

# SNOKIST GROWERS

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June 22, 2011

VIA EMAIL AND U.S. MAIL

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**Re: Snokist Growers Joint Responses to:**

**June 2, 2011 FDA Form 483 Observations  
FEI Number 3010202**

**June 2, 2011 Form AGR 425-2142  
WSDA**

Please accept this letter and the attachments as Snokist Growers responses to the observations made by FDA and WSDA investigators during their inspection that took place between May 3 and June 2, 2011 and reflected in the FDA form 483 and WSDA form AGR 425-2142 completed by FDA and WSDA investigators on June 2, 2011. We appreciate FDA's and WSDA's efforts and take the investigators observations with the utmost seriousness. As explained below in detail, we have taken corrective actions with respect to each observation by FDA and WSDA. We have also provided, where appropriate, additional information with respect to each observation to assist the FDA and WSDA in their assessment of the observations and Snokist's corrective action.

Snokist facilities are SQF level 2 certified and the company includes food safety as its top priority. We understand from our testing of finished product that none of the product sold by Snokist Growers other than product with a knocked-down flange that was recalled in Recall F-1406-2011 is contaminated, unfit for human consumption or subject to recall. We request, following your receipt and review of this response, an informal meeting to discuss whether FDA or WSDA has any further concerns at this time about Snokist Growers.

**FDA 483 OBSERVATION 1, WSDA Item 1.1: Failure to use a proven effective method of reconditioning adulterated food.**

**Snokist Corrective Action:** On 5/26/2011 Snokist instituted a reconditioning procedure that expands on the procedure approved by the FDA in March, 2009. As part of this reconditioning procedure, Snokist

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now **requires third party laboratory mycotoxin analysis** (i.e. patulin testing) for any product that exhibits mold contamination. Through this testing procedure, Snokist can evidence that the reconditioning method employed is a proven, effective method for reconditioning contaminated product. Attached are the following Exhibits 1-5 which document Snokist's new procedures:

1. Snokist Rework Procedure
2. Aseptic Spoilage Trouble Shooting Root Cause Guide
3. Rework Record for Canned and Aseptic Products
4. Thermal Process Guide for Canned Products
5. Snokist Process Guide for Aseptic System

Outside laboratory tests of our product that showed signs of spoilage determined the cause to be "post-process contamination, mold. . ." Their report further states "Upon microscopic exam hypha or multicellular filaments could easily be seen. Upon culturing on (b) (4) at <sup>(b) (4)</sup>C for approximately <sup>(b) (4)</sup> hours, morphological and microscopic observations show a mixed culture of Alternaria, Penicillium and Fusarium spp molds, typical of post-processing contamination . . ." The outside consultant report states "The molds in the spoiled samples are the same as found on the raw apples at the apple dump. . . The mold is entering the bags at the (b) (4) during the filling process due to (b) (4) " These molds are killed by a thermal process which heats the product above <sup>(b) (4)</sup>F. This is true for both raw product and reconditioned product. Our documented process for applesauce heats and holds the product above <sup>(b) (4)</sup>F for (b) (4) which kills any vegetative cells. Repairs to (b) (4) have been addressed in the corrective action to Observation 3A.

When post-processing issues become visible, it is our procedure to move any affected product to cold storage until a determination of disposition can be made. The reconditioning procedure requires each tote to be inspected. Where visual bubbling or strong fermentation odor is observed, the tote **will be destroyed**. If mold is present, third party laboratory testing for mycotoxins (patulin) must first be performed. **Any product with test results that show patulin levels above 50 ppb will be destroyed.**

Though we have instituted third party lab verification that no reconditioned product will include patulin levels that exceed 50 ppb, we believe it is important to point out that Snokist is not aware of any products previously shipped that had patulin levels above 50 ppb. Third party testing of multiple samples of product containing reconditioned product ( (b) (4) ) and a control sample with no reconditioned product all tested <10 ppb for patulin. Similarly, samples taken from the top, middle and bottom of a compromised tote all show patulin levels below 50 ppb. These lab results are attached as Exhibits 6-12.

We believe that the corrective action we have instituted demonstrates that our reconditioning procedures and subsequent thermal processes are an effective and proven method of protecting public health. This procedure has been reviewed by our outside process authority and meets the requirements of CFR Title 21 Part 820. (Exhibit 25)

**FDA 483 OBSERVATION 2, WSDA Item 9B: Failure to store finished food under conditions that would protect against chemical and microbial contamination.**

**Snokist Corrective Action:** Effective immediately Snokist has **increased the frequency of its warehouse audits from (b) (4)**. The goal of the audit is to remove any leaking container

and reduce the amount of secondary damage and insect infestation. Each audit will list a date and time of observation and provide a notation when clean-up is completed. A copy of the Warehouse Sanitation audit form is attached as Exhibit 13.

Snokist believes that this corrective action should ameliorate concerns by the FDA investigators about their observation of pallets that were in our warehouses that contained leaking containers. It is important to understand that the canning industry has generally set an action limit for container failures at greater than 1 in 10,000. Snokist's historical and current failure rate is below the industry standard.

Most of the pallets referenced in this Observation cited one leaking can. Because our products contain liquid topping media or low viscosity applesauce, secondary damage from one can usually affects other cans on the same layer or even over several layers.

It is our policy to remove any pallet with evidence of a leaking can to the salvage area when it is discovered. The affected pallet is broken down and all damaged cans are removed. Any leaking or severely rusted cans are destroyed and salvageable cans are placed on a pallet and sold to a salvage dealer. Good cans are returned to stock.

Snokist understands that FDA has sent damaged, rusty or leaking cans for laboratory analysis. Snokist expects that any damaged, severely rusted or leaking cans may be adulterated. As per Snokist policy, all severely damaged, rusty and leaking cans are destroyed.

**FDA 483 OBSERVATION 3, WSDA Item 9C: Failure to perform filling, assembling, and packaging in a manner that protects food from becoming contaminated.**

**A. Your firm's aseptic fillers do not package foods under conditions necessary to minimize the potential for growth of microorganisms.**

**Snokist Corrective Action:** Snokist has always been proactive when aseptic filler or finished product issues occur, as evidenced by the outside consultant and filler manufacturer's examinations and reports referenced in the Observation. Due to the nature of the fill process and aseptic container, it is sometimes difficult to detect issues at the time of fill. We are not certain who provided the information that only two of the six recommendations were implemented, but **all recommendations were addressed** in our effort to eliminate the source of post-process contamination that was determined by the outside sources we consulted.

1. We replaced (b) (4) and are completing all the regular maintenance and cleaning operations as recommended by the manufacturer's representative and outside consultant. The (b) (4) was also changed.
2. Doors are kept closed (b) (4) product is not being moved into the processing area in order to minimize any wind tunnel effect.
3. We have been using (b) (4) since the recommendation was made and have recently (b) (4) after (b) (4) run.
4. The quality control lab is monitoring delaminated sample bags at the end of (b) (4) days to check for any possible mold growth. An Aseptic Sample Bag Micro Record has been developed to record the findings and is attached as exhibit 14.
5. The bag manufacturer does not make a sample bag from the same material as a regular tote and so it could not be changed.

6. (b) (4) gloves were tried, but allowed too much slippage when (b) (4)  
We will try (b) (4) on the next run.

- B. Your firm does not package food in cans under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

**Snokist Corrective Action:**

- a. Double seaming operations will be monitored and maintained to have double seams meet can supplier recommended guidelines for all critical measurements. Our current procedures will be strictly followed and any cans where the minimum overlap is more than (b) (4) after the recheck will be placed on Hold for further evaluation. **A Seamer Repair log has been developed to record what corrective actions are taken for each out-of-specification finding.** It is attached as Exhibit 15. In addition, we have **written a Procedure for Out of Spec Seam checks that documents corrective action to be taken.** It is attached as Exhibit 16.
- b. Free chlorine levels are measured at (b) (4) to insure no bacteria can be pulled into a can as the product cools and a vacuum is formed. A trace of free chlorine or (b) (4) ppm at the discharge will show this. **Our charts have been corrected for both minimum and maximum levels and will include a space to record corrective actions for any out-of-specification readings.** A copy of the Cooler Temperature and Chlorine Residual chart is attached as Exhibit 17. We have also obtained confirmation from our Food Processing Industry Consultant regarding a measurable level of free chlorine at (b) (4). It is attached as Exhibit 24.
- c. Vacuums achieved on hot filled products can vary due to temperature range and headspace at the time of filling. When testing for vacuum, it is important to adjust the reading for the temperature of the product at the time of testing.

**Quality Control score sheets will show both the actual vacuum tested and the same reading corrected for temperature. Containers with temperature corrected vacuum below the established range will be placed on Hold for further quality control review. When containers are found with vacuum above the range, it will be noted on the Quality Control Deviation from Spec Log (Exhibit 19) and the supervisor notified so temperature and/or headspace can be adjusted. The supervisor must initial the notation. A copy of the Vacuum Correction chart is attached as Exhibit 18.**

- d. Headspace in applesauce will vary due to temperature and viscosity. Headspace measurements for diced pears vary due to fruit pressures (ripeness) at the time of filling.

**Quality Control grading sheets will show minimum and maximum allowable headspace measurements. USDA File code 130-A-10 that sets the maximum headspace at 10% of container volume will be used for the maximum limit. Minimum headspace will be established at (b) (4) dependent upon container size. This will allow for variable fill temperatures and fruit pressure and still provide space to form a vacuum. Products which fail these allowances will be placed on Hold for further Quality Control review. A QC Deviation from Spec log has been developed to show corrective actions and is attached as Exhibit 19. The Headspace Chart is attached as Exhibit 20.**

- e. The Snokist Thermal Processing Guide (Exhibit 4) establishes minimum lethalties based on center can temperature and finished product pH. The target fill temperature we have used for applesauce is conservative for high acid product and insures the lethality attained by our process is more than adequate to achieve commercial sterility. Utilizing the Thermal Processing Guide, the lowest fill temperature of (b) (4)°F recorded on 12/6/2010 and cited in this Observation, would produce a lethality above the minimum established because the pH of the product was 3.44.

**We have revised the Sauce Filler Log (Exhibit 21) to show the minimum fill temperature at (b) (4)°F with instructions that (b) (4) and the supervisor notified if the temperature falls below that point. If a reading below (b) (4)°F is obtained, all product from the time of the last temperature reading above (b) (4)°F will be placed on Hold for quality review. The QC Deviation from Spec Log (Exhibit 19) will be used to show corrective actions.**

- f. Cool can temperatures are recorded to establish that can temperatures are high enough when they exit the coolers to evaporate any moisture still on the can so rust does not develop at some future date. The first cans exiting the coolers at a start-up or after a period of downtime can be lower than the established limit because there has not been enough heat transfer to raise the temperature of the cooling water above ambient.

**Quality Control charts will be modified to show the correct cool can temperature range. The low cool can temperature standard has been revised to (b) (4)°F. Product below this limit for two consecutive readings will be placed on hold for further Quality Control review. The Cool Can Temperature Procedure and chart is attached as Exhibit 22.**

- g. pH measurements above (b) (4) on unsweetened applesauce generally indicate a pH meter that is not calibrated correctly. **Quality graders have been instructed to recalibrate the pH meter when they get a reading above (b) (4). Quality Control charts will be modified to show the correct acidity ranges.** If readings are above (b) (4) after recalibrating the meter, then the fill temperatures will be adjusted according to the Snokist Thermal Processing Guide (attached as Exhibit 4) to achieve the required minimal lethality for the pH of the product. **Products which fail these ranges will be placed on Hold for further quality review. The QC Deviation from Spec Log (Exhibit 19) will be used to show corrective actions.**

- h. Apple slices are (b) (4) to help soften them so we can achieve the drained weight specifications. Like peaches and pears, softened apple slices have not been shown to cause any issue with lid placement during the seaming operation.

**FDA 483 OBSERVATION 4, WSDA Item 90: Appropriate training in food handling techniques and food protection principles has not been provided to food handlers.**

**Snokist Corrective Action: Additional training of can tear down personnel will be undertaken in July, prior to the start of the new pack season. A technical representative from our can supplier will also be brought in at this time to conduct a training program for all can tear down personnel and supervisors. Training for any employee that transfers or is added to this position during the pack will also be documented. Each person will be required to pass a test after training to show their understanding of the specifications and procedures.**

The Procedure for Out of Spec Seam Checks (Exhibit 16) will be used to determine any corrective action needed and the Seamer Repair log (Exhibit 15) will be used to record all action taken to correct out of specification readings. Can seams which are out of specification after a recheck and adjustment by a seamer mechanic will be placed on Hold for further quality control evaluation.

**FDA 483 OBSERVATION 5, WSDA Item 8B:** Failure to maintain equipment, containers and utensils used to convey food in a manner that protects against contamination.

**Snokist Corrective Action:** The Snokist Check-Off Sheet for GMP's has been modified to specifically note any hydraulic leaks during routine plant inspections. The revised form is attached as Exhibit 23. **The leak that was noted was eliminated and a drip pan installed under the hydraulic line that was leaking.**

**Within the next 12 months, Snokist will begin replacing the current hydraulic fluid with a food grade fluid that meets H1 standards. Areas involving direct food contact will be the priority.**

**FDA 483 OBSERVATION 6, WSDA Item 2E and 7M:** Employees did not wash hands thoroughly in an adequate hand-washing facility before starting work and after each absence from the work station.

**Snokist Corrective Action:** We will add wash stations in areas within the apple processing facility before the start of the next processing season. Supervisors will periodically monitor to insure employees are washing their hands before they start work and after breaks and lunches and also wash their gloved hands prior to entering their work area. Hand sanitizing stations are established at each work area. Workers will continue to use hand sanitizers provided before starting work and after each absence from their work station.

**FDA 483 OBSERVATION 7, WSDA Item 5C:** Failure to properly hold toxic sanitizing agents in a manner that protects against contamination of food, food-contact surfaces and food-packaging materials.

**Snokist Corrective Action:** **This Observation was corrected immediately during the inspection.** As a part of our annual training conducted before the processing season, Supervisors and Sanitation inspection personnel will be trained to specifically look for and correct any situation where placement of objects above a food processing line could cause contamination. It is already a part of the GMP Check-off Sheet (Exhibit 23) that is completed during each shift of production.

**FDA 483 OBSERVATION 8, WSDA Item 8A:** Failure to maintain food contact surfaces to protect food from contamination by any source, including unlawful indirect food additives.

**Snokist Corrective Action:** The<sup>(b) (4)</sup>sliced apple diverters will be replaced by July 1 and maintenance supervisors and GMP Inspectors will be trained to look specifically for any item on or near a food contact surface that could contaminate food products. This item has been added to our GMP inspection form (Exhibit 23).

**FDA 483 OBSERVATION 9, WSDA Item 1:** The plant is not constructed in such a manner as to prevent condensate from contaminating food and food-contact surfaces.

**Snokist Corrective Action:** Our processes require the use of steam in most production areas and this steam can condense in areas with cooler ambient temperatures. Where condensate may form over food conveying or processing equipment, we will cover the contact area or use an appropriate means to prevent condensate from forming and contaminating food or food-contact surfaces. **For the items referenced in the Observation,**

- A. The plastic cup line will have a cover installed by July 1 to protect the cups in line to be filled.
- B. The water line has been insulated with a plastic food-grade covering.
- C. The water drain line located above the apple slice conveyor will be covered by July 1 with insulation and food-grade covering.

**FDA 483 OBSERVATION 10, WSDA Item 8B:** Plumbing constitutes a source of contamination to food, water supplies, equipment and utensils.

**Snokist Corrective Action:**

- A. The outlet of the potable water line has been moved so that it terminates above the product level in the final hold tank.
- B. The potable water line has been moved so that it is above the food level of tank (b) (4) in the applesauce production area.

**FDA 483 OBSERVATION 11, WSDA Item 6C:** Effective measures are not being taken to protect against the contamination of food on the premises by pests.

**Snokist Corrective Action:** Snokist uses an outside pest service and has requested them to increase efforts to eliminate pests and birds from the facility. **We are performing warehouse sanitation audits** (b) (4) Corrective action items will be assigned a deadline and the form must be initialed by the warehouse manager and maintenance manager indicating corrective measures that were taken. The warehouse inspection will be conducted by the SQF manager or his designate. A copy of the Warehouse Sanitation Audit form is attached as Exhibit 13.

**FDA 483 OBSERVATION 12, WSDA Item 4H:** Failure to provide adequate screening or other protection against pests.

**Snokist Corrective Action:** All gaps referenced in the Observation have been sealed. Additionally, all facility doors, windows and walls will be inspected as part of the (b) (4) Plant GMP audit (Exhibit 13) and corrective action items noted. Corrective action items must be completed and initialed by the appropriate department manager before the next audit.

The window in the women's restroom has had a screen installed.

**WSDA Item 4A:**

A) Flaking epoxy observed at the walk surface of the catwalk located above the raw apple conveyor.

**Snokist Corrective Action:** The epoxy on this walk surface has been replaced. Any flaking material that may contaminate the product has been added to the GMP Check-off Sheet (Exhibit 23) that is completed by the Sanitarian on a daily basis. Any items noted will be corrected by the maintenance department and noted as to when they are completed.

B) Floor surface at pulper machine noted with exposed aggregate and pooling liquid.

**Snokist Corrective Action:** The surface noted will be repaired as part of the off-season maintenance program.

**WSDA Item 5J:** The ladle used to collect small portions of product for testing was noted being stored in a container labeled "Hand Sanitizer Station" located near the applesauce mixing kettles for the cup line.

**Snokist Corrective Action:** This item was corrected when noted and the cup line supervisors have been instructed in proper cleaning and storage procedures.

Please let us know if you need any further information or wish to discuss further. It is in Snokist's utmost interest to address any concerns or questions that FDA might have. Snokist is committed to the highest standards of food safety and being an industry leader.

Again, we request the opportunity to meet with you informally to answer any questions you may have and to understand what, if any, additional concerns you may have.

Sincerely,

*Jim Davis*

Jim Davis  
President

Cc: (b) (4)

## Snokist Response to FDA 483 and WSDA AGR 425-2142

### List of Exhibits

Exhibit #1	Snokist Rework Procedure	(Ob. 1)
Exhibit #2	Aseptic Spoilage Trouble Shooting Root Cause Guide	(Ob. 1)
Exhibit #3	Rework Record for Canned and Aseptic Products	(Ob. 1)
Exhibit #4	Snokist Thermal Process Guide for Canned Fruit	(Ob. 1)
Exhibit #5	Snokist Aseptic Thermal Process Guide	(Ob. 1)
Exhibit #6	Patulin Results – (b) (4)	(Ob. 1)
Exhibit #7	Patulin Results – (b) (4)	(Ob. 1)
Exhibit #8	Patulin Results – (b) (4)	(Ob. 1)
Exhibit #9	Patulin Results – (b) (4)	(Ob. 1)
Exhibit #10	Patulin Results – (b) (4)	(Ob. 1)
Exhibit #11	Patulin Results – (b) (4)	(Ob. 1)
Exhibit #12	Patulin Results – (b) (4)	(Ob. 1)
Exhibit #13	Warehouse Sanitation Audit	(Ob. 2,11,12)
Exhibit #14	Aseptic Sample Bag Micro Record	(Ob. 3A4)
Exhibit #15	Seamer Repair Log	(Ob. 3Ba, 4)
Exhibit #16	Procedures for out of Specification Seam Checks	(Ob. 3Ba, 4)
Exhibit #17	Cooler Temps and Chlorine Residuals	(Ob. 3Bb)
Exhibit #18	Vacuum Correction Chart	(Ob. 3Bc)
Exhibit #19	QC Deviation From Spec Log	(Ob. 3Bd, 3Bg)
Exhibit #20	Gross Head Space	(Ob. 3Bd)
Exhibit #21	Sauce Filler Log	(Ob. 3Be)
Exhibit #22	Cool Can Temperature Procedure	(Ob. 3Bf)
Exhibit #23	Check off Sheet for GMP's and Corrective Actions	(Ob. 5,7,8,WSDA 5J)
Exhibit #24	Process Authority Letter Confirming Chlorine Level	(Ob. 3Bb)
Exhibit #25	Process Authority Review of Rework Policy	(Ob. 1)