

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

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22201 23rd Drive SE Bothell, WA 98021-4421 (425) 486-8788 Fax: (425) 483-4996 Industry Information: www.fda.gov/oc/industry	11/17/2009 - 11/20/2009
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	FEI NUMBER
TO: Mr. Paul Newell, Plant Manager	3010692

FIRM NAME	STREET ADDRESS
Willamette Shelling Inc	14975 NE Tangen Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Newberg, OR 97132-6856	Hazelnut Processor

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

Effective measures are not being taken to exclude pests from the processing areas.

Specifically,

1. On November 18, 2009, we observed apparent rodent excreta pellets (REPs), apparent nesting areas, and apparent gnawed hazelnuts in the following locations of the Dry Storage Warehouse south of the processing facility:

- a) At the southwest corner of the warehouse, in each of three stacks of old broken down large cardboards that were inspected, we saw at least 500 REPS within layers of cardboards, two to three piles of cardboard shavings that appeared to be nesting sites, and pieces of hazelnuts and skins.
- b) On the second row of pallets from the south wall, in three out of three pallets of old broken down large cardboards that were inspected, we observed at least 200 REPs within layers of cardboards and in-between pallets, two piles of cardboard shavings, and pieces of hazelnuts and skins. From one of these pallets, we observed apparent urine stains that fluoresced under the UV light.
- c) At the south end of the warehouse, we observed at least 100 REPS in between stacks of wooden racks of old broken down large cardboards.
- d) At the middle west wall of the warehouse, we saw at least 50 REPs in between stacks of wooden racks of broken down large cardboards dated 2007.
- e) On the third row of pallets from the north wall of the warehouse, we observed at least 20 REPs in between stacks of wooden racks of broken down large cardboards dated 2008.
- f) At the middle west wall of the warehouse, we observed three out of 15 hazelnut kernels that appeared gnawed on the floor under one pallet of partial boxes of hazelnuts.

2. The left bottom end of the screen covering the slotted window south of the In-Shell Warehouse was bent leaving an opening measuring 6 inches by 6 inches. Also, the holes of the screen on this slotted window measures approximately one inch wide.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jinke M. Vila Binayug, Investigator Graham N. Giesen, Investigator Jeffrey J. Leclair, Investigator	11/20/2009

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

DISTRICT ADDRESS AND PHONE NUMBER

22201 23rd Drive SE
Bothell, WA 98021-4421
(425) 486-8788 Fax: (425) 483-4996
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

11/17/2009 - 11/20/2009

FEI NUMBER

3010692

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Paul Newell, Plant Manager

FIRM NAME

Willamette Shelling Inc

STREET ADDRESS

14975 NE Tangen Rd

CITY, STATE, ZIP CODE, COUNTRY

Newberg, OR 97132-6856

TYPE ESTABLISHMENT INSPECTED

Hazelnut Processor

3. There is no physical barrier between the Dry Storage Warehouse, Finished Kernel Warehouse and the In-Shell Warehouse. There were at least five uncovered metal totes containing hazelnut kernels in the Finished Kernel Warehouse immediately next to the Dry Storage Warehouse. Additionally, there were 22 uncovered metal totes containing hazelnut kernels in the In-Shell Warehouse.

OBSERVATION 2

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

Specifically,

1. On November 17, 2009, after taking a lunch break at 12:30pm, 9 out of 16 employees did not wash hands prior to dipping in the sanitizing bath and 2 out of 16 did not change gloves before returning to the processing line. Two of the nine employees were observed smoking during the break. Also on the same date at 9:00am, at least 8 employees did not wash their hands prior to dipping in the sanitizing bath and prior to sorting and handling hazelnut kernels with bare hands during their hourly 5-minute break.
2. On November 18, 2009, at least 8 out of 16 employees did not wash their hands at 8:00am and after the first 5-minute hourly break at 8:55am prior to dipping in the sanitizing bath and prior to sorting and handling hazelnut kernels with bare hands.
3. On November 17 and 18, 2009, at least 5 employees out of 16 dipped only their fingertips in the sanitizing bath prior to sorting and handling hazelnut kernels with bare hands.
4. On November 17 and 18, 2009, one employee who was sorting the hazelnut kernels rubbed her nose with hand at least twice each day. This employee did not wash and sanitize her hands after rubbing her nose and prior to sorting and handling the hazelnut kernels with bare hands.

OBSERVATION 3

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

Specifically, the plastic curtains between the In-Shell and Kernel Warehouses have residual organic matter on its surfaces. On November 18, 2009, we observed the hazelnut kernels in a metal tote come in-contact with the

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Jinke M. Vila Binayug, Investigator *JMW*
Graham N. Giesen, Investigator
Jeffrey J. Leclair, Investigator *JL*

DATE ISSUED

11/20/2009

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

DISTRICT ADDRESS AND PHONE NUMBER

22201 23rd Drive SE
Bothell, WA 98021-4421
(425) 486-8788 Fax: (425) 483-4996
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

11/17/2009 - 11/20/2009

FEI NUMBER

3010692

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Paul Newell, Plant Manager

FIRM NAME

Willamette Shelling Inc

STREET ADDRESS

14975 NE Tangen Rd

CITY, STATE, ZIP CODE, COUNTRY

Newberg, OR 97132-6856

TYPE ESTABLISHMENT INSPECTED

Hazelnut Processor

plastic curtains while it was transported into the Kernel Warehouse.

OBSERVATION 4

Failure to manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically,

1. One employee was stepping on a black plastic stool by the spout of the metal tote when taking samples for grading and while flattening out heaps of hazelnut kernels. The hazelnut kernels exit from this spout during packaging and when emptying the metal tote.
2. The underside of the metal totes had cobwebs and dirt and was stacked above uncovered metal totes of hazelnut kernels in the In-Shell Warehouse.

OBSERVATION 5

Employees failed to remove unsecured jewelry or other objects which might fall into food, equipment, and containers.

Specifically, two employees were wearing uncovered earrings while sorting and handling hazelnut kernels in the Sorting Room. One of these two employees was wearing stoned studs while the other employee was wearing dangling earrings.

OBSERVATION 6

Failure to provide safety-type lighting fixtures suspended over exposed food.

Specifically, the light shield of one of the overhead light fixtures in the Sorting Room was cracked. This light fixture is approximately two feet away from the overhead conveyor.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Jinke M. Vila Binayug, Investigator *JMV*
Graham N. Giesen, Investigator
Jeffrey J. Leclair, Investigator *JJL*

DATE ISSUED

11/20/2009

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

DISTRICT ADDRESS AND PHONE NUMBER

22201 23rd Drive SE
Bothell, WA 98021-4421
(425) 486-8788 Fax: (425) 483-4996
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

11/17/2009 - 11/20/2009

FBI NUMBER

3010692

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Paul Newell, Plant Manager

FIRM NAME

Willamette Shelling Inc

STREET ADDRESS

14975 NE Tangen Rd

CITY, STATE, ZIP CODE, COUNTRY

Newberg, OR 97132-6856

TYPE ESTABLISHMENT INSPECTED

Hazelnut Processor

OBSERVATION 7

Personal clothing and belongings were stored in an area where equipment or utensils are washed.

Specifically, an employee personal street sweater was hanging next to clean processing smocks in an open closet in the break room.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Jinkee M. Vila Binayug, Investigator
Graham N. Giesen, Investigator
Jeffrey J. Leclair, Investigator

DATE ISSUED

11/20/2009