

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER USFDA Chicago District Office 550 W. Jackson Blvd. Suite 1500 Chicago, IL 60661 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 10/07-10/2014, 10/14/2014, 10/23/2014, 10/31/2014
	FEI NUMBER 3009495734

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Julia Y. Trinh, Owner, President, and Manager

FIRM NAME Wholesome Soy Products Inc.	STREET ADDRESS 1150 W. 40th Street
CITY, STATE AND ZIP CODE Chicago, IL 60609	TYPE OF ESTABLISHMENT INSPECTED Sprout Grower, Tofu Manufacturer, Dealer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

SPROUT GROWING OPERATION

OBSERVATION 1

Listeria monocytogenes was detected in the raw ready-to-eat sprout processing environment and in the peripheral warehouse area.

- a. 3 subs out of 110 environmental swabs collected from your sprout production area on 10/08/2014 tested positive for Listeria monocytogenes.
- b. 6 subs out of 134 environmental swabs collected from your warehouse and cooler floors on 10/07/2014 tested positive for Listeria monocytogenes.

This is a repeat observation from the previous inspection which closed on 09/03/2014 where environmental sample 844817 tested positive for Listeria monocytogenes

OBSERVATION 2

Employee practices allow for potential contamination of food contact surfaces and food products.

- a. Employees exited the sprout production area while wearing their rubber boots and aprons. These employees returned to the sprout production area and were handling food and food contact equipment, such as, sprouts and packaging materials without changing, cleaning, or sanitizing their equipment, over the course of several days.
- b. Throughout this inspection employees used the potable water hose in the production area to rinse off their boots, aprons, plastic bins, and CIP sprout equipment. The potable water from the hose created a spray, when bouncing off of the objects it was directed at, during the course of production.

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c. Your delivery van drove into the section of the warehouse located directly next to the sprout processing area to load finished sprout products. On 10/08/2014, the delivery van backed into the warehouse next to the sprout processing area and was parked approximately 5' from the open doors to the southern entrance of the sprout processing area to allow for bags of finished product sprouts to be loaded. Environmental swabs collected from the area of the warehouse the van drives through tested positive for *Listeria monocytogenes*.

d. Firm employees used a forklift to transfer sprout waste to the dumpster. The forklift drove right up to the sprout production area to load the pallet with bags of sprout waste onto the forks. The forklift then drove through the alley to the dumpster area. This employee also enters and works in the sprout production area.

e. White and yellow plastic bins in the sprout processing area were used to hold ice used in the production of sprouts, hold plastic bags of sprout waste, pretreat the beans, and hold sanitation equipment. The bins do not have any identifying labels or markings to designate a specific use, with the exception of one yellow bin labeled "USDA CONDEMNED USDA CENSURADO" in black writing. On 10/09/2014, the labeled yellow bin was holding ice to be added to the bags of finished product sprouts. The bins are rinsed out and stored upside down on the floor of the sprout processing area when not in use. The bins are not identified to show clean or dirty status. *Listeria monocytogenes* positive samples were isolated from the floor of the sprout production area.

f. A shovel made of plastic and wood is used as food contact equipment in the sprout production area. There are two shovels in the same sprout production area; one shovel to shovel waste sprouts into the corner and the other shovel is used to shovel sprouts into the sprout rinse machine. These shovels do not have any identifying marks to distinguish which shovel is used for which operation. During production, the shovels were observed stored on the floor, hanging on the wall, and inside of a plastic bin.

g. The southern doors to the sprout production area are propped open during processing. The area located outside of the opened doors is used for sprout storage and as a loading area.

h. A barehanded sprout packaging employee will stand in the warehouse area and reach into the sprout processing area, add ice to the plastic bags of sprouts using a scoop, seal the plastic bags by tying a knot, and transfer the bags of finished product to the wooden pallets in the warehouse area. The bags of sprouts are packaged while they are directly on the wet sprout production area floor. This employee will also assist in loading the delivery van or

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customer vehicles in the warehouse or outside of the facility. The employee was never observed washing their hands between packaging and loading sprout products.

i. On 10/08/2014, blue plastic finished sprout product bags in corrugated cardboard boxes were stacked on overturned plastic yellow bins in the sprout packaging area. The top two bags had droplets on the interior of the bags.

On 10/9/2014, two yellow waste bins in the upright position were being used to hold corrugated cardboard boxes containing blue plastic bags for finished sprout products. The open ends of the blue plastic bags were in contact with the lip of one of the yellow waste bins. These bags were used to package finished product sprouts.

This is a repeat observation from the previous inspection which closed on 09/03/2014

OBSERVATION 3

Equipment and utensils not properly maintained.

a. Metal components used to transfer sprouts through the (b) (4) are missing. There are empty holes where the metal spikes were once attached. No metal detection is utilized in your production operations.

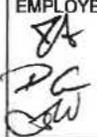
b. New irrigation hoses installed in both sprout growing rooms show wear from rubbing on the tops of the stainless steel sprout bins approximately every (b) (4) during watering cycles. The plastic is beginning to scrape off of the hose.

c. Wooden pallets on the floor of the warehouse are used to hold ready to eat finished product sprouts packaged in blue plastic bags. The wooden pallets are jagged and splintered.

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OBSERVATION 4

Cleaning practices are not adequate.

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a. On 10/07/2014, the door to the northern entrance of the sprout production area was propped open with a wooden 2X4. An employee was using a water hose to spray the warehouse floor, including the area directly outside the entrance to the sprout production area while the door was open. Water splashed from the floor of the warehouse into the sprout processing area.

b. The walls in the sprout growing rooms have an apparent mold-like growth present.

This is a repeat observation from the previous inspection which closed on 09/03/2014

OBSERVATION 5

Sprout production environment not properly maintained.

The floor in the sprout production area has cracks present.

OBSERVATION 6

Lack of effective pest control procedures.

Flying insects were present routinely throughout the inspection in the sprout production area. The southern set of doors between the sprout production area and the warehouse area are routinely left open during production.

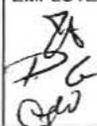
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TOFU MANUFACTURING OPERATIONS

OBSERVATION 7

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

a. On 10/07/2014, an employee in the tofu production area picked up the pistol-grip valve on a hose (water) that had fallen onto the ground and placed it directly onto the steam kettle. Neither the employees hands nor the valve

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of the hose were cleaned.

Later, the same employee was using the same hose to rinse out the basin collecting product coming out of the mill. The water from the hose was used as an ingredient in the tofu products and to rinse equipment and flooring in the tofu production area.

b. On 10/07/2014, the employee removing the tofu from the (b) (4) for final packaging repeatedly submerged their arm and a portion of their tee-shirt in the cooling water.

c. The (b) (4) of water used to hold and cool tofu products prior to packaging was uncovered while employees were spraying a (b) (4) onto the wall and equipment located approximately 3' away from the uncovered vat.

OBSERVATION 8

The plant is not constructed in such a manner as to allow floors and walls to be adequately cleaned and kept clean and kept in good repair.

Specifically,

a. The floor in the tofu manufacturing area is cracked and multiple sections of exposed concrete are present.

b. The table in the southwest corner of the tofu production area is not easily moved to allow for cleaning and sanitizing. All of the tofu press equipment is mounted and stored on or around the table. No spacing is present between the table and the wall.

This is a repeat observation from the previous inspection which closed on 09/03/2014

OBSERVATION 9

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility after each absence from the work station and at any time their hands may have become soiled or contaminated.

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Specifically,

a. Employees wearing gloves in the tofu manufacturing area would handle non-food contact surfaces (valves, hose, cart handles, plastic bins, and door handles) and then come into direct contact with food products or food contact surfaces without changing gloves. On 10/07/2014, a gloved employee with exposed arms was handling tofu containers and reaching into tofu cooling water past their elbow in the cooling tofu vat to collect the tofu.

This is a repeat observation from the previous inspection which closed on 09/03/2014

OBSERVATION 10

Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests.

Specifically,

On 10/07/2014 and 10/10/2014, flying insects were present on tofu containers and tofu production equipment in use at the time in the tofu production area. Insects were observed directly on food contact and non-food contact surfaces.

This is a repeat observation from the previous inspection which closed on 09/03/2014

OBSERVATION 11

Failure to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing.

Specifically,

a. On 10/07/2014, the cloths used to (b) (4) step were rinsed with hot water in a plastic bin prior to being used to (b) (4) The firm will sanitize these cloths inside of the steam kettle after tofu production has been completed for the day.

b. An employee used a wooden handled knife to cut pressed tofu into bricks. While the knife was not being used it was stored in a channel collecting fluid expelled from the tofu during the pressing process.

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- c. The food contact surfaces of the mill used in tofu production have chipped paint and rust present.
- d. Food residue is present on food contact equipment used in tofu production. The (b) (4) the bowl that holds the soybean slurry prior to being transferred to the the steam kettle, and the (b) (4) used to press the firm tofu have residual food residue present on the surface.

This is a repeat observation from the previous inspection which closed on 09/03/2014

OBSERVATION 12

Instruments used for measuring conditions that control or prevent the growth of undesirable microorganisms are not adequately maintained.

Specifically,

- a. The thermometer used to measure the temperature of the water in the (b) (4) has not been calibrated by the firm. A product user manual or factory calibration record was not available for review.
- b. The thermocouple and pressure gauge used in the production of tofu products have not been calibrated by the firm. A product user manual or factory calibration record was not available for review.

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