSN; Shannon R. Hoehna, ORA PSN; Avery B. Cromwell, ORA PSN; Kurt D. Nolte, CFSAN PSN; and Michael D. Garcia, HAFW5 Investigator.

This memorandum was written in its entirety by Jacob W. Reynolds, Investigator.

On 08/20/2020, the team listed above arrived at 444 Maple Ave., Holtville, CA, 92250 the current address provided for Thomson International, Inc. (Holtville, CA). We displayed our credentials and issued the FDA 482 to Jack S. Thomson, President/CEO who identified himself as the most responsible person (**Attachment 3**).

During the opening meeting, we discussed the purpose of our visit, and our intentions to follow the growing, harvesting, and packing of red onions lot 523 grown on (b) (4). After our initial meeting, the team split into teams of three and conducted different field activities throughout the Investigation. I, along with Investigators Hoehna and De La Garza followed the flow of product, from (b) (4), the harvesting activities conducted by (b) (4), and holding/shipping activities conducted by (b) (4). This team followed Mr. Thomson to (b) (4) and collected a soil sample from the field (INV1091980), drag swabs along the drainage for the field (INV1091981) in the (b) (4), and onion wrappings located in a ditch along the (b) (4) of the field (INV1091982). According to (b) (6), (b) (7)(C), Field Manager for (b) (4), the drainage along the (b) (4) portion of the field is used to carry drain water from the field directly (b) (4) of (b) (4). While in the field, we found this was currently growing (b) (4). This fact is discussed more in depth as **Discussion 2 with Management** in this memo.

The team did not note any adverse findings with the field during our sampling on 8/20/2020.

Investigators Cromwell and Garcia, and CFSAN PSN member Nolte focused on acquiring samples from the property owned by the (b) (4). They left the initial meeting and met with personnel from (b) (4). This team collected two (b) (4) samples of the (b) (4) water in the (b) (4) and drain (INV1146713 and INV 1146714), and one sediment sample near the (b) (4) (b) (4) (INV1146715). Additionally, Investigator Cromwell spent time with Mr. Thomson and (b) (6), (b) (7)(C) beginning to answer questions pertaining to the assignment and the FDA 3623-Farm Investigation Questionnaire (FIQ) which are attached to this memo as **Attachment 1 and 4**, respectively.

Onsite Investigation – Day Two

On 8/21/2020, Investigators De La Garza Hoehna and I arrived at (b) (4). This is an equipment storage yard for the field packing/packaging equipment utilized by (b) (4). (b) (4) is contracted for onion harvesting in the (b) (4) growing regions. The packing/packaging machine is utilized in both locations, and is dedicated to Thomson International, Inc operations. This is also the location where the burlap sacks (b) (4) the onions are currently being stored on covered trailers. We acquired sample INV1131802 from the packaging machines and trailers containing burlap sacks. We found the packaging equipment had areas of

disrepair and could potentially contribute to accumulation of micro-organism of public health concern; more on this topic can be seen in the **Discussion 1 with Management** portion of this memo.

Investigators Cromwell and Garcia, and CFSAN PSN member Nolte collected sediment samples from the (b) (4) drain (INV1146715, 11467176, and 1146754), a sediment and a one liter water sample from the drainage along the (b) (4) edge of (b) (4) (INV1146753 and 1146717), a sediment sample from the (b) (4) Drain (INV1146755), and a sediment sample from the (b) (4) main drain (INV1146757). The team decided to acquire sediment and water samples from the (b) (4) portion of (b) (4) because the field to the (b) (4) was currently being irrigated, and water was from the (b) (4) corner of the field to the (b) (4) corner of the field where it meets the (b) (4) drain managed by (b) (4). The water was observed contained to the drain and did not appear to enter the empty into the growing are of (b) (4). Additionally, Investigator Cromwell joined the team at the (b) (4) (b) (4) equipment yard and spent time with (b) (6), (b) (7)(C), Owner and Mr. Thomson to continue work on the assignment questions and FIQ.

Onsite Investigation – Day Three

On 8/22/2020, Investigator Cromwell and I met with Mr. Thomson to continue answering questions related to the assignment and FIQ.

Investigators De La Garza, Hoehna, and Garcia were tasked with driving in the areas around (b) (4) and try to find areas of concern that could lead to sampling or discussions with Mr. Thomson. The following was noted by the team: Observed (b) (4) field (b) (4) of (b) (4) with standing water present and a few hundred apparent birds and observed apparent ground squirrels on the (b) (4) side of (b) (4) (b) (4) by the (b) (4). Animal intrusion during growing and harvesting operations is expounded upon in **Discussion 2 with Management** section of this memo. Also, it was noted that there was (b) (4) storage and (b) (4) approximately (b) (4) of (b) (4); two (b) (4) (one approximately (b) (4) away and one approximately (b) (4) away) to the (b) (4) of the field of interest; and a (b) (4) type area where one of the drains widens to approximately (b) (4) approximately (b) (4) from the field. We did not see any direct linkage to the fields from these areas, and would be (b) (4) of any canals or drains that run by (b) (4).

Onsite Investigation – Day Four

On 8/24/2020, Investigators Hoehna, De La Garza and I visited (b) (4) located in (b) (4). The visit focused on collection of environmental samples, no produce was currently at the facility and the facility was currently under maintenance. All information about operations collected during this Investigation were supplied by Mr. Thomson. Environmental samples of storage areas and various equipment were acquired. All records associated with this visit are attached to sample collection report (CR) INV1137803.

After visiting the cooling facility, we moved back to a farm road that runs along (b) (4) and collected environmental swabs (INV1137804) of the (b) (4), reportedly used to germinate the onions on (b) (4). The (b) (4) was stored on trailers and left uncovered. We observed apparent bird scat beneath the trailers, and this was collected as INV1137805.

Investigators Cromwell, Garcia, and Nolte collected water samples (INV 1146757, 1146791, 1146793, 1146796, and 1146797) from the (b) (4) drain, (b) (4) drain, and water draining from (b) (4) (b) (4). Sediment samples (INV 1146792 and 11467694) were acquired from the (b) (4) drain and the (b) (4) for (b) (4). Additionally, an apparent bird scat sample (INV 1146795) was taken from the (b) (4) for (b) (4).

Investigators Hoehna and De La Garza were present for the final close-out with Mr. Thomson on 8/24/2020. While we did not issue a Form FDA 4056, Produce Farm Inspection Observations, with observations, we did have concerns which were verbally discussed with the farm and included with this memorandum under the section titled, **“Discussion with Management”**. We issued the Form FDA 484, Receipt for Samples (**Attachment 5**), to Jack S. Thomson, and closed this portion of the investigation on the farm.

Assignment Questions and Answers

1. Document and Information Collection

- a. Please identify the location of any Thomson International Inc. growing area(s) (fields or ranches) in (b) (4) including GPS coordinates (using a decimal degree format, xx.xxxxxx).

Thomson has (b) (4). They have the (b) (4) with (b) (4) acres (GPS coordinates provided during Bakersfield Investigation). (b) (4) grew about the same volume of onions at about (b) (4) sacks each.

- b. How many onions (by weight or volume) were grown in field (b) (4) in the 2020 harvest season? Provide amounts by types/varieties/colors.

(b) (4) ranch grew about (b) (4) pound sacks each. Lot 523 was exclusively red onions but (b) (4) (b) (4) ranch also grew yellow onions but the yellow onions were in a different lot.

- c. Describe what onions constituted Lot 523 grown in field (b) (4). Was the lot subdivided (523A and 523 B, etc.)? If so, how were the subdivisions assigned?

There was no subdividing of lot 523 consisted solely of red onions. The documentation detailing the shipment of lot “523A” of red onions from (b) (4) to Thomson International customers is the same as lot 523 listed in the assignment, this is attached as **Exhibit 1**. There is no differentiation of the products. (b) (4) has divisions and the north consisted of yellow onions, red onions in the middle and the south had (b) (4) growing. (b) (4) were not grown for Thomson International Inc.

- d. Were all onions from Lot 523 packaged in Bakersfield? If not, where else?

(b) (4) of bins went directly to Bakersfield for packaging. Mr. Thomson explained the farm also brought bins to (b) (4) after being packed into (b) (4) totes and shipped to customers and the Bakersfield packinghouse from the cooling facility. Some of the red onions from this lot were field packaged by (b) (4), and shipped to customers through (b) (4).

- e. *Please collect records (invoices, bills of lading, etc.) identifying all shipments of onions transferred from Holtville to Bakersfield during the 2020 harvest season. Please include harvest company, harvest date, lot information, and shipment dates for all types/varieties/sizes of onions in each shipment.*

Only (b) (4) of bins travelled from Holtville to Bakersfield via flat bed truck. There is no sale receipt available as it was just considered a transfer from one location to another. Some of the red onions were transferred to (b) (4) prior to shipment to the Bakersfield location; these shipments may be viewed in **Exhibit 1**.

- f. *Please collect a customer list for all onions harvested in 2020 from Thomson International, Inc. in Holtville, CA. If possible, list customers by onion type. Please identify which customers received onions from lot 523.*

Some of lot went straight to Bakersfield location in bins, and packaged and shipped from there to customers. The record of the customers for those products are listed in the document with larger lettering entitled "Thomson International, Inc. Red Onions Sales (b) (4)" attached as **Exhibit 2**. All customers on the list received lot 523.

Some of the lot would have been bulk packed in totes (b) (4) and 50 pound mesh sacks and sent to (b) (4) for shipment. Mr. Thomson provided a list of customers entitled "Shipping Detail Report", attached as **Exhibit 1**. The red onions on this document are listed as lot "523A", although this would be the same as lot 523. A portion of the red onions lot 523 sent to (b) (4) were shipped to Thomson International in Bakersfield for further packaging and distribution. These customers would be listed in **Exhibit 2**.

- g. *Were any of the onions that were shipped from Holtville, CA to Thomson International, Inc. in Bakersfield, CA stored onions from prior growing seasons?*

According to Mr. Thomson, his operation does not store onions from one season to another. All onions shipped were grown during this season and there were no hold overs as that long of a hold would lead to negative impacts on quality.

- h. *Document how lot numbers are assigned for onions, who assigns them, and what constitutes a lot. Please clarify how lot information is maintained.*

Lots are assigned in the same manner as they were in Bakersfield based on map, commodity, variety, and planting schedule. Discussed in detail during Bakersfield investigation.

2. Priority questions to be answered in addition to the completion of the FIQ. For the following questions were any procedures, operations, or practices different or unique for onions in Lot 523 from field (b) (4) as compared to other onions grown for Thomson International, Inc. in the Holtville, CA fields? :

Firm Operations:

- a. *Provide a brief overview of the farming operation in (b) (4) for Thomson International, Inc. Include the number of acres/ranches, topography and any noteworthy environmental concerns (such as above average bird activity), names of all companies owned by or associated with Thomson International, Inc. (this could include firms such as field labor crew providers, onion (b) (4) and*

storage facilities, pesticide applicators, fertilizer distributors and applicators and those which could maintain irrigation or other equipment).

Thomson receives product from (b) (4) (b) (4) (these numbers correspond to (b) (4) identified by the (b) (4) conducts maintenance activities on the (b) (4) which provide water to the fields, once it reaches the (b) (4) at the field, all other irrigation maintenance is conducted by (b) (4) (b) (6), (b) (7)(C) Farm Manager for (b) (4) . stated the company has an office located at (b) (4) (b) (4) total approximately (b) (4) acres. (b) (4) sits in the middle of agricultural land with adjacent land growing (b) (4) . According to (b) (6), (b) (7)(C) , he is unaware of any organic crops in production in the surrounding area and all of the crops are being grown conventionally. The owner of the land at (b) (4) is (b) (4) (b) (4) . Mr. Thomson explained the growing is (b) (4) between (b) (4) and Thomson International, Inc. (b) (4) is responsible for the on farm irrigation and conducts fertilization through the season. Fertilizer is (b) (4) based and run through the (b) (4) during the season. A list of pesticide/herbicide applications to (b) (4) can be viewed as **Exhibit 3**. According to (b) (6), (b) (7)(C) , (b) (4) applications are either done with equipment owned by (b) (4) or a contracted (b) (4) , (b) (4) .

(b) (4) is contracted to conduct weeding activities during the season as well as the harvesting, (b) (4) and packaging/packaging of equipment. According to Mr. Thomson, all onions are (b) (4) (b) (4) provided by Thomson International, Inc. They will either get packaged in the field by (b) (4) and sent to (b) (4) for shipment to customers, or will be packed in bins and shipped to the packinghouse in Bakersfield, CA. (b) (4) may restack pallets of packaged onions for shipment, but not other manipulation of the onions is conducted by them, according to Mr. Thomson. Mr. Thomson stated onions are normally stored at (b) (4) for less than (b) (4) .

During the inspection of (b) (4) no unusual animal activity was observed. No evidence of animal intrusion was observed either. (b) (6), (b) (7)(C) , during the growing season, observes (b) (4) ranch at least (b) (4) every (b) (4) and would flag and report any unusual animal activity. During the 2020 growing season he did not report any unusual animal activity to report. During our investigation, we observed a large amount of bird activity in the (b) (4) crop in (b) (4) directly (b) (4) of (b) (4) this is further discussed in **Discussion 2 with Management**.

b. How many additional firms (farms and facilities) in (b) (4) are owned and/or operated by or for Thomson International, Inc.? Where are the other farms/facilities located? Is any equipment or personnel shared between the different locations? If yes, describe.

Thomson is involved with (b) (4) (b) (4) is owned by (b) (4) . Prior to planting (b) (4) grew (b) (4) . After the onions crop this year there has been nothing planted on this ranch and they have only done tractor work on it. The equipment used by (b) (4) are shared amongst the fields they manage in the (b) (4) area. This would include equipment for irrigation, tractors, and (b) (4) applicators needed for the growing process.

Planting and harvesting equipment are managed and operated by Thomson International, and are shipped between the (b) (4) growing areas. According to Mr. Thomson, the

equipment is hauled to (b) (4) and then is brought back (b) (4) for planting and harvest. (b) (6), (b) (7)(C) explained that the harvesting equipment used for Thomson International is dedicated to their onion operations. He also stated that (b) (4) attempts to have approximately (b) (4) % of the same crew working on onion harvesting (b) (4). According to Mr. Thomson, equipment is cleaned (b) (4) and (b) (4) keeps a record of cleaning. This includes brushing equipment down, utilizing a (b) (4) soap and scrubbing the equipment, then rinsing with a (b) (4). Records of cleaning are kept by each of the supervisors for the harvesting crews.

- i. *Who owns the farms or facilities? Are they leased, contracted with other growers/packers, etc.? Please describe any such agreements.*

Mr. Thomson explained he has (b) (4) with (b) (4) to grow onions in the (b) (4) area. This is the (b) (4) season they have had the arrangement. (b) (4) owns the land, and conducts maintenance on the field during growing which includes irrigation and weed/pest control. Thomson International provides the planting and harvesting equipment. The equipment for planting and harvesting are shared between the (b) (4) operations. Mr. Thomson explained the land for onions is chosen prior to the season, and in the past (b) (4) seasons onions were not planted on the same ranches. He explained there should be approximately (b) (4) between onion plantings. (b) (4) does lease to other growers in the area, and conduct their own growing on owned land.

- ii. *How are the farms/ranches used when not growing onions? What other items are grown on the farms/ranches? Does the farm cover crop and what are the practices associate with that?*

Ranches may be used for a variety of seed crops such as (b) (4). (b) (4) of the ranch during the season was in (b) (4). (b) (4) may also grow (b) (4) under contract as requested by other customers. Most of their production is based on (b) (4).

According to Mr. Thomson, (b) (4) explained that the onions (b) (4) (b) (4). Would rotate through different fields from season to season, onions would not go into the same fields as this season.

- iii. *Does the firm harvest/pack or hold any produce for other firms? If so, what produce and which firms.*

According to Mr. Thomson, the farm does not handle other farms products, solely the onions in the (b) (4) area. (b) (4) where onions may be stored for a short period of time, is contracted by other companies, and their crops may be run through that facility at the same time. Mr. Thomson does not oversee operations at (b) (4). (b) (6), (b) (7)(C), owner of (b) (4) explained although the harvest crews work for multiple farms. All employees packing/packaging onions for Thomson International are dedicated to onions for the farm in (b) (4). A list of other companies contracting (b) (4) was not collected during the Investigation.

- c. *Describe the familiarity of the firm with the Produce Safety Rule (PSR) and other food safety programs. When was the firm last audited (and what audit)?*

Thomson International Inc. is responsible for the food safety at (b) (4). Mr. Thomson requested that (b) (6), (b) (7)(C) takes the Produce Safety Alliance course, which was reportedly completed in (b) (4). (b) (4) ranch was audited with a farm visit under (b) (4).

d. *What food products, particularly PSR covered fresh produce are grown, harvested, field packed by the firm? Please note the food type, planting and harvest dates, field packaging dates and corresponding field(s)/ranches/farms.*

Thomson International solely manages the growing and harvesting of onions in the (b) (4) area. Other crops are grown in the (b) (4) area. (b) (4) has a dedicated crew and equipment for onion harvesting for Thomson International, Inc.

e. *Determine if any farm activities were affected by operational changes for the most recent growing season (for example: changes in the source/method of water or chemical application; land use changes; equipment use changes; packing and storage practices; etc.).*

Mr. Thomson reported no operational changes were reported at (b) (4) ranch during the 2020 season.

f. *What is the land adjacent to field (b) (4) used for?*

(b) (4) is surrounded by other ranches. During the inspection (b) (4) ranch, directly (b) (4) of (b) (4) was currently growing (b) (4). Directly to the (b) (4) of (b) (4), there is a drain managed by the (b) (4).

i. *Are there any other farms (such as almond orchards, pistachio orchards, animal operations) adjacent to or near field (b) (4)?*

Yes, surrounding area is all agricultural growing land. A multitude of crops are grown, and unknown to Mr. Thomson. (b) (6), (b) (7)(C) of (b) (4) explained that there are no organic fields within an approximately (b) (4) radius of the (b) (4). The team noted that there was (b) (4) and (b) (4) approximately (b) (4) of (b) (4); two (b) (4) operations (one approximately (b) (4) away and one approximately (b) (4) away) to the (b) (4) of the field of interest; and a (b) (4) type area where one of the drains widens to approximately (b) (4) approximately (b) (4) from the field.

ii. *If so, do they share a water source with the firm's farm operations?*

Water used in irrigation is provided by (b) (4), operated by (b) (4) which feeds most of the agricultural land in the area. (b) (4) operations mentioned above does shares a similar water source as (b) (4) as they are both fed by the (b) (4) to the (b) (4) but (b) (4) and they do not interact.

iii. *What raw agricultural commodities are grown in the area adjacent to or near field (b) (4) that may share a water source?*

Adjacent land included (b) (4). All were reported as being grown conventionally. Crops produced vary from season to season, and not all land is managed by (b) (4) in the immediate area. It is unknown what is being from season to season on adjacent land, and would also change from season to season.

- iv. *Are there other local water uses that could influence growing onions at field (b) (4) e.g., animal operations, recreational facilities, etc.)?*

No other water uses observed in the surrounding areas. Water for the (b) (4) it sourced from the (b) (4), which is (b) (4) of (b) (4). There are (b) (4) activities that take place along the (b) (4).

- v. *What types of soil amendments (all types, including chicken litter, chicken pellets, almond husks, etc.) are used on adjacent lands? Are any adjacent lands used for organic farming?*

All adjacent land reported as conventional producers with no compost amendments reported.

g. **Collect maps**

- i. *Collect all maps with ranch/field/commodity designations and planting and harvest dates for each commodity grown for or by Thomson International in (b) (4). Please mark all locations on the map where samples are collected and record GPS coordinates using the decimal degree format (xx.xxxxx).*

Field maps, with GPS coordinates, were collected during the Bakersfield Investigation. These would include lot designations on the map.

- ii. *Collect all water flow (storage if reservoirs are used) maps.*

Water flow for the entire area can be viewed at (b) (4). Most, if not all, of the agricultural land in the area is serviced by (b) (4) managed by (b) (4). In general, water flows from (b) (4) and draining in the (b) (4). A (b) (4) along the (b) (4) edge of the agricultural land, and is brought to the (b) (4) by (b) (4). (b) (4) is serviced by the (b) (4).

Onion Practices in (b) (4) :

- h. *When are the planting, growing and harvesting seasons for bulb onions and sweet onions for Thomson International in (b) (4) ?*

Onions are planted in (b) (4) and the harvested in (b) (4) prior to locations in (b) (4). After planting they are germinated with (b) (4) which are removed in (b) (4) and then (b) (4) irrigated until harvest.

- i. *Describe how the onions are grown.*

Mr. Thomson explained the growing operations are (b) (4) managed by Thomson International, Inc. and (b) (4) was described as (b) (4)."

Between Mr. Thomson and (b) (6), (b) (7)(C), the following information was provided. The two companies will get together and decide which field is going to be utilized for the growing of onions, during the season ending in 2020, they decided on (b) (4) (located approximately (b) (4)). (b) (4) is responsible for prepping the ground per Thomson International, Inc. specifications. The growing process begins with employees and equipment supplied by Thomson International planting seeds, and (b) (4) (b) (4) (b) (4). This is the (b) (4) through (b) (4) process, all other (b) (4) supplied through the (b) (4).

Germination is completed with (b) (4) (managed by (b) (4)), supplied by (b) (4) from (b) (4). Planting for red onion lot 523 was conducted in (b) (4), and (b) (4) on this field were removed in (b) (4). The remainder of the irrigation is supplied through (b) (4), and the last irrigation approximately (b) (4) prior to harvest (b) (4). Applications of herbicides/pesticides throughout the season are conducted by (b) (4) or (b) (4).

i. Are other crops grown concurrently with onions on the fields/ranches farmed by the firm?

(b) (4) were grown on the (b) (4) of (b) (4) and (b) (4) varieties of yellow onions were grown on the northern half of (b) (4) along with red onions. The maps collected by the team in the Bakersfield Investigation detail which onion types were grown.

ii. When is the last time they watered prior to harvesting?

Last water applied (b) (4) days prior to harvest.

iii. Does the firm perform any pre-harvest microbiological assessment of onions prior to distribution? If so, describe these programs and include the microbial analyte, method, sampling program and testing laboratory.

No microbial testing of product or soil was reported as being performed. (b) (4) does do a preharvest inspection of area by walking field and looking for signs of animal intrusion, the harvesting crew training and procedures for animal intrusion are attached as **Exhibit 4**.

iv. Have there been any changes in these practices between the 2020 growing season and previous seasons?

No changes in farming activity reported for 2020 season.

j. Describe how the onions are harvested

Onions are harvested in an identical manner to those in Bakersfield. The information on how lot codes are tracked and harvesting is initiated is included in the Investigation reporting for the Bakersfield location.

(b) (4) is also responsible for the weeding at the (b) (4) location (b) (4). Weeding is done (b) (4) by crews trained in food safety and is done (b) (4). Removed

weeds are placed between rows. Weeding at (b) (4) occurred in late (b) (4) and took about (b) (4) (b) (4).

Harvesting is conducted by a combination of Thomson International employees and (b) (4). Thomson International sends a crew to the (b) (4) area to (b) (4), managed by Thomson International, to cut the onions out of the ground. The onions are (b) (4) for (b) (4) in this condition. Then a crew from (b) (4) will come through, and snip the tops and bottoms off the onions, and place them in burlap sacks, provided by Mr. Thomson. The onions are then (b) (4) (b) (4) for (b) (4). From there, the onions may be placed in bins and sent to the Bakersfield location for further packaging. Or, (b) (4) provides field packaging equipment which can package onions into 25 or 50 pound sacks, or (b) (4) totes.

- i. *What is the inspection, maintenance, and cleaning/sanitation program for the burlap sacks and other equipment used during harvest? How and where are these sacks stored during the off-season?*

(b) (4) is instructed to (b) (4) burlap sacks during packaging process. Burlap sacks are used (b) (4) (b) (4), the burlap sacks are dumped into (b) (4) (b) (4) or into bins sent to the Bakersfield location for packaging. Employees are instructed (b) (4) s that have become worn and torn. According to Mr. Thomson, the sacks are not sanitized between uses, and they allow the sacks to sit in the sun, in the field, prior to storage. During the off-season, the sacks are stored on trailers and covered with tarps.

- ii. *During harvest times, did the firm contract out harvest operations to another company?*

(b) (4) (b) (4)

1. *Is this equipment used on multiple fields?*

Harvest machines are used in multiple fields. Starting with (b) (4) and then to (b) (4) and then it is transported back (b) (4) growing fields. During this investigation, we observed the onion packaging equipment being stored in an equipment yard managed by (b) (4) along with the trailers containing burlap sacks.

2. *If owned, how long has the equipment been on site and/or was it previously used at a different location?*

Equipment operated by Thomson International is stored at the Bakersfield location while not in use, equipment owned/operated by (b) (4) is stored in the equipment yard in (b) (4).

3. *If rented, please collect name and contact information for the rental company.*

- iii. *Describe how, where, and when harvesting equipment used for onions are stored, maintained, clean/sanitized.*

The equipment used to cut the onions out of the ground is cleaned as needed by (b) (4). No records are created to record equipment cleaning. Equipment is stored in Bakersfield where it is maintained. Prior to harvest at (b) (4) ranch equipment was reported as being cleaned by Mr. Thomson.

During equipment maintenance they also reported changing the (b) (4) with a new one prior to 2020 season.

(b) (4) has created a program to clean the packaging equipment on a (b) (4) basis, this procedure is attached as **Exhibit 4**. Records are kept by the crew supervisors. Cleaning includes brushing off the equipment, applying a (b) (4) soap, and scrubbing the equipment. It is then sprayed with a (b) (4) sanitizer and left near the field to dry.

- iv. *Determine where mobile farm equipment that was used during harvest is currently or its destination if still en route.*

Planting and harvest machines are located in Bakersfield, CA at this time. The packaging machines used by the harvest crews are currently located at (b) (4) site in (b) (4)

1. *Note: At Thomson International, Inc.'s Bakersfield, CA facilities, (b) (4)*

- v. *Describe the system that the firm uses to identify harvest lots, the size of harvest lots, and how lots are accurately managed throughout the growing, harvesting, curing, storage and distribution process.*

Mr. Thomson explained this information will be identical to what was provided during the Bakersfield, CA Investigation.

- vi. *Have there been any changes in these practices between the 2020 growing season and previous seasons?*

Harvest operations have included COVID 19 prevention methods including social distancing and masks to prevent community spread.

- k. *Describe how the onions are field packed.*

- i. *Review and copy any documentation associated with monitoring of temperature and humidity.*

Records are not kept for monitoring temperature or humidity. All onions are field packed and would be exposed to the ambient environment.

- ii. *Are onions trimmed and/or dry brushed before or after storage?*

Onions are roots are trimmed (b) (4) during harvest when they are placed in buckets in the field. The buckets are then dumped into burlap sacks, and allowed to cure in the field. They are not brushed until they travel through the packing line, either (b) (4) (b) (4) or in the packinghouse at the Bakersfield, CA location, prior to packing where they are brushed immediately prior to packing. No field brushing was reported.

(b) (4) has employees (b) (4) onions during packing. These (b) (4) are (b) (4) but are sanitized at the field in a (b) (4) that is monitored ever (b) (4) (b) (4) for (b) (4) concentration (b) (4) are (b) (4) in the (b) (4) and then (b) (4) before

entering the fields. The (b) (4) are not allowed in the bathrooms either and they have a basket for holding them. A supervisor is on duty during harvest to monitor that all employees are following safety procedures.

Clipped onions are placed in buckets that are owned by (b) (4). These buckets are washed (b) (4) with (b) (4) and a (b) (4) solution (b) (4) that is recorded. Most buckets are replaced after a (b) (4).

iii. *Are onions ever re-run/re-packed? What does that process entail and how is that product tracked?*

Operations in Holtville, CA does not include any re-packing. Onions (b) (4) by (b) (4) (b) (4) are sent to (b) (4) (which will may re-stack pallets) or to Thomson International, Inc. Bakersfield location for re-packaging. Onions can be repacked for different markets. The time between repacking can be immediate or have take as long as (b) (4). Product lot codes are assigned while the product is in the field, the lot code would follow the product from harvesting through shipment.

iv. *When and how is the field packing equipment (including fans/driers) maintained and cleaned between lots? Fields? Harvests? Have there been any maintenance issues?*

(b) (4) conducts cleaning (b) (4). They may pack different varieties of onions and lots in the same day. Conduct cleaning (b) (4) with a (b) (4) from top to bottom, machines are sprayed with (b) (4) to remove soil and scrubbed, then a (b) (4) solution (b) (4) of free. Machines are left near the field during the day and overnight allowing to dry. Operations normally end around (b) (4) and equipment is left to get UV, heat, and wind dry. Records are kept for (b) (4) cleaning of equipment. See **Discussion 1 with Management** for issues noted with the packaging machine.

v. *Does the firm conduct routine environmental monitoring to verify cleaning and sanitation of field packing operations? If so, provide details of sampling and testing procedures and test results for the last 3 months.*

No environmental sampling is conducted. (b) (4) does a preharvest check where they look for signs of contamination and animal intrusion. This is the responsibility of management and they walk the field. No reports of animal intrusion, flooding or unusual events were reported at (b) (4) ranch. Additionally, Mr. Thomson explained a member of Thomson International is present during the harvesting, and would also be responsible for looking for any evidence of animal intrusion.

vi. *What is the shelf life of the onions?*

Different onion varieties can have different shelf lives. Onions grown up north could be stored for a season and then shipped; however, onions grown for Thomson International Inc. cannot be stored for such long periods without quality issues. No timeline was provided by Mr. Thomson, he explained it depends on the storage conditions.; cooler climate=longer storage possibilities. No onions were shipped in 2020 that had been grown in previous 2019 season.

vii. *Have there been any changes in these practices between the 2020 growing season and previous seasons?*

None reported.

- l. Describe how the onions are transported (from the growing field and/or field packing areas and sent to the Thomson International, Inc. packinghouse in Bakersfield, CA or other customers)*

Flatbed trucks are used to transport bulk bins from Holtville, CA to Bakersfield operations.

From field, onions in bins are loaded onto a flat bed uncovered trailer, up to (b) (4) per load. From (b) (4) facility, customer or destinations sets up trucking. Could either be flat bed trucking or cooled trailers. If a tarp is used, it will only be across the top, to allow air flow during shipping. (b) (4) of deliveries to customer from (b) (4) are hired by customer. Customers may pick onions up in flat bed trucks, and cooled or uncooled trailers for distribution. It would depend on where the customer is located in the country.

- i. Describe how, where, and when transport vehicles used for onions are stored, maintained, clean/sanitized.*

To the best of Mr. Thomson's knowledge, the trucking companies they contract are solely operating as produce carriers. There is no set procedure for checking flat beds in the field. However, an employee of Thomson International is present during harvest and Mr. Thomson reported he will visually inspect the flat bed prior to loading. At the packing house, they ensure the drivers sign in saying their trucks are clean prior to loading. Mr. Thomson is unsure if (b) (4) has any set procedures for trucks loaded on trucking contracted by any customers.

- ii. Were the onions treated in any way to reduce Salmonella? If so, can they provide information about the process?*

No set process.

- m. Please diagram the movement of the product from the field to the Thomson International, Inc. packinghouse in Bakersfield, CA or the sale to other customers.*

Loaded in the field, and delivered to packinghouse by (b) (4) in most cases. Products that are sent to (b) (4) will most likely be shipped to customers straight from that location. Onions are stored either in a carport type area, or ambient temperature indoor storage areas. Mr. Thomson stated a vast majority of the onions stored at (b) (4) were stored in the carport type area prior to shipment. Some of the larger totes and 50 pound bags packed by (b) (4) and sent to (b) (4) (b) (4) may be shipped to the Bakersfield location.

- n. Is there any potential for cross-contamination between the onions and other produce commodities grown by Thomson International in (b) (4) ?*

Employees of (b) (4) that work on ranches growing onions for Thomson International Inc. only work on his ranches in (b) (4). The crews that harvest product on (b) (4) were the same employees that harvested onions and (b) (4) (b) (4) total has about (b) (4) working in onions and (b) (4). The harvest company has been audited by (b) (4) and reportedly worked under (b) (4) guidelines. Once field packed, no other manipulation of the product is conducted

outside of the packinghouse in Bakersfield, CA. There are customers who received the (b) (4) (b) (4) totes and may do their own packing downstream according to Mr. Thomson.

- o. Describe the disposition of the previous crop year (2019). Were or are any of the onions grown and harvested in 2019 still in storage and in distribution during May/June 2020?*

Onions are not kept from season to season, according to Mr. Thomson.

- p. Determine how the farm culls product, both before and after storage and how culls are subsequently handled. Explain where culls are kept in relation to packed and in-line produce as well as how often it is removed from the premises.*

In field, harvesters are told to remove splits, abnormal, decayed or outside of what they determine to be a normalized product. Prior to packing into any type of storage unit, during the (b) (4) process, would just leave in the field. If they get through the burlap sack process, for field packaging the culls would also be dumped onto the ground. The way the packaging machine works the culls are kept away from the packaged material.

- q. Is any product left in the field post-harvest?*
i. If so, is this product collected or used at any time, even if not by the firm's contracted employees? If so, what is the use(s)?

The culls are left in the field. For the most part these are driven into the ground by the various pieces of equipment in the field during packing and harvesting.

Farming Practices:

- r. Are any soil amendments used on field (b) (4) If so, please collect further details, such as how they are received, stored and applied. Determine how the application equipment (spreaders, injectors, hoppers, augers and loaders) are cleaned and sanitized prior to use.*

On (b) (4) Ranch conventional fertilizers were reported as being applied by (b) (4) in (b) (4). (b) (4) applied (b) (4) in (b) (4) during (b) (4). No biological soil amendments of animal origin were applied. After the initial (b) (4) are supplied through the (b) (4).

- i. What types of soil amendments are used (provide information for any amendments, including chicken litter, heat processed poultry pellets (HTTP), almond husks, etc.)?*

No soil amendments reportedly being utilized by (b) (4) during or prior to the onion growing season.

- ii. Identify the supplier information of the soil amendments, including manufacturer. Collect bills of lading if available.*

Not applicable.

iii. *Collect nutrient label for soil amendments if available.*

Not applicable.

iv. *Are any of the crops grown organically?*

No organics in area, within approximately (b) (4) according to (b) (6), (b) (7)(C).

v. *If soil amendments are applied, what is the wait time interval prior to planting?*

Not applicable.

vi. *If compost or other soil amendments are received from another facility, please collect the name of the facility.*

Not applicable.

vii. *Have there been any changes in these practices between the 2020 growing season and previous seasons?*

None reported.

s. Water

i. *What is the source of the water that is used for field (b) (4)*

(b) (4) water is the only water used in irrigation. (b) (4) conducted by (b) (4) utilize municipal water. (b) (4) conducted by (b) (4) utilizes the (b) (4) as irrigation for mixing of chemicals.

(b) (4) also supply their own water during harvest for hand washing and drinking. The hand washing water is from (b) (4) water that is tested (b) (4) for E. coli. No historical spikes in these tests were reported.

ii. *What type of irrigation is used, i.e., drip, over-spray, combination?*

During germination (b) (4) are used and then removed in (b) (4) For remainder of growing cycle water is applied to crop by (b) (4) from (b) (4). The last water is applied approximately (b) (4) days prior to harvest.

iii. *How is water used for purposes other than irrigation (e.g., crop protection, dust abatement, etc.)?*

(b) (4) water used for pesticide/herbicide applications. No dust abatement or crop protection methods reported by the farm.

iv. *Is the irrigation water treated with a sanitizer? If so, describe the method, verification and monitoring program, and sanitizer used.*

None reported.

- v. *Does any of the water used in the firm's operations meet the definition of agricultural water (comes in direct contact with the harvestable portion of the crop)?*

(b) (4) utilized.

- vi. *Does the farm perform any water quality testing? If so, what microbes are they testing for?*

Yes, conducted (b) (4) for generic E. coli. For the 2020 season, water was collected in (b) (4) (b) (4) Nothing adverse noted during record review.

1. *Collect water quality test records from the start of the 2020 growing season to present, if available.*

- vii. *Are there any additional water sources that supply the farm?*

(b) (4) water is utilized by the (b) (4). Water testing records for Bakersfield and Holtville, CA operations were collected by the Bakersfield Investigation team.

- viii. *What is the difference between the water used in the fields for irrigation and any water used in the field packing?*

Water applied to field for irrigation is water from (b) (4). No water utilized for field packing. Water used for cleaning field packing equipment is reportedly supplied by (b) (4) source.

- ix. *Were any changes made to the irrigation system or any crop spray equipment prior to the start of the 2020 harvest? Please describe water application practices and any changes within the last harvest or year.*

None reported.

- x. *Is irrigation or water used for crop protection or weed management sprays treated with an antimicrobial (e.g. chlorine). If so, describe the microbial water treatment system in place to treat irrigation water and how is the system maintained and monitored.*

None reported.

- t. *Describe practices involving the mixing and application of pesticides, herbicides, etc. that could contact the crops.*

Applications conducted by (b) (4) utilizes (b) (4) water, and water used for (b) (4) applications utilizes (b) (4) water.

- i. *When are pesticides, herbicides, etc. applied in relation to harvest?*

For records provided attached as **Exhibit 3**, the range of application appears to be (b) (4) for any applications. Last application of treatment was conducted by (b) (4) contractor, (b) (4) (b) (4) which sources its water from (b) (4) source. Harvest was conducted in (b) (4)

u. *For the product on the market that represents the 2020 growing season:*

i. *Were there any significant or unusual weather events during the growing, harvesting, and/or packing season, such as excess wind or rain, flooding, or muddy conditions?*

None reported.

ii. *Were there significant changes to staffing labor? Did the COVID pandemic affect the firm's staffing levels? What was the impact of the labor shortage to harvest and packing, and to sanitation of equipment used in harvest and packing? Did this result in the firm changing the source of their labor?*

(b) (6), (b) (7)(C) stated that more than (b) (4) % of his crews are present from season to season. The only reported impact from (b) (4) was the addition of social distancing and masks as safety precaution. No other impacts were reported.

iii. *Was there any maintenance taking place either near the onion fields or the relevant water sources?*

None reported.

iv. *Have there been any changes in practices or equipment / deep cleaning and sanitizing of equipment?*

None reported.

v. *Please note signs of any animal activity (including birds) on the farm and packinghouse or adjacent property (to the extent possible).*

We did not observe bird activity on the farm during the Investigation. See **Discussion 2 with Management** for bird activity noted in the area.

Discussions with Management

While we did not issue a Form FDA 4056, Produce Farm Inspection Observations, with observations, we did have the following concerns, which we discussed with Mr. Thomson.

1) While sampling the field packaging equipment utilized by (b) (4) for onions, we observed a variety of places that did not appear to be smooth and cleanable, pictured as **Exhibit 5**. For example, we observed the following:

- Conveyor belt type material attached to metal pieces of equipment causing gaps beneath that accumulate extraneous materials and would appear to hold in moisture
- Apparent (b) (4) material being used as a food contact surface, or adjacent areas which appeared worn
- Painted metal which contained areas of missing paint, created uneven surfaces that apparently touched onions

I explained to Mr. Thomson and (b) (6), (b) (7)(C) these areas can accumulate extraneous material and moisture during cleaning and operations. This would provide an opportune growth area for bacteria.

These are niches which pathogens, specifically *Salmonella*, have been known to be found. I stated all food contact surfaces, and their adjacent materials should be constructed and maintained so that everything can be easily cleaned and dried. As we were unable to view the equipment during operation or cleaning, it would be hard for the team to note all areas that could be potential harborage for bacteria. I explained the places pointed out during the Investigation are just what we could see, and they should try to make similar alterations to all portions of the equipment as they see them. Mr. Thomson explained he has spoken with (b) (6), (b) (7)(C), and the equipment will be modified with these suggestions prior to the next harvesting season for onions.

2) During our Investigation we noted indications and presence of bird activity around the fields and equipment used in operations. For example, we noted apparent bird scat under the trailers storing (b) (4), apparent bird scat on the (b) (4) leading from the (b) (4), apparent bird scat along the edges of the (b) (4) adjacent to the fields, and a large amount of bird activity in the field directly (b) (4) of (b) (4) during irrigation. I explained that birds can be vectors for pathogens, especially known for carrying *Salmonella*.

I explained that although we did not see any bird activity in (b) (4) during the investigation, there was also not activity or product in the field to attract the birds. While observing the flood irrigation of the field directly to the (b) (4) currently growing (b) (4) a few hundred white birds (apparent Ibis) were seen in the field. I explained the drainage for this field runs along the (b) (4) side of (b) (4) and could be a way for pathogens to be introduced to the field. I explained that we were unable to see any of the operations for the onion growing season, but the (b) (4) irrigation of land in this area appears to attract birds. Mr. Thomson said he has seen this type of activity in different fields around the area, and is aware of the need to monitor for birds. Further, I explained the practice of (b) (4), and allowing them to be exposed to environment for multiple days could also act as an attractant to wildlife. Mr. Thomson agreed that this could be an issue, and explained that the fields are routinely monitored by (b) (4). Additionally, (b) (4) and a Thomson International employee is present during harvesting and routinely monitors for any sort of activity. The training provided to the harvest crew is attached as **Exhibit 5**, and includes instructions on how to monitor for wildlife activity, and what to do in case there is an issue. Mr. Thomson stated he understands the concern, and already has his team and contracted crews looking out for the potential issue.

Summary of Samples Collected

All sediment and water sample locations are mapped on (b) (4):

(b) (4) All other samples were acquired from (b) (4) equipment yard or (b) (4). GPS coordinates for all samples are attached to their respective collection reports. Some of the samples taken on 8/24/2020 were repeated from locations acquired on 8/20/2020. The samples shipped on 8/20/2020 did not arrive to the lab until 8/24/2020, and the team decided to acquire duplicates.

The following samples were collected during the investigation between 8/20/2020 and 8/24/2020:

- INV1091980 consisting of soil from (b) (4)
- INV1091981 consisting of drag swabs taken from (b) (4)
- INV1091982 consisting of onion wrappings taken from (b) (4)
- INV1137802 consisting of environmental swabs taken from (b) (4) packaging equipment

- INV1137803 consisting of environmental swabs from (b) (4)
- INV1137804 consisting of environmental swabs of (b) (4)
- INV1137805 consisting of apparent bird scat
- INV 1147613 consisting of (b) (4) at the (b) (4)
- INV1146712 consisting of sediment at the (b) (4)
- INV1146714 consisting of dead end ultrafiltration from the (b) (4) drain
- INV1146715 consisting of sediment from (b) (4) drain
- INV1146753 consisting of sediment from northeast corner of (b) (4)
- INV1146716 consisting of sediment from (b) (4) drain
- INV1146717 consisting of one liter grab water sample from (b) (4)
- INV1146754 consisting of sediment from (b) (4) drain
- INV1146755 consisting of sediment from (b) (4) drain
- INV1146756 consisting of sediment from (b) (4) drain
- INV1146757 consisting of (b) (4) from (b) (4) drain
- INV1146791 consisting of (b) (4) from (b) (4) drain
- INV1146792 consisting of sediment from (b) (4) drain
- INV1146793 consisting of dead end ultrafiltration on (b) (4)
- INV1146794 consisting of sediment from (b) (4) for (b) (4)
- INV1146795 consisting of apparent scat from (b) (4) for (b) (4)
- INV1146796 consisting of one liter grab sample from (b) (4)
- INV1146797 consisting of (b) (4) from (b) (4) drain

Exhibits

1. Shipping detail Report for customer shipments from (b) (4) . (8 pages)
2. Thomson International, Inc Red Onions Sales (b) (4) . (3 pages)
3. List of (b) (4) applications and water tests. (12 pages)
4. List of harvest crew training and animal intrusion practices. (4 pages)
5. Pictures of field packaging equipment. (pages)

Attachments

1. Assignment memo from CORE. (9 pages)
2. Investigation team personal safety plan. (5 pages)
3. FDA 482 issued to Jack S. Thomson, President/CEO on 8/20/2020. (3 pages)
4. FDA 3623 Farm Investigation Questionnaire. (34 pages)
5. FDA 484 issued to Jack S. Thomson, President/CEO on 8/24/2020. (4 pages)

Signature

Jacob W.
Reynolds -S

Digitally signed by Jacob W. Reynolds -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
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