

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

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 01/28/2010 - 02/23/2010*
	FEI NUMBER 3004252720

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: John G. Knoerr, Board Chairman**

FIRM NAME Thumb Oilseed Producers' Cooperative	STREET ADDRESS 2145 Leppek Rd
CITY, STATE, ZIP CODE, COUNTRY Ubly, MI 48475-9790	TYPE ESTABLISHMENT INSPECTED Manufacturer

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**

Food which has become contaminated to the extent of being adulterated within the meaning of the Act is not rejected or if permissible, treated or processed to eliminate the contamination..

Specifically, in the last fourteen months of production of lots of Non-GMO soy flour, your firm released finished product non-GMO soy flour found to be positive for *Salmonella* sp. on two separate occasions.

- a. On 12/22/08, you had a private laboratory analyze Non-GMO soy flour lot TF121608 for *Salmonella* sp. The lab reported this lot was positive for *Salmonella* sp. on 12/22/08. The lot was subsequently retested on 01/12/09 by the same private laboratory, and released into commerce in four different deliveries: (b) (4) 40-lb. bags on 01/13/09; (b) (4) 40-lb. bags on 02/04/09; approximately (b) (4) 40-lb. bags on 09/08/09; and (b) (4) 40-lb. bags on 03/27/09.
- b. On 10/02/09, you had a private laboratory analyze Non-GMO soy flour lot TF092409 for *Salmonella* sp. The lab reported this lot was positive for *Salmonella* sp. 10/02/09. The entire lot, a total of 4, random weight totes, was subsequently released into commerce as animal feed on 10/19/09.

**OBSERVATION 2**

Failure to manufacture, package, and store foods under conditions and controls necessary to minimize contamination.

Specifically, your firm engages in the following practices which could allow for the contamination of finished product Non-GMO soy flour, Non-GMO soy grits, Organic soy flour, Organic soy grits, and feed:

- a. Raw, direct from field, soybeans are processed through the extruders and the entire subsequent system for approximately (b) (4) minutes ((b) (4) lbs. of product) prior to the extruders reaching your firm's target temperature of (b) (4) F. This allows for potentially under heat treated soybeans which may contaminate the entire system including the (b) (4) (cook step), (b) (4) and all (b) (4) systems in between, until the product is diverted for use as animal feed. Once the extruder reaches the intended temperature of (b) (4) F, you continue to process soybeans into soy grits and soy flour, in both Non-GMO and Organic varieties without first cleaning or sanitizing. On February 2, 2010 an environmental sample taken by FDA at the (b) (4) 3 inches above the mouth of the (b) (4)

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**(b) (4)** tested positive for *Salmonella* sp.

b. Bulk transfer totes **(b) (4)** are used to hold and transport **(b) (4)** finished product up to 15 times before being discarded. These totes are dedicated to either Non-GMO or Organic products. Between uses, totes are stored in **(b) (4)** **(b) (4)** corrugated cardboard boxes. Two boxes were stored within six feet of the overhead door through which these same totes filled with product are transferred from the Crushing Plant to the Flour Plant. For example, a tote used for storage of Lot # TF012210 Non-GMO soybean flour (product code 285100-NFB) was previously used to store a total of 15 production dates that were observed to be written on the exterior of the mesh tote including the following: 12-4-08, 3-26-09, 4-9-09, 4-23-09, 5-28-09, 6-4-09, 7-6-09, 7-21-09, 7-23-09, 8-25-09, 8-27-09, and 9-10-09 (3 dates were illegible).

**OBSERVATION 3**

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food-contact surfaces.

Specifically, you do not utilize any sanitizer on food contact surfaces in your facility and the following cleaning procedures were observed during the inspection:

- On 02/01/10 your employee was observed to clean the expellers by gathering raw soybeans from the roller mill **(b) (4)** **(b) (4)**, transferring by a **(b) (4)** gallon bucket and flushing the expellers with the raw soybeans.
- On 02/05/10, your employee was observed to clean the **(b) (4)** Pulverizer and other equipment by banging the exterior with a rubber mallet to loosen debris that may be stuck inside. The **(b) (4)** is then flushed with finished product and all equipment is blown with compressed air to remove debris.

**OBSERVATION 4**

Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.

Specifically, an accumulation of adhering powdered substance was observed on equipment and floors throughout the inspection.

For example:  
On 02/02/10 the following was observed inside the crushing plant 11 days after the last production of 01/22/10.

- Not less than 1/16 inch of yellow powdered residue was observed adhering to the outer surface of the soy grit filler chute that is suspended directly above exposed heat treated soy grit product during the filling process into the reused bulk plastic

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mesh totes.

b. Not less than 1/16 inch of yellow powdered residue was observed on the top, outer surface of the hammer mill east of the raised staircase. This is the access point for the hammer mill screen and is immediately adjacent to the food contact surface of heat treated product.

c. Not less than 1/8 inch of yellow powdered residue was observed along approximately 6 feet on the outer surface of the auger used to reroute improperly sized grits back to the hammer mill. This residue was observed immediately adjacent to a gap not less than 1/4 by 3 inches in the closed system that exposed heat treated soy grits to the environment.

d. Not less than 48 ounces of accumulated yellow powdered residue was observed on two areas along the base of the hammer mill near the south production room staircase. In both locations an accumulation of product was at least 2 inches high and was located within 6 feet from the hammer mill screen access point.

e. Not less than 1/16 inch of yellow powdered residue was observed on the outer surface of the lid cover and the area immediately bordering the cover of the closed transport system above the feed line.

On 01/29/10, the following was observed during the packaging of approximately (b) (4) lbs. of low-fat soy flour with lot code TF012210 in the flour plant:

f. A gap at least 10 feet long x 1/4 inch wide x 2 inches deep located between two adjoining cement floor slabs of the packaging room floor was observed packed with a yellow powdered residue and was located within 7 feet from the filler where finished product soy flour and soy grits are packaged into 40 lb. bags. This same powdered residue was observed again on 02/01/10.

g. The area above the wheel base on the forklift, used to transfer bulk totes of finished product heat treated soy flour, was observed to have approximately 1/8 inch accumulated yellow powdered residue on its outer surface and was located not less than 2 feet from the exterior surface of the bulk tote and within 6 feet from the bulk tote opening. This same powdered residue was observed again on 02/01/10.

h. A metal tote platform was observed to have approximately 1/16 inch of adhering yellow powdered residue and was immediately adjacent to a reusable white tote labeled as feed grade with lot number TF011110. This residue was also located within 15 feet from the filler on the packaging line during production.

**OBSERVATION 5**

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

Specifically, on 01/28/10, a white-colored substance, appearing to be bird feces was observed on the exterior surface of the soybean cleaner that is used to separate debris from raw soybeans. One live bird was observed to be flying in the Cleaner

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Lisa J. Renick, Investigator  
Margaret N. Persich, Investigator  
Michele L. Forster, Investigator *MZF*  
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Room and not less than an additional 15 birds were observed to be in the adjacent waste storage room where discarded soy hulls are stored. These two rooms are connected by two access points, one is an approximate 1 square foot, square hole, the other is a 6 inch by two feet rectangular hole.

**\* DATES OF INSPECTION:**

01/28/2010(Thu), 01/29/2010(Fri), 02/01/2010(Mon), 02/02/2010(Tue), 02/05/2010(Fri), 02/08/2010(Mon), 02/12/2010(Fri), 02/17/2010(Wed), 02/23/2010(Tue)

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