



Situation Report - Submission Form

FDA Incident Management Group

Incident:	Salmonella tennessee\2010\Hydrolyzed Vegetable Protein (HVP)		
Organization:	SAN-DO	Date/Time:	02/21/10 16:25 PST

Submitter Information

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Inspection Summary (please include total number of personnel assigned to this incident)

On Friday, 2/12/10 SAN-DO initiated an inspection of Basic Food Flavors Inc., located at 3900 E. Craig Road, North Las Vegas, NV 89030 (FEI: 1000124040) in response to RFRs 1012025/1011997 (Nestle) that reported preliminary findings of *Salmonella Tennessee* in a raw food material, Hydrolyzed Vegetable Protein, manufactured by Basic Food Flavors.

According to the management of Basic Food Flavors Inc., this was the first time their finished product tested positive for any pathogen. This firm is a manufacturer of hydrolyzed vegetable protein (HVP), processed mainly as a dry powdered product. The firm also manufactures soy sauce and HVP paste. HVP is a flavor enhancer used in a wide variety of processed food products. The firm distributes HVP to other food manufacturers that include Nestle USA, Lipton's, Campbell Soup Co., and national restaurant chains. Additionally, the firm also has international distribution of its products. SAN-DO will obtain complete product lists and distribution patterns during the inspection.

The total batch size of the affected HVP product is 10,175 pounds, Lot # 909482, packaged in 185/55 lb. lined cardboard boxes. This product was manufactured on September 17, 2009. This is the only lot of this particular product made in the past year. However, the firm manufactures other similar dry products on the same production line. Nearly the entire lot was shipped to Nestle USA, Cleveland, OH except for 1 pallet of 2,256 pounds (41 boxes). The pallet is currently quarantined on the firm's premises. The firm sampled the remaining lot on Monday 2/8/10 for Salmonella analysis. The firm's process flow chart and HACCP plan related to the manufacture of HVP were obtained from the firm, and are also posted on the firm's website at www.basicfoodflavors.com

In January 2010, Basic Food Flavors conducted comprehensive environmental testing in their facility and one location tested positive for salmonella (no further information on the type). On January 13, 2010 60 comprehensive environmental samples collected in all 3 of the firm's processing areas resulted in 5 positive results.

On January 26, 2010, the firm collected 20 environmental samples focusing on the areas that yielded positive results and these resulted in another 5 positives. The location that yielded the positive results is in the same building as the finished product packaging operation, but in an adjacent room. All of the positive results were from near or on the floor. Following the positive results, the firm initiated very limited corrective actions that included cleaning the area and limiting foot traffic from that area to other production areas. Additionally, the firm has contracted to install a new floor in that area within a month.

According to the EON database, Nestle reports they have found a *Salmonella Tennessee* positive raw material, HVP made by Basic Food Flavors. The audit conducted by Nestle indicates that they have not found Salmonella in the factory environment but have found the presence of *Salmonella Tennessee* in a composite sample of four intact drums of one lot of HVP supplied by Basic Foods that was used in both positive lots of finished product that Nestle detected.

The environmental samples collected by Basic Food Flavors on 01/13/2010, 01/26/2010 and 02/08/2010 were analyzed by Silliker, Inc., Northern California Laboratory, 5262 Pirrone Court, Salida, CA 95368, phone number (209) 549-7508. SAN-DO will attempt to send a CSO to Silliker Inc. to collect the isolates and to obtain the complete analytical packages. SAN-DO will coordinate with DFS on the proper lab to where the isolates need to be sent.

SAN-DO now has confirmed that Basic Food Flavors supplies Tillamook Smoker and not Tillamook Creamery with HVP, as previously reported. Basic Food Flavors last shipped HVP to Tillamook in May 2009. The product shipped is identified as HVP M 308 which is a hydrolyzed corn protein

Basic Food Flavors does not speciate Salmonella findings out of their samples, however Nestle reports *Salmonella Tennessee*. The current environmental finding of Salmonella from Basic Food Flavors has not been reported through the RFR process by this firm.

On 2/14/10 a team of four SAN-DO investigators conducted a walkthrough of the firm's entire production (excluding liquid product), followed by the collection of 52 environmental swabs under FDA Sample #INV 584434. Sample #INV 584434 has currently been delivered to the SAN-LAB via hand delivery by one of the team investigators.

The swabs were collected in the drying, grinding, mixing, and blending production areas of the firm. The firm was not in production and the swabs were primarily collected from direct food contact surfaces such as the belt dryer, from within dismantled pipe connection points and mixers that would not normally be accessible while the firm is processing. The firm also collected swabs from some but not all areas sampled by FDA investigators.

During the environmental swabbing operations, FDA investigators noted some GMP issues such as standing water, drains that were not flowing properly and foul odors that appeared to be associated with the drains.

Thus far, the firm has been very cooperative. They have expressed no objection to FDA photography. They have taken concurrent photographs of some but not all areas photographed by FDA investigators.

An additional investigator, a GS-13, Food Specialist, arrived in Las Vegas on the evening of 2/14/10 and joined the inspection team on 2/15/10.

On 2/15/10, the 5 SAN-DO CSOs continued the inspection at the firm, in an inspection team approach. The team followed up with the firm regarding their air circulation system and the possibility of obtaining portions of the system's air filters for microbial analysis. Additionally, the team continues to explore any possible connections between Basic Food Flavor, Inc. and products sent to Tillamook Creamery. The team continued environmental sampling at the facility, with 30 sub samples consisting sample number INV 584435 collected today. The samples were collected from non food contact areas (zone 2). The samples were collected mostly in the dry product grinder and mixer area. Air filters and packaging tables were also swabbed today. Sample was delivered via FEDEX overnight delivery.

The inspection also covered CGMP areas such as sanitation of the enclosed process, building design problems and air intake. Firm's cleaning in place (CIP) procedure was evaluated by the investigators, which reveal concerns on its adequacy. The team also covered HACCP plans implemented by the firm, which allegedly incorporate a critical control point at the steaming stage. Also, the inspection revealed that the firm does not validate their process and does not conduct end product sampling for most of their products. End product sampling is only performed upon customer request.

The team obtained a list of customers and distribution of products to several states and international locations. Further, the team obtained shipping documents for shipments of HVP to Tillamook Creamery in Oregon.

On Tuesday, 2/16/10, a team of four SAN-DO investigators continued on with their inspection of the facility. The firm was in production on this day processing product code B-83 Hydrolyzed Soy Protein Hydrogenated Soy Oil packaged into 55 lb. cardboard boxes. Also, at the spray drier mixer, product code M192, a soy protein product, was being packaged into a 2,000 lb tote.

A total of 32 environmental swabs of primarily non-food contact surfaces were collected under Sample #INV 584436. Surfaces swabbed included: a squeegee blade/handle/rack used in the production area; plastic strip curtains in the direction facing the grinder/mixer room; a forklift (wheels, steering wheel, gear shifter) that is used in the receiving, production and finished product areas; a weigh scale scoop, a floor scrubber (including wheels, brush and scraper), mixer switch and the handle on a mixer cover. Sample #INV 584436 was sent overnight to SAN-LAB via FED-EX.

Discussion with the firm concerning their customer distribution list found that only 4 of their customers require any microbiological analysis of finished product: Truest Fill Inc., Flavor Consultants, Nissin, and Ingredients Corporation. Additional information is still being gathered.

Investigators identified problems associated with the firm's SSOPs. Specifically, employees provided conflicting information concerning the frequency of cleaning and the firm does no verification of cleaning records. Records seem to indicate that that cleaning occurs on a weekly, not daily basis. Up until 2/12/10 the firm was wet cleaning in the grinding, mixing, and blending areas. As of 2/12/10 the firm was advised by Silliker to discontinue this practice.

The firm is no longer on a 24-7 schedule. They currently operate Monday – Friday and hours are dependant on customer orders. The firm reports that their quality assurance manager starts work at 6:00 am, Monday – Friday. The production records for Lot 909482 of HVP indicates that production started at 11:30 pm on 9/16/09, and was completed on 09/17/2009.

Currently, the firm is continuing manufacturing operations, however, they agreed on voluntarily stopping distribution temporarily. They advised that the Hydrolyzed Soy Protein Hydrogenated Soy Oil currently in production will be analyzed prior to distribution. At this point, the firm had not received any final results on the 40 environmental swabs collected in their facility on 2/8/10, though they confirmed that they had received presumptive positives. The firm declined to disclose how many of the swabs were found with presumptive positive results. The firm agreed to provide authorization to obtain isolates for positives samples analyzed by Silliker Labs.

On 2/17/10, the team did not to go to the firm. The team met with two supervisors in the field location to review collected information and documents and prepare for an ORA/Center/OE/EMPOS/SAN-DO/CIN-DO call on the progress of the investigations in both Districts. The team then held a subsequent evening meeting to discuss the next steps for 2/18/10. The team planned to collect finished product samples of the product remaining at the firm, which is from the same lot as the product sent to Nestlé-- 909482.

On 2/18/10, the team (5 investigators) returned to the firm to continue their inspection. The investigators learned that the firm has received the results on 40 environmental swabs they collected on 2/8/10. According to the firm, the analyzing lab, Silliker, Inc., found 12 positives for salmonella of different types. The location of the 12 positives from the 2/8/10 firm environmental swabs, as well as the positives from their 1/13/10 and 1/26/10 environmental swabs are in the same drain area in the finished paste product packaging room. In addition, the 2/8/10 environmental swab positives included the floor area adjacent to a caramel color tank. The firm agreed to release the isolates of the 2/18/10 positive environmental swabs to FDA.

SAN-LAB results on Sample #584434, reported on 2/17/10, revealed that subs 6, 15 and 16 are “CRO” or “Cannot Rule Out” for Salmonella. Additionally, SAN-LAB results on Sample #584435 reported on 2/18/10, found that sub 59 is also CRO for Salmonella. The CRO areas were swabs of the drain in the finished paste product packaging room and a large paste mixer in this same area.

Four samples were collected, including 2 samples of the HVP, Lot #909482, that the firm manufactured on 09/17/09; process water (municipal source) from a faucet near the paste mixer; and environmental swabs from the drain area in the finished paste product packaging room.

Sample #555168 consisting of 30/4 oz subs of the HVP was collected under for Salmonella analysis. Additionally, Sample #555169 of the HVP consisting of 2/4 oz sub of the HVP was collected for water activity analysis. Sample #INV 576311 consisting of 2/100 ml subs of the firm’s process water was collected for micro analysis.

Another set of environmental swabs, sample # 584437 consisting of 32 environmental swabs (sub-sample numbers 115-146) were also collected. The areas swabbed included the drain area of the finished paste product packaging room and expanded out further from the drain area to a large paste mixer and the paste mixer pump which was leaking product, and a spout and

spout handles used for packing paste from this mixer. Also, areas around the caramel color tank, tank spout and spout handle were sampled. In addition, as a result of their observations of the firm's processes, investigators swabbed mixing barrels and a forklift used to convey raw ingredients to the paste mixer.

All samples were sent via FedEx overnight delivery to SAN-LAB.

During the environmental swabbing, investigators noted that although the odor in the drain area was especially foul on this day, the firm employees appeared to be acclimated to it. Investigators also noted that some of the firm's plumbing systems appear to be leaking. More coverage on this aspect is expected early next week.

On 2/19/10, part of the team returned to the firm and continue working on obtaining documentation related to distribution and interstate commerce.

Based on firm's environmental samples described above, SAN-DO management decided to call firm's most responsible individuals to know what they are going to do regarding the Salmonella situation in their plant.

At 9:30 AM (PST), SAN-DO held an initial call with the firm and conveyed concerns revealed during the inspection. The firm required some time to have internal discussions. DIB Solorzano agreed and it was decided to have a subsequent meeting with the firm later.

At 11:30 AM (PST), SAN-DO held a second conference call with the firm. On this conference call was present staff from CFSAN, OE, and DFI. SAN-DO proceed to summarize concerns one more time, and ask firm's officials for their action plan. The firm agreed to the following: Stop manufacturing operations, hire consultants on recall issues and Salmonella contamination, stop shipping of their products until the situation is resolve, holding their products, issue a notification to their customers about the Salmonella situation in their plant. According to firm's officials this actions cover products manufactured in the paste and dry goods line since September 17, 2009.

SAN-DO received firm's draft customer communication for review.

At approximately 3:25 PM (PST), SAN-DO contacted the firm regarding their notification letter draft, as well as to inform the firm of positive results found in FDA's sample INV584434. Part of that determination would involve receiving reports from FDA regarding FDA's collected samples, as well as waiting for results of samples of finished product (lot 909482, a portion of which was shipped to Nestlé) from Silliker. These results are expected by Monday. The firm stated that they only received verbally results from Nestlé.

Currently, the firm feels that the matter is an isolated incident. SAN-DO provided initial feedback and comments regarding the firm's draft notification letter. The firm requested that SAN-DO provide a verbal description of the locations of the positive sample results' locations where swabbed to the firm. The firm stated that they had sampled in the same areas as FDA did and got negative results. During the call, the firm stated that after seeking advice from legal counsel, they had decided to not release any notification to customers until they have determined that this issue is not an isolated incident.

On 02/20/10, SAN-DO contacted the firm to provide the sample positive swabs' location description to the firm. Inspection will continue at the firm on Monday. SAN DIB and two SCSOs provided verbal confirmation of sample results to the firm as well as swab location descriptions. The firm was notified that three subsamples collected from 02/14/2010 were from food contact areas. One of the SCSOs asked the firm QA manager to confirm if this area had been cleaned and sanitized prior to sampling, and if it was ready for manufacturing. The firm confirmed that the area was indeed cleaned and sanitized. The firm QA manager stated that he would communicate the findings to the firm's owners as he did not have the authority to make a final decision on issuing the firm's notification letter.

Sample Collection

Include type of sample (product, environmental, in-process, intact or open containers), where the sample was collected at the firm, sample number, product name, number of subs and servicing laboratory.

FDA Sample #INV 584434, collected on 2/14/10, and consisting of 52 environmental swabs, was delivered that night to the SAN-LAB sample custodian via hand delivery by one of the team investigators. Preliminary sample results are expected by 02/18/2010.

On 2/15/10 team collected 30 sub samples out of sample number INV 584435. The samples were collected from non food contact areas (zone 2). The samples were collected mostly in the dry product grinder and mixer area. Air filters and packaging tables were also swabbed today. Sample was delivered via FEDEX overnight.

On Tuesday, 2/16/10 the team collected Sample #INV 584436, consisting of 32 environmental swabs of primarily non-food contact surfaces while the firm was in production. Surfaces swabbed included a squeegee blade/handle/rack used in the production area, plastic strip curtains in the direction facing the grinder/mixer room, a forklift (wheels, steering wheel, gear shifter) that is used in the receiving, production and finished product areas, a weigh scale scoop, a floor scrubber (including wheels, brush and scraper), mixer switch and the handle on a mixer cover. The sample was sent overnight to SAN-LAB.

On Thursday, 2/18/10 four samples were collected that included 2 samples of the HVP, Lot #909482, that the firm manufactured on 12/17/09, under Sample #555168 and Sample #555169, respectively, for Salmonella analysis and water activity analysis; process water (municipal source) from a facet near the paste mixer was collected under Sample Sample #INV 576311 for micro analysis; and environmental swabs were collected under Sample # 584437 for Salmonella analysis. All samples were sent overnight to SAN-LAB.

Sample #555168 consisting of 30/4 oz subs of the HVP was collected under for Salmonella analysis. Additionally, Sample #555169 of the HVP consisting of 2/4 oz sub of the HVP was collected for water activity analysis. Sample #INV 576311 consisting of 2/100 ml subs of the firm's process water was collected for micro analysis.

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areas around the caramel color tank, tank spout and spout handle were sampled. In addition, as a result of their observations of the firm's processes, investigators swabbed mixing barrels and a forklift used to convey raw ingredients to the paste mixer.

All samples were sent via FedEx overnight delivery to SAN-LAB.

Laboratory Results

List results by sample number. Include information on type of sample, analysis, and findings.

FDA Sample #INV 584434, collected on 2/14/10. Three swabs (subs 6, 15 and 16) positive for Salmonella.

FDA Sample #INV 584435, collected on 02/15/10. One Swab positive so far for salmonella.

Related Import Activities

NA

Related Recall Activities

Firm initially agreed to notify customers and ask them to hold products, however, after seeking advice from legal counsel, they had decided to not release any notification to customers until they have determined that this issue is not an isolated incident. The firm wants to see copies of FDA's analysis

Related Consumer Complaints

NA

Center Update

NA

CDC Update

NA

Communication Update

NA

Legal/International/Other Update

NA