

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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| DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax: (303)236-3100 | DATE(S) OF INSPECTION 10/28/2024-11/12/2024* |
| | FEI NUMBER 1783599 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher M. Hallee, President

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| FIRM NAME Taylor Farms Colorado, Inc. | STREET ADDRESS 890 N Newport Rd |
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| CITY, STATE, ZIP CODE, COUNTRY Colorado Springs, CO 80916-2741 | TYPE ESTABLISHMENT INSPECTED Manufacturer |
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
OBSERVATION 1**

You did not implement your sanitation preventive control, monitoring, corrective action and verification procedures.

Specifically,

Your firm processes ready-to-eat (RTE) produce products including slivered onions. Your RTE produce products are exposed to the environment prior to packaging and do not undergo a lethal treatment step for pathogens. The hazard analysis titled, "Processed Vegetables Hazard Analysis" dated 10/23/2024 is used for slivered onions. This hazard analysis did not identify the preventive control for the hazard, recontamination of environmental pathogens. The food safety plan titled, (b) (4) - Sanitation Preventative Controls- Processed Vegetables" dated 10/23/24 has the product description listed as "Diced Tomatoe." This food safety plan lists "environmental pathogens, such as Salmonella and Listeria" as hazards that require a "sanitation control". According to firm management, this food safety plan is used for all processed vegetables at this location, including slivered onions. Slivered onions are exposed to the environment from the peel step to the finished packaging step.

After your (b) (4) steps in your hazard analysis, biological hazards in your hazard analysis are not identified at the following steps: (b) (4)

(b) (4) Slivered onions and other processed vegetables

AMENDMENT 1

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are RTE and exposed to the environment from the (b) (4) step to the “(b) (4) step. According to management, the (b) (4) is not a lethal treatment that would remove the biological hazard. The biological hazard is still present after the (b) (4) steps. The product does not undergo any lethal treatments for biological hazards, and it is still considered RTE and exposed to the environment.

I observed areas throughout the facility where recontamination of environmental pathogens could occur. For example, on the inspection dates 10/28/24 to 10/31/24 and 11/4/24 to 11/5/24, I observed numerous areas in your facility that could support pathogenic growth on various food contact surfaces, and non-food contact surfaces. The production rooms in your facility are maintained at temperatures that would support the growth of pathogenic organisms, such as Listeria. For example, pooling water was observed near the (b) (4) cutting area. This area tested positive for Listeria spp. on 1/26/2024 and 1/30/2024 and is considered a non-food contact surface. More pooling water was observed on the floor and equipment (b) (4) rooms that are not food contact surfaces. Several non-food contact surface areas in the production rooms tested positive for Listeria spp., and these include:

1. “Drain behind (b) (4) on 2/9/2024;
2. “Line (b) (4) line (b) (4)” on 2/9/2024;
3. “(b) (4) line (b) (4) line (b) (4) on 2/16/2024;
4. “(b) (4) RTE products on 5/15/2024;
5. Floor (b) (4) for “line (b) (4) on 6/5/2024;
6. “(b) (4) er the (b) (4) for line (b) (4) on 6/14/2024;
7. “Drain (b) (4) Room” on 8/14/2023, 8/18/2023, and 8/19/2023;
8. “Drain, (b) (4) Line (b) (4) on 10/9/2023;

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- 9. "Drain (b) (4) on 10/23/2023;
- 10. "(b) (4) line drain for Line (b) (4) on 10/28/2023;
- 11. "Floor for high traffic area Line (b) (4) on 10/23/2023; and,
- 12. On the floor "employee high traffic area Line (b) (4) on 3/20/2023.

Your corrective action procedure in your food safety plan for environmental monitoring does not address how your process will be addressed, and how the action taken will reduce the likelihood of the problem from reoccurring in the future. Your corrective actions listed in your "Environmental Monitoring" plan dated 8/19/2024 explains that you will (b) (4) your results are returned from the third-party lab for (b) (4)". However, environmental monitoring records reviewed for 2023 and 2024 demonstrated this was not consecutively being completed. For example, in 2023, a positive result for *Listeria spp.*, was received on (b) (4), and the (b) (4) tests were completed on (b) (4). This was not completed the day after the test results were received (b) (4). On 1/28/2024, you received a positive result for *Listeria spp.*, and your follow-up test on (b) (4) indicated a positive result on (b) (4) and the (b) (4) tests were completed on (b) (4). The follow-up test was not completed (b) (4) were received as stated in your corrective action plan for Environmental Monitoring.

The verification methods for using (b) (4) to verify your hazard, "Environmental pathogens, such as Salmonella and Listeria" is not designed to identify "Salmonella and Listeria" as stated in your food safety plan. The (b) (4) used at your facility are designed to measure the amount of (b) (4) on surfaces and are not designed to determine the types of pathogens present on a surface. Also, the monitoring procedures, (b) (4) inspection after cleaning by QC tech" don't explain how the (b) (4) are monitored.

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We observed numerous equipment with apparent biofilm and large amounts of food debris present after the firm's post-operation cleans. This is evidenced by the pre-operation observed on 11/5/2024, the document titled, "Pre-Op Inspection from Today (11/05/2024)", the firm entered "Pass" for the (b) (4) inspection on several food contact surfaces that were not visually clean and should have been marked as a "Fail". For example, on 11/5/2024, the (b) (4) were marked as "Pass" at 5:51 a.m. and the finished product hopper/scale chute for line (b) (4) were marked as "Pass" at 5:54 a.m. Both food contact surfaces mentioned above had apparent biofilm and/or food debris present on 11/5/2024 that could be placed in products that share these food contact surfaces. This is evidenced by the firm's recent compliant on 9/23/2024, a customer received the finished product that should only have green peppers, and onions were present. During the inspection dates 10/28/2024 to 10/31/2024, I observed several food contact surfaces (e.g., finished product hopper) with food debris present after several full rounds of the firm's (b) (4) - step sanitation process".

On 11/4/2024, we observed the following in plant observations during the production of lettuce on line (b) (4) green peppers on line (b) (4) and (b) (4) celery:

- (b) (4) production aprons parts were observed inside the handwashing sink and commingled with various parts at the handwashing station during the inspection. The (b) (4) apron ties were touching the inside and outside of hand washing sink basin, and the ties are touched by production employees hands that handle food and food contact surfaces.
- Employees were observed to only sanitize their gloved hands after they touch insanitary surfaces and resume touching RTE food and various food contact surfaces. Employees were not observed removing gloves, washing hands, and donning new gloves. According to firm management, it is common practice for employees to only use hand sanitizer stations in the production areas.

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3. Production employee was observed using a (b) (4) hose to spray down the hopper while exposed ready-to-use food contact surfaces, i.e., spin baskets, and nearby that could become contaminated from aerosolized water droplets. One of these spin baskets was used during the cutting of the RTE, green peppers before it was placed in the (b) (4).

4. Several pieces of equipment that come into contact with RTE produce manufactured at the firm had (b) (4). We observed food particles in the crevices of the welds on line (b) (4), the (b) (4) (b) (4) lines. Also, there was trapped water and food debris present in the pitted areas of the food contact surfaces, which was also observed on inspection dates 10/28/24 to 10/31/24 when the firm was not in production on line (b) (4).

5. Several white cutting boards used to chop RTE lettuce and celery were severely discolored, and deep cracks and crevices.

6. Production employees handling RTE produce and food contact surfaces, were not observed using any of the handwashing sinks in the facility. Employees would sometimes use the hand sanitizer over their gloved hands only. This is evidenced by the production employee sanitized his gloved hands only after touching the hose on the floor.

On 11/05/2024, the following issues were observed during pre-operations walk through:

1. Apparent biofilm and food debris was present on (b) (4), on the slicer and (b) (4) for (b) (4) in numerous (b) (4) bins used for all (b) (4) lines, and the scale/ finished packaging hopper for line (b) (4), and the QC signed off as "Pass" result for visual cleanliness on the pre-operation document that documents the visual cleanliness for 11/5/2024.

2. We observed torn and damaged belts, especially the one for the carrot line, that had a torn piece of

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belt that would come into direct contact with RTE food prior to packaging.

3. I observed two different production employees washing their gloved hands at the handwashing station outside of the production room, and then proceeded to go into the production room to start production and handle food contact surfaces.

OBSERVATION 2

You did not have sanitation control monitoring, corrective action and verification records.

Specifically,

Your firm processes ready-to-eat (RTE) produce products including slivered onions. Your RTE produce products are exposed to the environment prior to packaging and do not undergo a lethal treatment step for pathogens. The hazard analysis titled, "Processed Vegetables Hazard Analysis" dated 10/23/2024 is used for slivered onions. This hazard analysis did not identify the preventive control for the hazard, recontamination of environmental pathogens. The food safety plan titled, (b) (4) Sanitation Preventative Controls- Processed Vegetables" dated 10/23/24 has the product description listed as "Diced Tomatoe." This food safety plan lists "environmental pathogens, such as Salmonella and Listeria" as hazards that require a "sanitation control". According to firm management, this food safety plan is used for all processed vegetables at this location, including slivered onions.

The (b) (4) cleanliness check documents titled, "Pre-Op Inspection from Today 9/24/2024 and 10/5/2024" were missing, and are used as monitoring and verification for sanitation control. The PCQI trained individual signed off on all preventive control monitoring records in the production packet for 9/24/24 and 10/5/24, and did not note the missing records. There was no corrective action report

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generated by management due to the missing records for 9/24/2024 and 10/5/2024. According to management, the records were not in the electronic tracking software or production packets the PCQI trained individual reviewed and signed.

OBSERVATION 3

You did not conduct operations under conditions and controls necessary to minimize the potential for contamination of food.

Specifically,

Your firm processes ready-to-eat (RTE) produce products including slivered onions. Your RTE produce products are exposed to the environment prior to packaging and do not undergo a lethal treatment step for pathogens. The hazard analysis titled, "Processed Vegetables Hazard Analysis" dated 10/23/2024 is used for slivered onions. This hazard analysis did not identify the preventive control for the hazard, recontamination of environmental pathogens. The food safety plan titled, (b) (4) Sanitation Preventative Controls- Processed Vegetables" dated 10/23/24 has the product description listed as "Diced Tomatoe." This food safety plan lists "environmental pathogens, such as Salmonella and Listeria" as hazards that require a "sanitation control". According to firm management, this food safety plan is used for all processed vegetables at this location, including slivered onions.

According to firm management on 11/4/2024, fully submerged food contact surfaces (e.g., knives stored (b) (4) solution) are stored in sanitizing solutions and are not air dried after the food contact surfaces are removed from sanitizing solution. The sanitizing solution concentration level for food contact surfaces on the food contact surfaces are directly applied to RTE produce. For example, (b) (4) and the knives are directly removed from the (b) (4) sanitizer solution. The knives are immediately used to chop RTE produce. The manufacturer

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label for (b) (4) states, “place sanitized utensils on a rack or drain board to air dry.”

Equipment is constantly wet due to the wet processing environment and cold temperatures. This is by evidenced during production on 11/4/2024, a (b) (4) used in production was removed from a (b) (4) sanitizing solution that measured over 200ppm (range should be 50-200ppm for food contact surfaces in (b) (4) Since the (b) (4) was not air dried, the (b) (4) sanitizing solution that measured over 200ppm could be transferred to the RTE lettuce when it came into contact with the (b) (4) (b) (4)

The (b) (4) sanitizer is (b) (4) on surfaces and not air dried. On 11/4/2024, the (b) (4) slicers (food contact surface for RTE produce) were observed to be sprayed with (b) (4) and not air dried while these (b) (4) were observed to be connected and disconnected to the chopper machine for the peppers. An employee with gloved hands was observed to be touching other food contact surfaces after touching various insanitary surfaces, such as the hose on the floor. In response to the employee touching insanitary surfaces and touching food contact surfaces for the chopper, the firm had an employee spray (b) (4) sanitizer directly onto the (b) (4) slicer and other food contact surfaces that was used within minutes of being sprayed with this sanitizer.

Production employees mix (b) (4) to create a mixture to use on food contact surfaces when (b) (4) fail. According to management, production employees use this mixture as their “reclean step” to scrub on the food contact surfaces prior to retesting the surface with (b) (4) The production employee performing the reclean on 11/5/2024 stated he mixes the (b) (4) together routinely. The firm could not find the source of this recipe used for mixing (b) (4) during the inspection. Management could not provide a manufacturer label and/or manufacturers/chemical

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representatives stating that mixing these chemicals listed above was designed for this use.

***DATES OF INSPECTION**

10/28/2024(Mon), 10/29/2024(Tue), 10/30/2024(Wed), 10/31/2024(Thu), 11/04/2024(Mon),
11/05/2024(Tue), 11/07/2024(Thu), 11/12/2024(Tue)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."