

ENVIRONMENTAL ASSESSMENT: 2013 Cyclosporiasis outbreak in Iowa and Nebraska – Findings and Recommendations

November 2013

TABLE OF CONTENTS

Acknowledgements
Introduction
Processing Facility
Ranch Assessments (Ranches A, B, C, D, E)
Taylor Farms de Mexico Sample Summary
Conclusions

ACKNOWLEDGEMENTS

The FDA and the authors wish to thank the following organizations for their assistance in conducting this Environmental Assessment:

U.S. Centers for Disease Control and Prevention (CDC)
Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS)
Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA)
Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA)
Comité Estatal de Sanidad Vegetal de Guanajuato (CESAVEG)
Dirección General de Protección Contra Riesgos Sanitarios, Estado de Guanajuato
Taylor Farms de México

INTRODUCTION

An FDA Environmental Assessment (EA) as part of the response to a foodborne illness outbreak or a contamination event is an on-site systems based approach to determine how the environment may have contributed to the introduction and or transmission of agents that cause illness or could cause illness. Environment is everything external to the host, including air, food, water, animals, plants, climate, etc. as well as people, social and built environments. All aspects of the external environment can be listed as variables that, in relation to transmission are neutral, conducive, or protective. From this description contributing factors and environmental antecedents to an outbreak or food contamination event may be determined. The FDA works with the involved firm and the appropriate government agencies, domestic or foreign, when conducting EAs. The FDA analyzes the observations made by the EA team, as well as the results from environmental and product samples, and makes conclusions regarding the adequacy of the firm's preventive controls, and suggests improvements as necessary.

Environmental Assessment Report: 2013 Cyclosporiasis outbreak in Iowa and Nebraska

This EA was conducted August 12 – 19, 2013 in response to a 2013 multi-state foodborne illness outbreak of *Cyclospora cayetanensis*. Epidemiologic and traceback investigations by the states of Iowa and Nebraska, the CDC and the FDA linked salad mix supplied by Taylor Farms de Mexico to Olive Garden and Red Lobster restaurants, which are owned by Darden Restaurants, to the outbreak. The last date that someone who had eaten in one of these restaurants in those states reportedly became ill with cyclosporiasis was on July 2, more than five weeks prior to the start of the EA.

The salad mix was produced by a processor of foodservice salads, Taylor Farms de Mexico, which is located in Doctor Mora, Guanajuato, Mexico. A traceback investigation identified three ranches of interest (among two growers) in the Guanajuato region. This report covers an EA that included these three ranches, two additional ranches added during the EA based upon information provided by Taylor Farms de Mexico, and the Taylor Farms de Mexico processing facility.

For current information on the CDC and FDA investigations of this outbreak please refer to the following websites:

CDC: <http://www.cdc.gov/parasites/cyclosporiasis/outbreaks/investigation-2013.html>

FDA: <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm361637.htm>

The suspect bagged salad mix consisted of iceberg lettuce, romaine lettuce, green leaf, red cabbage, and carrots. With the exception of carrots, all of the components in the suspect salad mix were grown for Taylor Farms de Mexico on multiple ranches in the State of Guanajuato, Mexico. The carrots were grown on one ranch in the State of Sonora, Mexico. The traceback investigation identified three leafy green ranches of interest with a total of nine growing fields of interest. These three ranches and two additional ranches in Guanajuato were assessed as part of this EA, as was the Taylor Farms de Mexico processing facility. The carrot ranch was not assessed because the carrot harvest season had ended prior to the initiation of this assessment, and because of the remote location of the carrot ranch relative to the leafy green and red cabbage ranches and the processing facility.

Humans are the only known reservoir of the microscopic parasite *Cyclospora cayetanensis*, which causes intestinal infection and is endemic in many developing countries. The parasite is transmitted via ingestion of contaminated water or food. Direct person-to-person transmission is unlikely because the immature form of the parasite shed in the feces of an infected person must mature outside the host, in the environment, to become infective for someone else. The maturation process is thought to require days to weeks under favorable conditions. *Cyclospora* is unlikely to be killed by routine chemical disinfection or sanitizing methods, including chlorination.

PROCESSING FACILITY

On August 12, 2013, the EA began at the Taylor Farms de Mexico processing facility in Doctor Mora, Guanajuato, Mexico. The processing facility assessment covered the construction and design of the processing facility, the processing water system, the sanitary water system, the receipt of raw agricultural commodities, lettuce mix production procedures and practices, employee health, and the distribution of finished products.

Environmental Assessment Report: 2013 Cyclosporiasis outbreak in Iowa and Nebraska

The EA team considered the incoming raw ingredients, the facility employees, and the facility sewage system as potential sources of *Cyclospora cayetanensis*. The assessment of incoming raw ingredients is covered under the section titled “Ranches” in this assessment.

On August 12, 2013, Taylor Farms de Mexico officially informed the FDA that, as of August 9, 2013, the company voluntarily suspended production and shipment of any salad mix, leafy green, or salad mix components from its operations in Mexico to the United States. The facility was not actively processing at the time of the EA, although a demonstration of the processing operation was provided for the EA team.

Taylor Farms de Mexico processing employees are provided with protective clothing including hair nets, face masks, smocks, arm guards, cloth gloves, impermeable disposable outer gloves, and rubber boots. Hand washing occurs after work boots are on and before gloves and other protective gear are put on; a one-way turnstile between the boot-up and the glove-up areas prevents back-and-forth traffic. After donning all of the protective clothing the employees walk through a quaternary ammonium sanitizing foot bath upon entering the processing facility and do so again at the entrances to each section of the processing facility. Sanitizing chlorine hand dips are also used when initially entering the processing facility and again at the entrance to each section of the facility. The cloth gloves and smocks are washed onsite daily. The disposable protective clothing articles (hair nets, face masks, arm guards, and outer gloves) are replaced each time that the employees re-enter the processing facility after meal breaks, restroom breaks, etc. There is no bare hand contact with in-process salads.

The processing facility employees are also provided with onsite medical care and ill employees are sent home for recovery. The medical care also includes home visits by a nurse if home recovery is required. The nurse confirms the employee’s recovery and also that no other household member exhibits illness symptoms prior to the employee being allowed to return to work. Medical care records are maintained and were made available during the EA.

The processing facility restrooms were all found to be in good repair and maintained in sanitary condition. The restroom hand washes are located immediately outside of the restroom entrances, and employee hand washing is monitored. The onsite waste water treatment facility is located approximately 300 meters from the processing facility, it is secured by a locked gate, and is operated by a dedicated staff that does not enter the processing facility. The processing employees do not have access to the waste water treatment plant. The EA team found no potential plumbing cross-connections or other potential route of contamination from the restroom plumbing or the waste water treatment plant to the processing water system or to the processing facility in general.

The assessment of the processing facility identified the washing of the combined salad mix components in recycled wash water as one point in the production process that could create the potential for cross-contamination and spread of the outbreak pathogen if it were determined that *Cyclospora cayetanensis* is a reasonably likely food safety hazard associated with the Guanajuato growing region. Fresh water is continuously added to the recycled wash water, and a complete change-out of the wash water occurs on a regular schedule. The frequency of the change-out of the recycled wash water is increased/decreased depending upon the soil load of the incoming raw ingredients. The firm maintains free chlorine in the recycled wash water at a target concentration of 10 ppm, and phosphoric acid is utilized to maintain the pH of the recycled water at 7.0 or lower to facilitate free chlorine formation. However, *Cyclospora cayetanensis* is known to be resistant to halogen-based sanitizers including chlorine. If *Cyclospora*

Environmental Assessment Report: 2013 Cyclosporiasis outbreak in Iowa and Nebraska

cayetanensis contaminated raw ingredients were introduced into the recycled wash water, the potential to spread the outbreak pathogen onto additional product could be created. The low infectious dose of *Cyclospora cayetanensis* (estimated to be between 10 – 100 sporulated oocysts) increases the potential for such processing cross-contamination to result in an illness outbreak. Micro-filtration can eliminate *Cyclospora cayetanensis* from water. However, the high turbidity of the recycled salad wash water inhibits micro-filtration and thus such filtration is not utilized for recycled wash water in the cut salad industry.

Samples of recycled salad wash water were collected from the processing facility for analysis by the FDA Southeast Regional Laboratory (SRL), in Atlanta, and the CDC Atlanta laboratory. In addition, fresh processing water was collected for analysis by the CDC Atlanta laboratory. The FDA recycled wash water sample was collected jointly by the FDA and COFEPRIS. The FDA / COFEPRIS water sample, collected under FDA sample number 744382, consisted of two-10 liter containers of recycled leafy green wash water (subs 1 and 2) and two-10 liter containers of recycled carrot and red cabbage wash water (subs 3 and 4) for analysis via the [Bacteriological Analytical Manual](#) (BAM) method for *Cyclospora cayetanensis*. The CDC recycled wash water sample consisted of the micro-filtration of approximately 6.6 liters of recycled leafy green wash water collected at the same location as the FDA/COFEPRIS sample; the turbidity of the recycled wash water prevented the pumping of a larger volume of water through the CDC sampling filter. The CDC also collected a filtration sample representing 100 liters of fresh processing water from the exterior fresh processing water storage tank. The CDC micro-filtration samples were sent to the CDC Atlanta laboratory for analysis via a CDC developed method. Analysis results for FDA sample 744382 were inconclusive; the turbidity of the recycled wash water inhibited analysis by the BAM method. The fresh and recycled water samples collected by the CDC tested negative for the outbreak pathogen.

RANCHES

During the assessment of the five ranches the EA team considered the ranch workers and the onsite sanitary facilities as potential sources of *Cyclospora cayetanensis*; with the exception of one residence adjacent to one ranch, no other potential sources of the outbreak pathogen were identified on or in the immediate vicinity of any of the ranches.

The planting of seedlings, weeding, fertilizing, pest control, and all other work performed during the growth of the lettuce is done by the employees of each ranch. Harvesting is performed by Taylor Farms de Mexico harvest crews. Harvesting equipment is maintained onsite at Taylor Farms de Mexico, including cleaning and sanitizing. All ranch workers are local citizens that commute to the growing fields. No indication of ranch worker camps was observed in the vicinity of any growing location. No ranch worker housing was provided on or in the immediate vicinity of any of the assessed ranches. Each ranch is required under Taylor Farms' contract to provide sanitary facilities to their workers and to comply with GAP-based sanitary standards. Other specific requirements of the Taylor Farms contract include the exclusion of septic pump trucks from the growing areas and a dedicated portable restroom pump-out location separated from the growing areas, the exclusion of children and animals from the ranches, and providing an employee meal break area away from the growing fields. Compliance with these contractual requirements is confirmed via routine ranch audits utilizing the evaluation system of the California Leafy Green Marketing Agreement.

Environmental Assessment Report: 2013 Cyclosporiasis outbreak in Iowa and Nebraska

All five ranches are completely fenced and have 24 hour security.

Taylor Farms de Mexico provides medical care to all of their employees. Ill employees are sent home, and a company nurse performs home visits to confirm the employee's recovery and that no other household member exhibits symptoms prior to the employee returning to work. The table below provides a synopsis of individual harvest crew member medical care within the outbreak time of interest. No diagnosis was recorded by the firm as to the probable cause of the employee illnesses.

TFM HARVEST CREW INDIVIDUAL PRESCRIPTIONS

Date of Visit	Medication provided	Crew
3/6/2013	trimetropin sulfa metazol	C
4/24/2013	dicloxacillin	A
4/24/2013	dicloxacillin	A
5/8/2013	ampicillin	E
5/22/2013	dicloxacillin	T
5/29/2013	dicloxacillin	Driver
6/26/2013	<i>loperamide</i>	<i>E</i>
7/3/2013	<i>loperamide</i>	<i>O</i>
7/10/2013	<i>loperamide</i>	<i>S</i>
7/10/2013	ampicillin	T
7/24/2013	<i>loperamide</i>	<i>X</i>
7/31/2013	dicloxacillin	T
8/7/2013	trimetropin sulfa metazol	O*
8/7/2013	trimetropin sulfa metazol	O*

Colors indicate patients of the same crew.

Medications were provided based on availability.

*Medication due to expire, chosen for economic reasons.

Environmental Assessment Report: 2013 Cyclosporiasis outbreak in Iowa and Nebraska

Trimetropin Sulfa Metazol is a broad spectrum antibiotic that is effective against some bacterial infections and also against infection with the parasite *Cyclospora cayetanensis*.

(<http://www.cdc.gov/parasites/cyclosporiasis/treatment.html>)

The firm doctor stated that he did not suspect *Cyclospora cayetanensis* or other parasitic infection when he prescribed Trimetropin Sulfa Metazol, and that this drug was prescribed because it is effective against some bacterial infections and because he wanted to use this particular lot of antibiotics before the expiration date.

Loperamide is an anti-diarrheal medication that is available with or without a prescription. This medication is sometimes prescribed for other uses.

(<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682280.html>)

Ampicillin is a broad spectrum penicillin-like antibiotic used to treat certain infections caused by bacteria such as pneumonia; bronchitis; and ear, lung, skin, and urinary tract infections. This medication is sometimes prescribed for other uses. (<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a685002.html>)

Dicloxacillin is a penicillin-like antibiotic used to treat certain infections caused by bacteria such as pneumonia and bone, ear, skin, and urinary tract infections. This medication is sometimes prescribed for other uses. (<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a685017.html>)

All five of the ranches assessed as part of this EA utilize self-contained portable restrooms that include hand washing stations. One ranch also had a permanent restroom with a subterranean cement septic tank. For the portable facilities observed during this EA the sewage cleanout access point is through the toilet opening; there were no exterior valves or other openings to the sewage holding tanks of the portable restrooms observed. Portable restroom pump-outs occur at designated locations away from the growing fields (observed pump-out areas were approximately 70 to 90 yards from growing areas); the septic pump trucks do not enter the growing areas. All of the restrooms are serviced under contract. Ranch employees do not service the restrooms. The portable restrooms are serviced on a regular schedule when in use with the frequency depending upon the size of the work crew; service records are maintained on the restrooms. The one permanent restroom septic tank observed is accessed by the pump-out truck via a fenced road that is also separated by a distance of approximately 120 feet from the assessed growing fields and does not appear to drain towards the assessed growing fields; this septic tank was installed in 1999 and is serviced approximately every 6 months. The EA team did not observe any potential route of contamination from any of the observed onsite sanitary facilities to any irrigation water systems or growing fields.

Hand washing facilities encountered on the portable sanitary trailers do not appear to be of sanitary design in that the valve handles create the potential for cross-contamination. The EA team observed hose-spigot style valve handles, pet water-like valves in which the water flows over a protruding cone-shaped valve handle when the valve handle is touched, and typical sink-like valve handles. None of the portable sanitary facility hand washing stations utilized hands-free faucets.

All five of the assessed ranches use well water for irrigation. All of the wells share common design characteristics including depths in the 200 – 300 meter range, pipe casing that extends all the way to the

Environmental Assessment Report: 2013 Cyclosporiasis outbreak in Iowa and Nebraska

water table, conduit access portals for electrode-based water table depth measurements, and cement surface seals.

The EA team did recommend minor improvements to some of the wells including backflow protection for hose connections and other potential plumbing connection points, the replacement of absorbent sealing material with non-absorbent sealing material, the repair of cracks in the cement seals, and the capping of access conduit. The EA team found no indication of flooding or other potential irrigation water contamination at any of the wells.

Three of the assessed ranches utilize elevated irrigation water holding ponds; both lined and un-lined ponds were observed. The elevated irrigation holding ponds serve two purposes; some of the wells lack adequate flow rates for direct irrigation, and electrical rates to operate the well pumps are much lower at night than during daylight hours. All of the irrigation water holding ponds are completely fenced, which combined with the ranch perimeter fencing creates two physical barriers to human and animal intrusion. As previously stated, all of the assessed ranches are under 24 hour security surveillance. The EA team walked the entire perimeter of each holding pond and found no indication of human or animal intrusion at any of the irrigation water holding ponds.

The EA team evaluated the potential for *Cyclospora cayetanensis* to be introduced into each growing area from the environment surrounding each of the ranches. The EA team did not identify any significant potential outbreak pathogen sources or route of contamination from the environments surrounding the five assessed ranches.

Irrigation water samples were collected at all five of the assessed ranches for analysis by the FDA SRL laboratory and the CDC Atlanta laboratory. The FDA irrigation water samples consisted of two 10-liter containers of water per sampling point and represent sampling by both the FDA and SENASICA. The CDC micro-filtration irrigation water samples represent 100 liters of water per sampling point. All irrigation water samples tested negative for the outbreak pathogen.

RANCH A

Ranch A was not identified for inclusion as part of the EA by the FDA Coordinated Outbreak Response and Evaluation Network (CORE) traceback analysis team, but was added to the EA based upon a recommendation by Taylor Farms de Mexico after they noted a potential for rainwater runoff in the vicinity of two growing fields that provided cabbage during the time of interest. Taylor Farms de Mexico identified two lots in these growing fields that were in production during the outbreak time of interest: lots two and seven. These two lots provided 100% of the red cabbage used in Taylor Farms de Mexico salad mixes during the Iowa and Nebraska outbreak timeframe.

There are three wells on this ranch; one well provides irrigation water to lots two and seven. The EA team focused the assessment of this ranch on these two lots and the associated well.

The EA team examined the well and recommended replacing absorbent foam used as a seal with a non-absorbent sealing material, capping an access conduit used for electrode water table depth measurements, and installing a backflow prevention device on a hose connection at the well head. The EA team did not observe any indication of flooding or other potential for the contamination of this well.

Environmental Assessment Report: 2013 Cyclosporiasis outbreak in Iowa and Nebraska

The EA team found a subterranean cement septic tank on the east side of a permanent restroom building approximately 70 feet from the well. Sanitary pump trucks access the septic tank from a road on the east side of the building. An approximately 4-foot tall fence separates the septic access road from Ranch A's growing fields, and the septic pump hose is dropped over this fence to access the septic tank port. The EA team did not observe any indication of septic tank overflow, and a visual examination of the septic tank found the liquid contents approximately eight feet below the ground surface. Taylor Farms de Mexico's routine testing of the well water has found no fecal indicators. In addition, in response to the outbreak, feces were collected from this septic tank by Taylor Farms de Mexico for *Cyclospora* analysis; *Cyclospora* was not detected.

There was significant rainfall in the days prior to our assessment of Ranch A. The EA team walked fields two and seven and did not observe any indication of flooding or erosion. The land has a slight slope and it appears that the natural course of drainage for fields two and seven is from the northeast to the southwest. The EA team did not observe any potential for drainage from the septic tank area to these lots or from any other potential outbreak pathogen source to these lots.

RANCH B

At Ranch B, five lots from one growing field were identified by the traceback investigation as providing iceberg lettuce to Taylor Farms de Mexico during the outbreak time period of interest.

Two wells provide irrigation water to this ranch. The water of both wells is combined in a single elevated reservoir prior to use for irrigation. The reservoir water is treated with copper sulfate to prevent algae growth. The reservoir is fenced, which combined with the ranch perimeter fencing provides two physical barriers to human and animal intrusion. In addition, there is 24 hour security surveillance on the ranch. The security guards are provided with portable restrooms with a hand washing station, and with primitive shelter. No indication of human or animal intrusion was observed in or around the reservoir.

Well # 1 is co-located with the reservoir. The EA team observed one hose connected at this well that appeared to lack a backflow prevention device. The hose was long enough to become submerged if there was any standing water around the well. The EA team recommended installing a backflow prevention device at this hose connection.

Well # 2 is located across two lots over from well # 1. There are no hose or other plumbing connections attached to well # 2, and a vacuum-breaker is installed at the well head to prevent backflow. The EA team had no suggestions for improvement at well # 2.

RANCH C

At Ranch C, the traceback investigation identified two lots as providing iceberg lettuce to Taylor Farms de Mexico during the outbreak time period of interest: lots 4 and 5

There is an unrelated residence immediately to the north of lots 4 and 5 that maintains small herds of horses and cattle (only one bull was observed), a small community approximately 1.5 kilometers SW of the ranch, and a chicken ranch approximately 1.5 kilometers east of the ranch. Based upon human inhabitation, the EA team considered the residence and the small community as potential sources of the

outbreak pathogen, but the EA team did not identify any potential outbreak pathogen route of contamination from the residence or the community to the Ranch C growing areas. The EA team did not consider the chicken ranch to be a potential source of the outbreak pathogen due to the distance separating the two operations and because humans are the only known hosts of *Cyclospora cayetanensis*.

Ranch C has two wells which are identified as the north well and the south well. The water from both wells is combined at a sand filtration/fertilizer injection station that is co-located with the south well. The plumbing for the two wells is directly connected immediately prior to the sand filters.

At the north well, the EA team recommended replacing absorbent sealing material with non-absorbent material, capping a conduit access portal, and repairing cracks in the cement seal. The EA team did not observe any indication of or potential for flooding at this well or any other potential route of contamination to this well.

At the south well, the EA team recommended replacing absorbent sealing material with non-absorbent material and repairing cracks in the cement seal. The EA team did not observe any indication of or potential for flooding at this well or any other potential route of contamination to this well.

The EA team also recommended the installation of a backflow prevention device for a hose connection at the sand filtration system.

RANCH D

At Ranch D, three lots were identified by the traceback investigation as providing iceberg lettuce to Taylor Farms de Mexico during the outbreak time period of interest.

Ranch D is serviced by three wells. Well # 1 and well # 2 are co-located with irrigation water reservoirs, and both of these reservoirs are capable of providing irrigation water to all of the growing lots on the ranch. Well # 3 is used primarily for foliar application mixing and is connected to an elevated water storage tank.

The EA team had no suggested improvements for well # 1. There are no hose connections or other plumbing connections on well # 1. Irrigation water was collected from the associated reservoir.

For well # 2, the EA team recommended installing a backflow prevention device on a two-inch plumbing connection. The submerged well pump had been replaced on the day prior to our assessment of this ranch.

RANCH E

Ranch E is located adjacent to railroad switching tracks and immediately north of Ranch D. Ranch E has a single well, an irrigation water reservoir, an elevated water tank used to supply truck mounted tanks, an employee hand washing station near the employee meal break area, and an uninhabited residence on the property. Portable sanitary facilities are also provided for field workers.

Ranch E was not identified for inclusion in the EA by the CORE traceback team, but was added to the EA when the EA team's review of Taylor Farms de Mexico routine irrigation water testing records found a positive fecal coliform test result for water collected from drip irrigation tape. Under the firm's system for

irrigation water testing the rolling mean average of 5 fecal coliform samples must be at or below 126 MPN / 100mls., and no single sample can be equal to or greater than 235 MPN / 100mls. If either of these two standards is not met the crop cannot be harvested for salad production. The positive fecal coliform finding did not trigger any corrective action by Taylor Farms de Mexico because additional sampling was negative so the firm's rolling mean-average metrics system for monitoring irrigation water did not trigger a response, and because the result of the fecal coliform sample was found at 200 MPN / 100mls., which is below Taylor Farm's single positive irrigation water sample action trigger level of 235 MPN / 100mls.

The EA team did not consider the uninhabited residence as a potential source of the outbreak pathogen due to the fact that the residence is uninhabited and was unused during the entire growing season of interest. The EA team also assessed a primitive shelter found at the adjacent train tracks as a potential source of the outbreak pathogen but no indication of feces was observed in the area of the shelter and no potential route of contamination was identified from the shelter to the growing areas. This shelter is used by nighttime train track switch operators. Empty packaging for three medications was found scattered around this switch operator shelter; research determined that the three medications were an aspirin-like anti-inflammatory drug, the anti-acid drug ranitidine, and a palm-oil based dietary supplement. According to an on-duty security guard at Ranch E, the train switch operators never enter the ranch property.

At Ranch E's sole well, the EA team suggested the installation of a backflow prevention device for the hose connection on the well plumbing.

TAYLOR FARMS de MEXICO SAMPLE SUMMARY

In response to the outbreak, Taylor Farms de Mexico initiated their own EA during which they assessed and collected samples from their processing facility and 30 ranches. A complete EA report has been provided to the FDA. In total 793 samples were collected by Taylor Farms de Mexico, including produce samples, process water samples, irrigation water samples, environmental samples including standing water, and human feces samples from sanitary facilities. The outbreak pathogen was not detected in any of these samples. The table below summarizes the sampling performed by Taylor Farms de Mexico.

It should be noted that prior to resuming operations on August 25, 2013, Taylor Farms de Mexico implemented a comprehensive *Cyclospora* sampling program for leafy green and other products from their farms and processing facility in Mexico. This includes both sampling of their products and water and continued monitoring of the sanitary conditions of their facilities.

Cyclospora Testing Summary

(As of August 19, 2013)

Sample type	Number of samples (Negative)
Sanitary	273
Sanitary Waste	259
Sanitary Pump-Out Truck	8
Gray Water	4
Septic System	2
Agricultural Inputs	238
Well	81
Foliar Application	52
Reservoir/Storage	48
Cintilla/Drip	47
Plant Tissue (Nursery)	10
Pre-Harvest	164
Plant Tissue (leafy greens used in salad mixes)	164
Environment	47
Run-Off/Standing Water	10
Drain Ditch	8
River/Stream/Canal	7
Soil	6
Reservoir/Storage	6
Post Process: Settled	3
Reservoir/Storage: No longer Active	3
Post Process: Treated discharge	3
Post Process: Unscreened	1
Finished Product	42
Plant Tissue (leafy greens used in salad mixes)	42
In-Process	29
Plant Tissue (leafy greens used in salad mixes)	27
In Process: Primary Water	2
Grand Total	793

CONCLUSIONS

At the processing facility the EA team considered the incoming raw ingredients, the facility employees, and the facility sewage system as potential sources of *Cyclospora cayetanensis*. The assessment of incoming raw ingredients is covered under the ranch assessments.

- Based upon the above-described processing facility's employee risk reduction practices and procedures, the EA team determined that, at the time of the assessment, the processing facility employees would not likely be a source of the outbreak pathogen.
- Based upon the above-described processing facility observations, the EA team determined that, at the time of the assessment, the processing facility restrooms, the associated sanitary plumbing, and the onsite waste water treatment facility would not likely be sources of the outbreak pathogen.

In the assessment of the five ranches the EA team considered the ranch workers, the harvest crews, and the onsite sanitary facilities as potential sources of *Cyclospora cayetanensis*. The EA team also evaluated the potential for irrigation water and growing fields to become contaminated from surrounding environmental sources. With the exception of one residence adjacent to one ranch, no other potential environmental sources of the outbreak pathogen were identified on or in the immediate vicinity of any of the ranches assessed.

- Based upon the above-described ranch employee and harvest crew risk reduction practices and procedures combined with onsite observations, the EA team determined that, at the time of the assessment, the ranch employees and harvest crews working on the five assessed ranches would not likely be sources of the outbreak pathogen.
- Based upon the above-described risk reduction practices and procedures combined with a lack of an observed potential route of contamination to irrigation water or growing fields the EA team determined that, at the time of the assessment, the sanitary facilities observed on the five ranches assessed would not likely be sources of contamination by the outbreak pathogen.
- Based upon the lack of an observed potential route of environmental contamination to the irrigation water and growing fields, and the negative irrigation water samples, the EA team determined that, at the time of the assessment, irrigation systems and growing fields of the five assessed ranch would not likely be contaminated with the outbreak pathogen.

This EA, which included assessment at four leafy green ranches, one red cabbage ranch, and the Taylor Farms de Mexico processing facility, did not identify any significant potential sources of the outbreak pathogen or any significant potential route of contamination to the firm's salad products. Based on a thorough review of the information collected during the EA, to date, the FDA has not been able to definitively determine how or at what point in the supply chain *Cyclospora cayetanensis* contaminated the salad mix associated with the outbreak.

FDA suggests that the following additional activities be considered:

Environmental Assessment Report: 2013 Cyclosporiasis outbreak in Iowa and Nebraska

1. One ranch located in the State of Sonora, Mexico, supplied 100% of the carrots used in the salad mix implicated in the Iowa and Nebraska outbreak clusters. The carrot ranch was not included in this EA because the carrot harvest season ended prior to the initiation of this assessment, and because of the remote location of the carrot ranch relative to the Guanajuato leafy green growing region. The EA team recommends that an assessment of the carrot growing environment be performed prior to the next carrot harvest.
2. In the combined sampling efforts of the CDC, the FDA, and Taylor Farms de Mexico, approximately 835 product, water, and environmental samples were analyzed, including over 269 human feces samples collected from on-ranch sanitary facilities. These samples all tested negative for the outbreak pathogen, except one FDA sample which was inconclusive due to the turbidity of the recycled wash water inhibiting analysis by the BAM method. The EA team recommends research to determine if this pathogen is reasonably likely to be a food safety hazard associated with the Guanajuato leafy green growing region. If it is determined that *Cyclospora cayetanensis* is a reasonably likely food safety hazard associated with the Guanajuato growing region, the EA team recommends that Taylor Farms de Mexico re-evaluate their salad mix processing procedures to assure controls are in place to mitigate the potential for *Cyclospora cayetanensis* cross-contamination at the salad mix washing step.
3. In reviewing Taylor Farms de Mexico employee medical care records the EA team found instances in which anti-diarrheal drugs and broad spectrum antibiotics were administered to employees. Ill employees are treated by the Taylor Farms de Mexico company doctor and sent home to recover. A Taylor Farms de Mexico nurse performs home visits to confirm that the employee has recovered and that no other household members exhibit symptoms prior to the employee returning to work. The EA team recommends that Taylor Farms de Mexico take advantage of the home visits by the company nurse to encourage employees with diarrhea or other gastro-intestinal symptoms to submit stool samples for *Cyclospora cayetanensis* analysis as part of the above-recommended research to determine if this pathogen is a reasonably likely food safety hazard associated with the Guanajuato region.
4. The hand washing faucets observed on the portable sanitary facilities at the assessed ranches could create a potential for cross-contamination in that the employees must handle the valves before and after washing their hands to turn the water on and off. The EA team recommends that the firm establish procedures for the hand wash facilities to facilitate the control, reduction, and elimination of human pathogens from employee hands, by evaluating the worker hygiene facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.