

**FPA Supplier Audits for Food Excellence (SAFE)  
Audit Checklist #6YSLEC**

**Supplier Information**

**Facility Name:** Best Company Mills  
**Facility Location/Address:** 0007 Superior Way  
 Anywhere , 00000 France  
**Closest Major Airport:** Charles DeGaul  
**Type of Audit Performed:** Food Safety

**Is the facility required to be registered with the FDA?**  Yes  No  
**Is the facility registered with the FDA?**  Yes  No

**Parent Organization (if applicable)**

**Company Name:** Prodika Supplieix  
**Address:** testxxx  
 test  
 test, test USA  
**Company Public Web Site:**

**Plant Contact Information**

Job Title/Position	Name	Telephone	Fax	Email Address
<b>Plant Manager:</b>	Kathy Wybourn	xxx-xxx-xxxx	xxx-xxx-xxxx	kwybourn
<b>Quality Manager:</b>	Jill Gerken	xxx-xxx-xxxx	xxx-xxx-xxxx	jgerken

**Current Audit Information**

**Audit Date:** Jun 16, 2006  
**Auditor Name:** Joe Auditor  
**Length of Audit:** 4 Days (32 hours)  
**Supplier Personnel With Auditor:** Doreen Greate - Responsible for Operations, Helen Ricardo - Responsible for Quality (Quality Manager at time of audit), Berle Rapore - Responsible for Technical Issues, Sophie Bonnet - Responsible for Quality (New Quality Manager - June 2006)  
**Exit Interview With:** Doreen Greate - Responsible for Operations, Helen Ricardo - Responsible for Quality (Quality Manager at time of audit), Berle Rapore - Responsible for Technical Issues, Sophie Bonnet - Responsible for Quality (New Quality Manager - June 2006)

**Overview of site, operation, scope of Product(s) Produced**

<b>Does this facility audit their supplier either through a first/second/third party audit?</b>	YES
<b>Identify the auditing company that performs those audits:</b>	A-OK Auditing Company, Inc.
<b>Products Produced:</b>	Bugles Corn Pellets Half Product
<b>Processing Method:</b>	The corn is mixed with other raw materials and cooked, prior to grinding, sheeting and forming into pellet cones. The formed cones are dried through dryers prior to in line metal detection and bulk or bag packing.
<b>Type of Primary Packaging:</b>	The facility uses food contact tote liners and bags which are made from low density polyethylene.
<b>Sizes of Primary Packaging:</b>	The facility uses 220kg bulk totes and 22.5kg bags which are packed 12 per tote.
<b>New Product(s) Offering:</b>	N/A
<b>Channels of Trade:</b>	The facility ships nationally/internationally direct to further processors.
<b>Hours of Operation:</b>	The facility operates 5 shifts (24 hours per day / 7 days per week).

<b>Months of Operation:</b>	The facility operates 365 days per year.
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**Structure Size, Construction, and Design**

<b>Year Built:</b>	2002
<b>Year(s) Updated:</b>	N/A
<b>Size of Facility:</b>	4,000 square meters (located on same site as Seretram - total site is 70,000 square meters). Seretram is responsible for control of some operations i.e. waste management and logistics.
<b>Number of Employees:</b>	The facility has 20 employees and 3 management personnel.
<b>Property Size:</b>	The facility has 2,000 square meters for production and 2,000 square meters for warehousing.
<b>Neighboring Land Use:</b>	The facility is located in a rural area near Labatut in South West France. Seretram is located on the same site as Best Company Mills in a westerly direction; a transport company exists to the east, Seretram settlement ponds are present on land to the south and a wooded/natural area is to the north.
<b>Building Materials, Exterior Walls:</b>	The exterior walls are composed of pre-fabricated metal panels.
<b>Building Material, Interior Walls:</b>	Wall surfaces in processing have a durable coating (approved for the food industry) on metal sections sandwiched with foam. Some ceramic tiles (waist height) are located on a wall near sanitation room in the extrusion area. Pre-fabricated metal wall panels are located in the warehouse.
<b>Building Material, Floors:</b>	Epoxy resin, non slip flooring throughout processing areas with raised skirting. Reinforced concrete floor in the warehouse area.
<b>Building Material, Exterior Roof:</b>	The exterior roof is composed of pre-fabricated metal panels.
<b>Building Material, Interior Ceiling:</b>	Ceilings have a durable coating (approved for the food industry) on metal sections sandwiched with foam. Foil covered ceiling panels were noted in packing and warehouse areas.
<b>Areas of the Plant Excluded from the Audit:</b>	No areas of the facility were excluded from the audit.

**Post Audit Information**

**Dates of Previous FPA-SAFE Audits:** Jun 14, 2005

**Executive Summary - Part 1**

Auditor Judgement Summary		Auditor Judgement					
Category	Section	Fully Meets	Substantially Meets	Partially Meets	Does Not Meet	Critical Failure	Not Applicable / Auditable
1.0 MANAGEMENT RESPONSIBILITY	1.1 Management Commitment and Review	✓					
2.0 FUNDAMENTALS	2.1 Infrastructure		✓				
	2.2 Sanitation			✓			
	2.3 Pest Control	✓					
	2.4 Chemical Control	✓					
	2.5 Personnel Practices	✓					
	2.6 Training & Education	✓					
	2.7 Handling Storage & Delivery	✓					
	2.8 Vendor Approval	✓					
	2.9 Packaging Approval for Use	✓					
	2.10 Control of Materials	✓					
	2.11 Sanitary Design	✓					
	2.12 Traceability and Recall Management	✓					
	2.13 Crisis Management	✓					
	2.14 Food Defense		✓				
	2.15 Calibration Measuring and Test Equipment		✓				
	2.16 Traffic Control						✓
	2.17 Maintenance	✓					
3.0 FOOD SAFETY & HACCP SYSTEMS	3.1 HACCP/Food Safety	✓					
	3.2 Microbiological Testing	✓					
	3.3 Analytical Testing for Food Safety and/or Regulatory Compliance						✓
	3.4 Food Allergens and Chemical Sensitivities						✓
	3.5 Foreign Material Control	✓					
4.0 MANUFACTURING QUALITY SYSTEMS	4.1 Conformance to Customer Specifications	✓					
	4.2 Process Control						✓
	4.3 Inspection & Test	✓					
	4.4 Control of non conforming Materials		✓				
	4.5 Good Laboratory Practices			✓			
	4.6 Document Control and Record Keeping	✓					
	4.7 Corrective and Preventive Action	✓					
	4.8 Continuous Improvement	✓					
	4.9 Customer/Consumer Complaints		✓				
	4.10 Internal Auditing	✓					
5.0 REGULATORY CONSIDERATION	5.1 Labeling Approval	✓					
	5.2 Regulatory & Industry Compliance	✓					
	5.3 Management of the Regulatory Inspection Process	✓					

**1.0 MANAGEMENT RESPONSIBILITY****Section 1.1 Management Commitment and Review**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
1.1.1	A Quality Policy is documented and communicated to all levels of the organization	<p>The facility has a documented Quality Policy. The facility quality policy states, "The customer is our primary focus. We will strive for excellence both in food safety and quality to protect ourselves and our valued customers."</p> <p>The quality policy is authorized by the Regional Quality Vice President for Best Company Mills.</p> <p>Employees are made aware of the Quality Policy through training briefs. The Quality Policy is also displayed on a white board prior to the hand hygiene area before the entrance to the production facility.</p> <p>Two process employees were asked about the Company's Quality Policy and the content. Both employees were able to explain the key points within the policy and were able to demonstrate an appreciation of its content.</p>
1.1.2	A Quality Manual is documented	<p>There is a documented Quality Manual present at this facility. The Quality Manual is available in hard copy which is managed by the Quality Manager. Copies of policies and procedures are available to all staff through the Achiever computer system.</p> <p>The Quality Manual is well structured with top level policies and detailed procedures concerning required documentation. Primary contents of the Quality Manual include sections which are based on the facility's direction which covers top level policies following the ISO 9001:2000 Standard. Top level policies cover maintenance, human resources, logistics, fabrication (HACCP), sanitation and raw materials. Specific procedures exist for all departments within the facility.</p>

1.1.3	An organizational chart indicates which positions are responsible for compliance to the Quality System	<p>This facility has an up-to-date organizational chart showing responsibilities for food quality and security.</p> <p>The organizational chart highlights the reporting structure within the business. The structure is dated September 19, 2005 (Directive 140, Revision 1) and details the key management structure for the Seretram facility including management for the Best Company Mills. Human resources and crisis management functions for Best Company Mills are provided by Seretram. There is a flat management structure due to the small size of the Company. All employees are responsible for food safety and quality. The Quality Manager has total oversight for food safety and quality. The Quality Manager reports directly to the Operations Manager who reports to the Operations Director for the whole facility (which includes Seretram). Any issues relating to the safety or quality of a product are communicated to the Quality Manager. Job descriptions are documented in the Quality Manual for key management (i.e. Operations Manager, Quality Manager and Engineer Manager) and were available with document reference: DIR 140; Revision 1; September 19, 2005. The Quality Manager has the responsibility to ensure product released conforms to specification thus ensuring food safety and the protection of the customer interest. The Quality Manager responsibilities include review of the Quality Manual, HACCP Plans, Internal Audits, Positive Release for finished product, client relations, supplier approval, Quality Systems and Research &amp; Development.</p> <p>The groups responsible for quality and food safety are given sufficient authority to protect product and the customers' interests.</p> <p>The Quality Manager was able to explain the main responsibilities of her job function relating to food safety and quality. The Quality Manager is competent in her role within the business and was able to explain in detail her responsibilities with respect to food safety, product quality and customer service/satisfaction.</p>
1.1.4	Quality System Effectiveness Reviews are conducted routinely	<p>Quality System Effectiveness Reviews are performed by management. The management team at Best Company Mills conducts Quality System Effectiveness Reviews annually. The last review was conducted on March 23, 2006. The Operations Manager, Engineer Manager and Quality Manager were all part of the Quality System review including the Administration &amp; Finance Director (responsible for Human Resources). Group Quality meetings are also held semi-annually and last approximately 4 days. Quality Managers from several Best Company Mill sites all meet to discuss issues and common topics of discussion. The last Group Quality meeting was on April 21, 2006. Due to the small number of management on site, meetings are in fact conducted more frequently than the formal scheduled meetings. The Quality System Effectiveness Review meetings include various topics of discussion relating to food safety and quality. There is a set agenda which includes for example, the results of internal/external audits, process conformance, customer satisfaction and the status of preventive and corrective actions. According to the company, the Quality System Effectiveness Reviews are a useful tool to identify strengths, weaknesses and to identify key issues going forward.</p> <p>Proper Quality System Effectiveness Reviews are performed by management.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>

**SECTION SUMMARY:**

The facility quality policy states "The customer is our primary focus. We will strive for excellence both in food safety and quality to protect ourselves and our valued customers." The quality policy is authorized by the Regional Quality Vice President for Best Company Mills. The Quality Manual is well structured with top level policies and detailed procedures concerning required documentation. The organizational chart highlights the reporting structure within the business. The structure is dated September 19, 2005 (Directive 140, Revision 1) and details the key management structure for the total Seretram site including management for the Best Company Mills. The Quality Manager was able to explain the main responsibilities of her job function relating to food safety and quality. Quality System Effectiveness Reviews are performed by management. The management team at Best Company Mills conducts Quality System Effectiveness Reviews annually. The last review was conducted on March 23, 2006.

**Facility's Response to Auditor's Observations**

## 2.0 FUNDAMENTALS

### Section 2.1 Infrastructure

	AUDIT ITEM	OBSERVATION
2.1.1	Facility site and buildings are of suitable size construction and design to facilitate maintenance and sanitary operations	<p>All floors, walls and ceilings, including any overhead attachments, were in good to excellent condition.</p> <p>Drains in production area are sunk into the ground and constructed with stainless steel gullies and grill coverings. Drains are in good condition with the interior flooring graded towards the drains.</p> <p>No potential for product contamination was observed from foreign materials, condensation, dust, rust, peeling paint, etc. coming from overhead equipment, pipes or surrounding structures.</p> <p>Equipment was spaced to allow proper sanitation and maintenance. There were no issues observed with regards to the placement of the equipment.</p>
2.1.2	Exterior grounds and structures are maintained in a condition that protects against the contamination of food or facility	<p>After inspection of exterior grounds and structures, no issues were observed to indicate that exterior grounds could cause contamination concerns, either to the facility or the food items stored and/or produced.</p> <p>Grounds were sloped in such a way as to drain water away from the structure and/or prevent the accumulation of water immediately around the physical building.</p>
2.1.3	There are appropriate environmental controls (controlled temperature air filtration humidity lighting etc)	<p>Effective/documented controls of environmental monitoring were noted at this facility. The site has ISO:14001 accreditation. Environmental controls on site are managed by Seretram which deals with all waste (i.e. metal, plastic, cardboard) destined for recycling. Food waste is managed by the facility and an approved waste contractor which takes the waste for animal feed. All waste water goes to Seretram which has a waste water management program in place where all water is subject to separation of solids, aeration and several settlement stages in adjacent lagoons. Discharge limits (e.g. suspended solids, biological oxygen demand, chemical oxygen demand and pH) are monitored both by the site and also by the local authority (DRIRE) prior to release into Gare de Pau river. Best Company Mills has installed dust collectors on the dryers to prevent particulate emission to the atmosphere. Air handling is in place for environmental air such as cooking, forming and packing areas.</p> <p>Records indicate that effective environmental control systems are utilized by this facility.</p> <p>Environmental air is filtered at this facility. Environmental air supplied into the cooking and forming areas is filtered through a 3 stage filter system with filter sizes of G3, G4 and F8 respectively. Packing areas also have filtered air to the same level.</p> <p>Air filter cleaning and replacement are part of the preventive maintenance (PM) program. Records were maintained that verified this program is effective. Environmental air filters are monitored approximately at weekly intervals with planned replacements annually or more often if required. Pressure indicators are present which measures the pressure of pre-filtration and post filtration air to denote whether filters need changing.</p> <p>Lighting in the facility meets the plant's internal requirements and appears adequate to maintain product safety and facilitate cleaning. All areas within the facility were well lit. High temperature glass covered halogen lights were present in the warehouse.</p>

2.1.4	All food contact surfaces are made of materials appropriate to the application eg stainless steel food grade plastics etc	<p>There is a policy describing the materials by which food-contact surfaces should be constructed. There is a Best Company Mills Group Policy regarding the condition of food-contact surfaces which states they should be impervious, non-corrosive and easily cleanable.</p> <p>Stainless steel (Grade:316) is used for process equipment with food contact conveyors being constructed from suitable (hard plastic) food contact material.</p>
2.1.5	The quality of potable water and food contact water ice steam and gases is suitable for its intended use All food contact water is determined to be from a controlled potable source	<p>All water used within the facility is supplied from the local authority (Sidec).</p> <p>Water at this site is not treated. Water is not subject to on site water treatment as it is received from Sidec already complying to French local legislation for potable water (Decret No. 2001-1200, 20 Dec 01).</p> <p>Food-contact steam is used on-site and boiler chemicals meet government regulations. Culinary food contact steam is used in the cooking operation which is raised through a conventional boiler process with water being softened through an ion exchange resin system. Culinary steam passes through a 150 micron stainless steel filter and is delivered throughout the facility via stainless steel piping.</p> <p>Food-contact ice is not used at this location.</p> <p>Best Company Mills has a comprehensive water testing plan in place which meets the requirements of national law. Water is subject to microbiological analysis for Coliforms, E. coli, Total Viable Count at 22 Degrees Centigrade and 36 Degrees Centigrade and Enterococci. Physio/chemical analysis is also conducted and includes ammonium minerals, odor, color, free/total chlorine, conductivity, pH and turbidity. Water analysis results were also available from the local authority for a full suite of microbiological and chemical analysis to include all of the aforementioned tests including pesticides, nitrates, nitrites and iron.</p> <p>Microbiological and chemical water results reviewed from Laboratoires des Pyrenees were all within their specified limits (report no. 052456, 5/4/06).</p> <p>Properly filtered food-contact compressed air is currently utilized by this facility. The facility uses compressed air for various mechanisms within the process. It is primarily used to empty the corn bulk tanker, to transfer the corn bits from the external silo to the internal store and to transfer the mix of raw materials to the cooker. Compressed air is supplied by either oil free air compressors or air compressors which contain food grade oil.</p> <p>No food-contact gases are used at this facility.</p> <p>Compressors which contain food grade oil are filtered and monitored so that the maximum permitted oil level at the exit of the filter is 0.003mg/cubic meter.</p>
2.1.6	Procedures are in place to protect water systems from backflow	<p>All water systems are protected against backflow.</p> <p>Backflow prevention devices are regularly inspected for functionality. Records were reviewed verifying that this program is up-to-date. Backflow prevention devices are checked and changed on an annual basis by SOCLA (external contractors). Last change was conducted on 20/04/06. Records were available and documented for this check.</p> <p>During the audit of this facility, no negative employee practices were observed that could cause backflow contamination.</p>

2.1.7	Employee welfare areas and production hand wash stations are properly equipped and fully functional	<p>There are separate changing facilities in place for men and women and both were clean, orderly and well maintained. A cleaning schedule is posted on the changing room doors that are signed off hourly by the cleaning staff.</p> <p>Restrooms and locker rooms do not open directly into processing or packaging areas.</p> <p>Restroom doors observed throughout the facility have functional, self-closing mechanisms. All doors were properly closed.</p> <p>Restrooms and locker rooms have ventilation that exhausts to the exterior of the facility.</p> <p>Plumbed systems in the restrooms and locker rooms are fully functional.</p> <p>. Hand washing stations are readily available where needed.</p> <p>Hand washing signs are posted at the point of use in restrooms, locker rooms and dining areas. Hand wash signs, written in French, were present at all sinks with pictorial and written guidance. Furthermore, signs were posted at all entry ways into the production facility which stated "Clean Hands Before Entering This Area" (translated from French).</p> <p>Hand wash stations were hands free (knee operated) taps that had liquid anti-microbial soap present in dispensers, paper towels and foot operated lidded bins. Although most hand-wash stations were adequately equipped, three stations located in the cooking and drying area were missing foot operated lidded bins.</p>
<b>SECTION JUDGMENT:</b>		<b>Substantially Meets</b>
<b>SECTION SUMMARY:</b>		<p>The facility overall was in excellent condition. Drains in production area are sunk into the ground and constructed with stainless steel gullies and grill coverings. Drains are in good condition with the interior flooring graded towards the drains. Air handling is in place for environmental air such as cooking, forming and packing areas. Air in direct contact with product, e.g., air supplied to the dryers, is also filtered. Environmental air supplied into the cooking and forming areas is filtered through a 3 stage filter system with filter sizes of G3, G4 and F8 respectively. Packing areas also have filtered air to the same level. All areas within the facility were well lit. All water used within the facility is supplied from the local authority (Sidec). Water is not subject to on site water treatment as it is received from Sidec already complying with French local legislation for potable water (Decret No. 2001-1200, 20 Dec 01). Although most hand-wash stations were adequately equipped, three were missing covered trash bins</p>

#### Facility's Response to Auditor's Observations

**ISSUE:** Not all hand wash stations were supplied with trash bins with covers.

**DETERMINATION OF CAUSE:** Procedures for servicing these stations were not clearly taught or documented. The Sanitation Manager only works third shift and by the time she sees a problem, one or two earlier shifts may already have been affected.

**CORRECTIVE ACTIONS:** All hand wash stations were re-supplied with covered trash bins as soon as the situation was pointed out by the SAFE auditor. A checklist is now posted at each station, and also in restrooms and the break room where the shift sanitation worker will sign off that all materials are in place. All sanitation workers have been retrained.

**VERIFICATION:** At the start of each shift, production management will check each station to make sure it is properly equipped. Any problems are communicated to the Sanitation Manager in writing, with a copy to the Assistant Plant Manager. Daily, the Sanitation Manager reviews the sign-off lists.



**Section 2.2 Sanitation**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
2.2.1	There is a written comprehensive plant and equipment sanitation program	<p>This facility has a documented cleaning and sanitation program.</p> <p>The master sanitation schedule includes all areas in this facility to include periodic cleaning of locations such as ceilings, walls and high level areas (e.g., girders in the sheeting area).</p> <p>Cleaning and sanitation frequencies are included in the cleaning and sanitation program, and those frequencies are followed. Major area cleaning and sanitation is conducted every 6 weeks. Interim cleaning such as sweeping and vacuuming is carried out daily. Equipment is cleaned on a weekly basis. All tasks have been signed off by the employee who cleaned the area/equipment and the quality manager who inspected the area/equipment after the cleaning process was completed and before production was re-initiated.</p> <p>The facility cleaning and sanitation programs are effective. Process equipment in the sheeting area was inspected for cleanliness (i.e. rollers and cutters) and said equipment appeared clean. Overhead attached equipment, the rafters and the ceiling in all parts of the plant appeared clean. Dock pits, the boiler room and other remote locales were noted to be clean as well.</p>
2.2.2	Maintenance of the facility and its equipment ensures safe manufacture of wholesome foods	<p>The equipment is designed, constructed and situated to facilitate easy cleaning.</p> <p>Process equipment viewed was all in good condition with no evidence of corrosion or rust. The facility was built in early 2002 therefore all equipment is still relatively new.</p> <p>Examined welds and seams appeared to be of good to excellent quality.</p> <p>No dead sections/dead ends/dead spaces of pipes were indicated.</p>
2.2.3	The facility follows written standard operating procedures (SOP) or work instructions	<p>This facility follows documented work instructions for cleaning and sanitation.</p> <p>Standard operating procedures exist for all processing equipment including environmental cleaning of process areas. SOP's include full instructions of how to clean, chemicals to be used including chemical concentration/contact time. SOP's were examined which included step by step instructions for cleaning preparation, dismantling of equipment, cleaning with detergent, contact time, rinse, disinfection, rinse, visual inspection and equipment re-assembly. There were no exceptions noted.</p> <p>The facility verifies that sanitation procedures are sufficient through ATP swabbing results, GMP audits and visits from the chemical supplier (Johnson Diversey).</p> <p>This facility does not use clean-in-place (CIP) systems.</p>

2.2.4	Brushes and other utensils used for cleaning food contact surfaces are clearly identified and properly controlled	<p>The facility follows a system for the control of brushes and other utensils used for cleaning food-contact surfaces. This program controls all cleaning utensils which includes, hand brushes, pans, floor brushes and squeegees.</p> <p>Food contact surface brushes and non food contact brushes and cleaning equipment are color coded so that they are correctly used for their specific purpose. White brushes are used for food contact surfaces and red is used for non-food contact surfaces. Black brushes are used for drains.</p> <p>Employees have been trained on the color coding system concerning the cleaning utensils. In addition to the color scheme, the site has signs above each cleaning utensil storage rack/hook. Annual refresher training is also provided to all employees.</p> <p>The facility has specific locations designated for storage of controlled utensils.</p> <p>The food contact surface hand brush and pan used in the weighing/mixing area were the same color as that used for non-food contact surfaces, red. Although, there was a sign positioned directly above the utensils on the wall, the employees in this area were utilizing the wrong colored brushes.</p>
2.2.5	Measures are in place to verify and monitor the effectiveness of cleaning methods	<p>The facility takes steps to monitor the effectiveness of cleaning methods.</p> <p>Due to the nature of this continuous process, pre-operational equipment inspections are not conducted. The facility selects several food contact points in wet cleaning areas (e.g. cooking and sheeting areas) and verifies the effectiveness of cleaning after the detergent and before disinfection through visual inspection and ATP bioluminescence testing. There are a total of 10 food contact areas selected based on Johnson Diversey recommendations. ATP bioluminescence rapid swabs are to be taken to verify the effectiveness of cleaning. The acceptable result is any reading below 1500 RLU (relative light units) otherwise a re-clean and re-swab is necessary. Visual inspections are conducted at a minimum daily but are not recorded.</p> <p>All personnel who perform pre-operational testing are trained specifically for this purpose. The quality manager trains the technicians on how to use the ATP bioluminescence testing equipment on an annual basis.</p> <p>Results from pre-operational inspection and/or testing are reviewed by management on a frequent basis. The Quality Manager reviews the test results on a weekly basis. Results of any repeated non-conforming areas are highlighted with an action plan implemented.</p> <p>Documented corrective actions are determined when cleaning/sanitation standards are not met. A non-conformance is raised when an ATP result is greater than 1500 RLU's. The slitter ATP result on August 20, 2005 was recorded as 1700 RLU's. The slitter was re-cleaned and re-sanitized prior to a new ATP test being conducted. The results of the new ATP test was 15 RLU's and the equipment was approved for production.</p> <p>There is a responsible individual identified for management of the cleaning/sanitation program. Team Leaders are responsible for ensuring all process equipment and environmental areas are clean and properly sanitized. The Quality Manager oversees the sanitation program.</p> <p>A process employee was questioned over the verification of the sanitation program which includes ATP swabbing and equipment sign offs. A satisfactory response was provided in relation to the methodology, reporting of results and any corrective action required.</p>

2.2.6	For water free (dry) processing zones effective procedures are in place to clean equipment and structures	<p>Procedures exist for cleaning water-free processing area, equipment and structures.</p> <p>The facility has documented procedures for the cleaning of water-free zones.</p> <p>The mixing and the dryer areas are the only two areas requiring dry cleaning methods.</p> <p>Dry cleaning procedures include use of the newly installed vacuum system, the use of compressed air to remove loose/dry particles and hand brushes. Dry cleaning is conducted during deep cleaning approximately every 6 weeks. Vacuuming can occur at any time to clean up spills.</p> <p>Water is sometimes used for cleaning in these dry zones. External corn bit storage silos are subject to an annual cleaning and disinfection by an approved external contractor. Records were available for the last annual cleaning which was conducted on February 26, 2006 with Dichlorvos at a specified strength. Cleaning and disinfection also includes the inspection for any insects associated with cereal products of which none were identified. Further checks are conducted to ensure there are no internal cracks in the silos. Dry cleaning is normally carried out on the bucket elevator in the drying area; however, this piece of equipment is subject to a deep cleaning using water and chemicals every six months. Periodic deep cleaning using water and chemicals at a high level is scheduled on areas such as walls and overhead metal structures. The periodic cleaning schedule is recorded on an excel spreadsheet with difficult areas scheduled for cleaning according to the production program. Air conditioning socks in the cooking, sheeting and packing areas are removed and cleaned by an approved external laundry contractor every 6 months.</p> <p>Dry cleaning records verify that the described plant procedures are followed correctly.</p> <p>Employees responsible for dry cleaning were able to communicate the procedures followed and the reporting methods for each area and piece of equipment.</p>
<b>SECTION JUDGMENT:</b>		<b>Partially Meets</b>
<b>SECTION SUMMARY:</b>		<p>Major cleaning and sanitation is conducted every 6 weeks. Interim cleaning is carried out during production such as vacuuming dry areas and sweeping up. Production employees are responsible for cleaning the process areas. All items of equipment including the process environment are subject to cleaning. Frequency of cleaning is specified at each shut down or planned at weekly/monthly frequencies dependent upon the area. Process equipment viewed was all in good condition with no evidence of corrosion or rust. The facility was built in early 2002 therefore all equipment is still relatively new. Standard operating procedures exist for all processing equipment including environmental cleaning of process areas. SOP's include full instructions of how to clean, chemicals to be used including chemical concentration/contact time. Due to the nature of this continuous process, pre-operational equipment inspections are not conducted. Best Company Mills selects several food contact points in wet cleaning areas (e.g. cooking and sheeting areas) and verifies the effectiveness of cleaning after the detergent and before disinfection through visual inspection and ATP bioluminescence testing. The mixing and the dryer areas are the only two areas requiring dry cleaning methods. Although, there was a sign positioned directly above the utensils on the wall explaining the color coding system, the food contact surface hand brush and pan used in the weighing/mixing area were the same color, red, as that used for non-food contact surfaces. Visual inspections are conducted at a minimum, daily, but are not recorded.</p>

**Facility's Response to Auditor's Observations**

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ISSUES: 1) Misapplication of color-coding system for cleaning tools.

2) Not all line checks are documented

DETERMINATION OF CAUSES: 1) A shipment of new red (sanitation) brushes were purchased and put to use without regard to existing color schemes. 2) A policy of documenting the results of routine visual inspection had not been established.

CORRECTIVE ACTIONS: 1) When the SAFE auditor pointed out this discrepancy, we immediately removed all brushes from the rack, cleaned and sanitized them, and replaced them on the rack according to color-code. All other racks were also checked and no other discrepancy was found. The next day during shift meetings, the Sanitation Supervisor reinstructed all relevant employees regarding our strict color-coding system. Additional placards were placed in the employee lunch room and in the hall Safety-First display. 2) New procedures were written and forms were designed to cover the daily visual inspection referred to by the auditor.

VERIFICATIONS: 1) We have added instructions to inspect brushes and utensils (color and condition) used for various tasks to the pre-shift inspection that is performed by all shift supervisors. Also, QC will look for and document any discrepancies found during their hourly rounds. 2) The new checklist is itemized as part of our morning document review of prior-day operations.



**Section 2.3 Pest Control**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
2.3.1	A documented pest control program is in place	<p>There is a documented pest control program available at this facility.</p> <p>Responsibility for pest control is split between company employees and a third-party pest control company. The pest control program at Best Company Mills is managed by Rentokil as well as routine inspections conducted by employees of Best Company Mills in between contractor visits. Seretram trained personnel are responsible for checking external baits on the perimeter of Best Company Mills.</p> <p>Facility personnel at Best Company Mills conduct internal checks on pest control points on a weekly basis. Contents of electric fly killer units are collected on a weekly basis then counted and identified. Rentokil oversees results of the internal pest inspections.</p> <p>The facility's pest control program identifies targeted pests, e.g., rodents, insects (spiders, ants, Indian Meal Moths) and other non-rodent pests (birds, reptiles, domestic animals). The services the facility's pest contract covers are rodents, flying insects and crawling insects.</p> <p>During the audit, no evidence of current, uncontrolled pest activity was observed within or without the facilities.</p>
2.3.2	Building exterior is protected from rodent and pest entry	<p>There were no exterior structural issues observed that would permit entry of rodents and/or other pests. The exterior of the building is protected against the ingress of pests. All doors are fully proofed, drains were covered with grills, surface of interior walls are intact and ventilation grills in the utility room are screened with no tears or holes.</p> <p>This facility uses pest exclusion devices to protect openings into the facility. Plastic strip curtains are used on external doors or doors have rapid closing shutter doors. These pest exclusion devices were in good working condition and the plastic strips were not torn or broken.</p> <p>There is a clear, vegetation-free zone adjacent to production or storage buildings. There is a twenty-four inch clear perimeter located directly around and adjacent to the building. This vegetation free zone is mostly made up of asphalt with some areas of large loose bark chips in the front of the facility. Additionally, directly by the entrance way into the offices is a small area of planted shrubs.</p> <p>Building exteriors are free of pest harborage sites such as obsolete equipment, maintenance materials and pallets stored too close to facility structures.</p> <p>Packaging waste material is segregated into plastic, paper and metal and stored in designated areas in the warehouse prior to removal under the control of Seretram and subsequent recycling. This area was noted to be neat, orderly and clean. Food waste material is stored in a covered external dumpster which is collected daily by Promic S.A. The dumpster is located approximately 20 meters from the rear exit, on an asphalt surface, against the perimeter fence. This area was also found in an orderly and clean condition.</p>

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2.3.3	The pest control program addresses devices and inspections	<p>Best Company Mills has several types of pest control devices. There are external rodenticide bait stations, internal Ketchalls, internal glue boards, crawling insect monitors, pheromone traps and electronic fly killer units. There is some bird netting protecting the external, covered shipping and receiving dock; preventing birds from landing on the support rafters. All controls are appropriate for the targeted pests and are effectively utilized.</p> <p>Rentokil visits the facility 12 times per year for routine inspections with an additional field biologist inspection conducted annually. In addition, Best Company Mills monitors internal pest control points weekly and Seretram monitors external baits around the whole facility weekly. Ultra violet light tubes in electronic fly killer units are changed annually by Best Company Mill employees.</p> <p>The facility has a schematic (map) indicating current placement of pest control devices; e.g., bait boxes, mechanical traps, glue boards, ILTs, pheromone stations, etc. The schematic is dated March 6, 2005 and includes all exterior bait stations, internal glue boards, internal Ketchalls, crawling insect monitors, pheromone traps and electronic fly killer units. All devices checked during the audit corresponded to the current schematic.</p> <p>Poison bait stations are used at the facility to control pests. There are two zones with regards to the placement of bait stations. One zone is around the fence line and the other is around the immediate plant exterior. The bait stations located at the perimeter fence are located approximately 50 meters apart and contain a rodenticide. The baits stations located against the building are placed every 15 - 30 meters apart. Additionally, added bait station were noted around the dumpster area.</p> <p>The facility uses curiosity traps in its pest control program. Mechanical traps were noted spaced approximately 5 - 10 meters apart around the interior of this facility. Added protection was noted near entranceways into the facility as both glue boards and Ketchalls are all placed 5 meters apart and on both sides of doors as recommended by Rentokil.</p> <p>Insect Light Traps (ILT) are properly deployed by the facility to control flying insects. Electronic fly killer units with shatterproof ultra violet light tubes are positioned throughout the facility; i.e. in warehouse, near entry points to processing areas and inside processing areas. There are a total of thirteen units installed.</p> <p>. Pheromone traps were located in storage areas within this facility. There are 2 pheromone traps positioned at different points within the warehouse and 1 trap in the mixing area. They are used to monitor the grain weevil populations.</p>
2.3.4	Deficiencies are documented and corrective action taken	<p>Deficiencies revealed by the facility pest control program are documented.</p> <p>When problems are uncovered through the facility pest control program, documented corrective actions are taken to minimize or eliminate the issue.</p> <p>Rentokil inspection records were reviewed for internal rodent traps which indicated no activity within processing/warehouse areas. Any concern raised by the Rentokil employee, during their surveillance inspection of the property (e.g., structural, cleaning, etc.) is placed onto a corrective action report and upon the correction of the identified issue, the entry is signed off by the quality assurance manager.</p> <p>As part of the ongoing pest control program, areas with repetitive pest activity are identified and corrective actions are taken.</p>

2.3.5	Pesticide applications are performed by certified applicators a licensed pest control contractor or under direct supervision of the same	<p>Spraying of pesticides externally is completely managed by Rentokil who is licensed to perform this task. There is no spraying of internal areas with exception to the silos which are sprayed annually to control insects by an approved external contractor.</p> <p>Regulations governing this facility do not require pest control companies to carry or present a business license. There was no copy of a pest control company business licenses kept by this facility. Rentokil is licensed with Agreement Number A.I.F. 0119 with 'Service Regional De La Protection Des Vegetaux d'Ile-De-France.</p> <p>The pest control company's certificate of insurance was up-to-date. Rentokil's liability insurance certificate (Attestation D'Assurance Responsabilitie Civile' is valid from November 2005 - September 2006.)</p> <p>Regulations governing the facility do not require pest control applicators to have individual licenses. They are covered under the general company business license.</p> <p>Training of applicator/technician was verified during the audit. Training of employee pest inspectors at Best Company Mills and Seretram is conducted by Rentokil on an annual basis. The last annual training session was conducted in June 2005. Records reviewed indicated this training was completed for all employees working in the program.</p> <p>Rodenticide blocks (e.g. Difapaq - 0.005% Difenacoum) are used in external rodent bait stations.</p> <p>Restricted Use Pesticides are not applied at this facility.</p>
2.3.6	The facility maintains and enforces written procedures for the application of pesticides	<p>. Other than rodenticides and the pesticides sprayed on the external grounds and in the silos; no other pesticides are used at this facility.</p> <p>Pesticide application records include all key information required by appropriate regulatory agencies. This includes 1) Government registration number, 2) targeted pests, 3) name of pesticide, 4) method of application, 5) concentration, 6) rate of application, and 7) the date of treatment.</p> <p>Record retention for pesticide applications meets all regulatory requirements.</p>
2.3.7	All chemicals used in pest control are accurately labeled and securely stored	<p>. Only rodenticide blocks are stored in a locked cabinet at Seretram under the supervision of Seretram's management. Rodenticide blocks are stored in their original packaging at the bottom of a locked metal cabinet in the machine store and spare parts area at Seretram.</p> <p>Pesticide storage areas are secured and restricted, except to designated, authorized individuals. Pesticide storage areas are secured and restricted, except to designated, authorized individuals. The Store Manager holds the key to the locked cabinet where rodenticide blocks are stored.</p> <p>Expired/obsolete pesticides stored at this facility are destroyed/disposed in accordance with regulatory requirements.</p>
2.3.8	The facility formally audits contracted Pest Control Operator performance	<p>This facility formally audits contracted Pest Control Operator performance. The performance of Rentokil is monitored through internal audits and the approved vendor program.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>

**SECTION SUMMARY:**

The pest control program at Best Company Mills is managed by Rentokil as well as routine inspections conducted by employees of Best Company Mills between contractor visits. Seretram trained personnel are responsible for checking external baits on the perimeter of Best Company Mills. Best Company Mills have several types of pest control devices. There are external rodenticide bait stations, internal Ketchalls, internal glue boards, crawling insect monitors, pheromone traps and electronic fly killer units. There is some bird netting located in the shipping and receiving area. The external pest contractor visits 12 times per year for routine inspections with an additional field biologist inspection conducted annually. In addition, Best Company Mills monitors internal pest control points weekly and Seretram monitors external baits around the whole facility weekly. Ultra violet light tubes in electronic fly killer units are changed annually by Best Company Mills' employees. Spraying of pesticides externally is completely managed by Rentokil who is to perform this task. There is no spraying of internal areas with exception to the silos which are sprayed annually to control insects by an approved external contractor. Training of employee pest inspectors at Best Company Mills and Seretram is conducted by Rentokil on an annual basis. The last annual training session was conducted in June 2005. Records reviewed indicated this training was completed for all employees working in the program. Pesticide storage areas are secured and restricted, except to designated, authorized individuals. The performance of Rentokil is monitored through internal audits and the approved vendor program.

**Facility's Response to Auditor's Observations**

**Section 2.4 Chemical Control**

Section 2.4 Chemical Control	
AUDIT ITEM	OBSERVATION
<p>2.4.1 A chemical control program manages the use storage and handling of non food chemicals</p>	<p>There is a documented control program for managing non-food chemicals at this facility.</p> <p>The non-food chemical control program verifies that such chemicals are approved before use. Chemical suppliers must go through the Best Company Mills vendor approval system which investigates the suitability for use in contact with food, availability of material safety data sheets including evidence of any third party accreditation such as ISO:9000. All chemicals must be approved by Best Company Mills prior to use.</p> <p>During the audit, no unapproved non-food chemical was observed in the facility.</p> <p>The facility follows procedures that control the purchase of chemicals. Cleaning chemicals may only be purchased from the approved vendor list. Changes to this procedure are only permitted with prior approval from the Quality Manager.</p> <p>Cleaning chemicals in use are stored in fully labeled containers on a chemical spillage pallet in a dedicated storage area in the warehouse. Maintenance lubricants are also stored away from finished product on lubricant spillage pallets in the Best Company Mills warehouse. The main storage area for holding cleaning chemicals is at Seretram. This is a separate, well ventilated chemical storage facility which is locked when not in use.</p> <p>All primary and secondary chemical containers for non-food chemicals observed during the audit were accurately and legibly labeled.</p>
<p>2.4.2 Material Safety Data Sheets (MSDS) or non USA equivalent are available for all non food chemicals</p>	<p>All Material Safety Data Sheets (or non-USA equivalent) or applicable chemical documentation requested by the auditor were made available for review. MSDS's were available for cleaning chemicals reviewed in the cleaning chemical storage area (e.g. Johnson Diversey Ultraclean VK3L Detergent). MSDS's were also available for Softcare Plus Hand Soap with bacteriocidal action and Kluberoil 4UH1 which is a food grade lubricant. MSDS was also available for the disinfectant used by the external contractor who is appointed to clean the corn silos on an annual contract. There were no omissions for any chemicals selected at random during the audit.</p> <p>All MSDS's were quickly retrieved from a central file located in the laboratory/process control room by a Team Leader who was familiar with the importance of having such MSDS's readily available.</p> <p>Material Safety Data Sheets (or non-USA equivalent) include both pesticides and food-contact sanitation chemicals.</p> <p>During the audit, employees demonstrated a clear understanding of how to access Material Safety Data Sheets (or non-USA equivalent) or applicable chemical documentation and were familiar with their purpose and use.</p>
<b>SECTION JUDGMENT:</b>	<b>Fully Meets</b>

**SECTION SUMMARY:**

All chemicals purchased and used within Best Company Mills must follow their documented chemical control program. Cleaning chemicals may only be purchased from the approved vendor list. Changes to this procedure are only permitted with prior approval from the Quality Manager. Cleaning chemicals in use are stored in fully labeled containers on a chemical spillage pallet in a dedicated storage area in the warehouse. Maintenance lubricants are also stored away from finished product on lubricant spillage pallets in the Best Company Mills warehouse. The main storage area for holding cleaning chemicals is at Seretram. This is a separate, well ventilated chemical storage facility which is locked when not in use. MSDS's were available for cleaning chemicals reviewed in the cleaning chemical storage area (e.g. Johnson Diversey Ultraclean VK3L Detergent). MSDS's were also available for Softcare Plus Hand Soap with bacteriocidal action and Kluberol 4UH1 which is a food grade lubricant. MSDS was also available for the disinfectant used by the external contractor who is appointed to clean the corn silos on an annual contract. There were no omissions for any chemicals selected at random during the audit.

**Facility's Response to Auditor's Observations**

**Section 2.5 Personnel Practices**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
2.5.1	All employees wear in an effective manner hairnets and beard covers while in areas where food products packaging and ingredients are exposed	<p>The facility maintains a written policy with respect to the wearing of hair restraints. Hair is required to be completely covered through the wearing of blue disposable mob caps and white hard hats. Beard snoods are required to be worn although there are no employees with beards.</p> <p>All employees, visitors to the plant or contractors observed during the physical inspection of the facility properly adhered to the hair restraint policy.</p>
2.5.2	The wearing of jewelry is controlled to prevent contamination	<p>The facility has a written policy with regards to the wearing of jewelry, including body piercings, false fingernails, fingernail polish, watches, medical alert identification, earrings, necklaces, bracelets, excessive makeup, etc.</p> <p>All employees, visitors to the plant and contractors observed during the physical inspection of the facility properly adhered to the jewelry policy.</p>
2.5.3	Employees follow proper hygiene practices to prevent contamination	<p>There is a written policy covering personal hygiene and hand sanitation practices. All employees are required to wash their hands with soap and warm water after using the rest room, or leaving their work station for any reason.</p> <p>During the audit, employees were observed thoroughly washing their hands with soap and warm or hot water, in compliance with Good Manufacturing Practices.</p> <p>This facility does not provide hand sanitizing stations in addition to wash sinks.</p> <p>.</p> <p>.</p>
2.5.4	Employee gloves used for food safety related purposes are maintained intact clean and sanitary	<p>This facility uses gloves; however, there was no written policy/procedure with regards to glove control for food safety related purposes.</p> <p>.</p> <p>.</p> <p>.</p>
2.5.5	Eating drinking gum chewing snacks and tobacco products are prohibited in processing and packaging areas	<p>The facility has a written consumption policy that prohibits eating, drinking and tobacco use in processing and packaging areas.</p> <p>There are no exceptions to the eating/drinking policies.</p> <p>There are specific areas designated by management for the storage of personal effects and consumption of food and tobacco.</p> <p>All employees, visitors and contractors observed during the audit of the facility properly adhered to the facility consumption policy.</p> <p>During the audit, no personal items were observed being improperly stored.</p>

2.5.6	Employees with symptoms of illness or open cuts/lesions are excluded from sensitive food handling jobs	<p>Personnel health procedures require employees with symptoms of illness or open wounds to be adequately protected, reassigned to non-sensitive work or sent home.</p> <p>Supervisors are trained to recognize and respond to personnel health issues.</p> <p>All employees, visitors or contractors observed during the audit appeared to properly comply with the facility's personnel health policy.</p>
2.5.7	Uniforms and outer apparel are designed or controlled in a manner to prevent risk from foreign materials	<p>There is a facility apparel policy prohibiting the use of top pockets in uniforms but it does not cover other outer apparel.</p> <p>In addition to pockets, the facility policy prohibits carrying loose objects anywhere above the waist.</p> <p>The facility apparel policy prohibits the use of clothing materials that can cause foreign material contamination; e.g., beads or rhinestones, and materials that can shed fibers or other types of debris and contamination.</p> <p>All employees, visitors or contractors observed during the audit appeared to properly comply with the facility's apparel policy.</p>
2.5.8	Uniforms and outer apparel are maintained in a clean manner	<p>The apparel cleanliness policy includes uniforms, but does not cover other outer apparel worn in food-sensitive areas. Employees are issued five clean uniforms and are required to wash and maintain them. They are further required to wear closed toed shoes when reporting to work each day. Cloth/Tennis shoes are not authorized to be worn in the facility.</p> <p>. There are no microbiological sensitive areas within the facility.</p> <p>. The uniform cleanliness policy does not include restrictions on the use of uniforms, shoes or other specialized clothing when exiting the work area.</p> <p>During the audit, all employees, visitors and contractors observed near exposed food, ingredients, food packaging or food-contact surfaces wore appropriate, clean outer garments.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>Hair is required to be completely covered through the wearing of blue disposable mob caps and white hard hats. The facility has a written policy with regards to the wearing of jewelry and all employees were in compliance to that company policy. Employees do use gloves; however, there was no written policy/procedure with regards to glove control for food safety related purposes. All employees are required to wash their hands with soap and warm water after using the rest room, or leaving their work station for any reason. The facility has a written consumption policy that prohibits eating, drinking and tobacco use in processing and packaging areas. All employees were in compliance to that plant requirement. During the audit, no personal items were observed being improperly stored. All employees, visitors or contractors observed during the audit appeared to properly comply with the facility's personnel health policy. Employees are issued five clean uniforms and are required to wash and maintain them. They are further required to wear closed toed shoes when reporting to work each day. There are no microbiological sensitive areas within the facility. Employees, visitors and contractors were adhering to all facility personal hygiene policies/procedures.</p>

**Section 2.6 Training & Education**

Section 2.6 Training & Education	
AUDIT ITEM	OBSERVATION
2.6.1 Training needs are assessed and training is conducted and documented accordingly	<p>The facility has a documented personnel training program.</p> <p>There are several training programs in place related to food safety such as food hygiene, cleaning, pest control, HACCP and the facility GMP's. There is a Personnel Management System (PMP) in place for the facility which is managed by Seretram. Seretram is also involved in the advertisement and recruitment of new employees including ongoing individual Development Plans (IDP).</p> <p>Training is conducted on a weekly basis and these training sessions last between 30 and 60 minutes. The area supervisor is responsible for training the employees in his/her area. Make up training is provided to absent employees. These training sessions are tail gate style. Once a year, facility personnel gather at a local restaurant for refresher training on the company's polices. This classroom style training is usually 4 to 6 hours. New employees are trained using individualized training.</p> <p>Training records are held by Human Resources at Seretram on the Access computer system. Training records for on the job training, HACCP and hygiene were reviewed for several process employees including one who was responsible for monitoring a critical control point (metal detection). Training records were also reviewed for a process team leader, a packing employee and a team leader who was responsible for verifying cleaning procedures. All training records requested during the audit were available and signed by the appropriate supervisor.</p> <p>Training is verified through a "Training Evaluation" questionnaire which is handed out at the end of the training session for employee feedback. Tests are also given at the end of training to verify the understanding of the training session by the employee. On the job observations are conducted to verify that training was effective. Competency is continually assessed through the "IDP" where key objectives are set and strengths/weaknesses measured.</p>
2.6.2 Authorized personnel conduct food safety related training	<p>Induction training and training for jobs specific to food safety is provided by the Best Company Mills Quality Manager or a Senior Manager in different formats depending upon the role of the employee. This can be delivered either by classroom training sessions, video sessions or via the internet.</p> <p>A member of the Human Resources Department at Seretram is a qualified "Train the Trainer". This individual attended the University of Pau in France. The Best Company Mills Quality Manager has a certificate in HACCP principles and works with the Seretram's qualified "Train the Trainer" for other internal training courses.</p> <p>Training is provided in the language of all employees working at the facility.</p>
<b>SECTION JUDGMENT:</b>	<b>Fully Meets</b>

**SECTION SUMMARY:**

There is a comprehensive induction and training program in place at Best Company Mills which includes food safety training such as food hygiene, cleaning, pest control, HACCP and the facility GMP's. There is a Personnel Management System (PMP) in place for the facility which is managed by Seretram. Seretram is also involved in the advertisement and recruitment of new employees including ongoing individual Development Plans (IDP). Training is conducted on a weekly basis and these training sessions last between 30 and 60 minutes. The area supervisor is responsible for the weekly training sessions of his/her employees in his/hers area of responsibility. Furthermore, there is an annual training session that covers the plant's policies and procedures and that training last 4 - 6 hours. Training records are held by Human Resources at Seretram on the Access computer system. Competency is continually assessed through the "IDP" where key objectives are set and strengths/weaknesses measured.

**Facility's Response to Auditor's Observations**

**Section 2.7 Handling Storage & Delivery**

Section 2.7 Handling Storage & Delivery	
AUDIT ITEM	OBSERVATION
<p>2.7.1 Stored goods are protected from damage contamination and deterioration</p>	<p>The facility food safety program includes the protection or inspection of stored goods.</p> <p>The stored goods food safety program includes inspection of on-site storage. This facility does not utilize any additional storage sites beyond the audited facility. Ambient storage facilities are inspected as part of the internal audit program. The GMP inspection covers sanitation, pest control and traceability systems. Audits are conducted by Senior Management (e.g. Quality Manager, Operations, Engineering etc) with any issues being raised as a non-conformance deviation. The internal audit is subsequently scored as a percentage through the Best Company Mills "Quality System Database" (QSD). Corrective actions for non-conformances are verified during the next monthly audit in order to close out the non-conformance.</p> <p>The inspection frequency of the internal storage facility is monthly.</p> <p>. GMP audit records/reports of the storage inspection are maintained on file. The reports are reviewed by the Director of the facility during weekly staff meetings.</p> <p>Records reviewed with regards to the inspection of storage sites show effective implementation of the storage food safety program. GMP audit records were reviewed with regards to the storage facility and revealed effective implementation of this program. A GMP audit which was conducted on May 5, 2006 received a score of 80 percent.</p> <p>Warehouse storage areas within the facility were very clean and maintained in good order with no evidence of any pest issues.</p> <p>Finished product cases are not used for anything other than their intended purpose; e.g., not used as stools, door stops, step ladders, etc.</p>
<p>2.7.2 Temperature for humidity sensitive items are maintained at proper temperatures to ensure proper food safety and maintain quality</p>	<p>There are no temperature- or humidity-sensitive items stored at this facility. All ingredients and finished products are stored at ambient (uncontrolled) temperatures.</p> <p>.</p> <p>.</p> <p>.</p>

2.7.3	Carriers are routinely inspected for acceptability	<p>There are inspection procedures in place for all inbound carriers. Raw material deliveries received by Seretram include a visual inspection, vehicle cleanliness (appearance and odor), integrity of the raw material packaging including batch codes and product description details.</p> <p>There are inspection procedures for all outbound carriers. Outbound inspection of vehicles is managed by Seretram who follow Best Company Mills procedures which includes a check on the cleanliness of the vehicle, presence of pests and any foul odor prior to loading finished product.</p> <p>Receiving and Shipping records were reviewed and they revealed that established procedures were followed and documented as required by the plant's policy.</p> <p>Policies and procedures require the use of seals on inbound and outbound carriers.</p> <p>This facility does not receive or ship product using "Less than Truck Load" (LTL) carriers.</p> <p>Actual observation and/or review of records indicated that all seal numbers from inbound carriers are cross-checked and verified against receiving documents before product is accepted. The receiving records were reviewed for the period January - March 2006 and revealed that seal numbers were verified as matching the corresponding transportation documentation, Bill of Lading (BOL).</p> <p>Procedures are in place for handling inbound carriers arriving with broken or missing seals. The delivery is not permitted to be unloaded until all the required checks are completed. Any issues relating to security seals are dealt with directly by the Quality Manager who assesses the situation prior to any release.</p> <p>The facility has no policy regarding the materials back-hauled by vehicles on return trips. However, there is an unofficial policy that all employees in the shipping/receiving area understood and stated.</p>
2.7.4	Pallets are managed for contamination sanitary and physical conditions	<p>Raw materials are delivered on wooden pallets which are checked for unsanitary conditions including any damage as stipulated in the Best Company Mills pallet management program. Finished product is palletized onto either virgin, non treated wooden pallets (1200x1000mm) or re-enforced cardboard pallets (1140x1140mm).</p>

2.7.5	Bulk raw materials are protected against contamination during unloading and loading	<p>Bulk carriers are received at this facility. Corn bits is the only item received by bulk tanker at this facility.</p> <p>. The facility has procedure for unloading bulk carriers.</p> <p>. Bulk unloading activities observed during the audit appeared to conform fully to sanitary standards.</p> <p>Raw material bulk corn tankers are accompanied with documentation which contains details of the cleaning of the tanker, all information relating to the load and a Certificate of Analysis.</p> <p>Bulk transfer hoses used for the unloading of corn from the tanker to the silo belong to the facility. The hoses are stored inside the building while not in use and have caps at each end to prevent entry of pests/foreign bodies. Access to loading ports on the two corn silos are locked inside a small room at the base of each silo. Process supervisors are the only individuals that have access to this area.</p> <p>A receiving record for a corn bits delivery received on May 9, 2006 with lot number 5512506 was reviewed and included all corresponding documentation related to the cleaning of the tanker, seal numbers and the Certificate of Analysis including the quality analysis report for the sample. All records reviewed followed company established procedures.</p>
2.7.6	A schedule of inbound materials includes condition of storage and expiration date	<p>Current receiving procedures explain shelf life requirements for raw material acceptance.</p> <p>An employee who is responsible for the receipt of raw materials (excluding corn) was interviewed during the audit to verify his understanding of Best Company Mills raw material acceptance procedures. The employee was able to explain the checks required and demonstrated what information needed to be recorded. A process team leader at Best Company Mills was also questioned on the receipt of a bulk corn delivery and responses received were verified against the receiving procedures.</p> <p>The facility's product receiving procedures ensure raw materials are protected from deterioration and adulteration while awaiting storage.</p> <p>The facility's product shipping procedures ensure finished goods are protected from deterioration and adulteration while awaiting shipment.</p>
2.7.7	Materials are used and shipped with suitable rotation to prevent degradation	<p>The facility has procedures and requirements regarding shelf life and the release status of finished goods. The release of finished product is dependent upon the customer specification. Shelf life is usually 12 months from date of manufacture although this is not specified in a procedure. Best Company Mills can store approximately 3 weeks capacity of finished product in the warehouse.</p> <p>Materials intended for domestic and foreign consumption are used and shipped with suitable shelf life to prevent deterioration. Product is released based on first in first out (FIFO) principles and is normally less than 1 month old when shipped.</p> <p>.</p> <p>A "Bugles Half" finished product released on May 9, 2006 followed FIFO when cross-checked against the SAP inventory system.</p> <p>There is a verifiable exception policy regarding the stock rotation program and what customers it applies to.</p>

2.7.8	Returned goods are handled in such a manner as to protect against contamination or the contamination of other goods	This facility does not accept returned goods. . .
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		Storage facilities are inspected on a monthly basis as part of the internal audit program. The inspection covers GMP's, sanitation, pest control and traceability systems. Audits are conducted by Senior Management (e.g. Quality Manager, Operations, Engineering etc) with any issues being raised as a non-conformance deviation. GMP audit records/reports of the monthly storage inspection are maintained on file. The reports are reviewed by the Director of the facility during weekly staff meetings. Warehouse storage areas within the facility were very clean and maintained in good order with no evidence of any pest issues. Raw material deliveries received by Seretram include a visual inspection, vehicle cleanliness (appearance and odor), integrity of the raw material packaging including batch codes and product description details. Outbound inspection of vehicles is managed by Seretram who follow Best Company Mills procedures which includes a check on the cleanliness of the vehicle, presence of pests and any foul odor prior to loading finished product. Receiving and Shipping records were reviewed and they revealed that established procedures were followed and documented as required. Raw materials are delivered on wooden pallets which are checked for unsanitary conditions including any damage as stipulated in the Best Company Mills pallet management program. Raw material bulk corn tankers are accompanied with delivery note which contains details of the cleaning of the tanker and all information relating to the load. Accompanying the delivery note is a Certificate of Analysis for the corn. The release of finished product is dependent upon the customer specification. Product is released based on first in first out (FIFO) principles and is normally less than 1 month old when shipped. The facility has no written policy regarding the materials back-hauled by vehicles on return trips but there was an unofficial policy that all employees in the shipping/receiving area understood and stated.

**Facility's Response to Auditor's Observations**

**Section 2.8 Vendor Approval**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
2.8.1	There is a Vendor Approval Process for ingredients food contact packaging and services affecting food safety and quality	<p>The facility has a vendor approval program. The vendor approval program includes an evaluation of the vendor's food safety program based on the risk of the raw material. Evaluation takes the form of a food safety questionnaire, raw material specifications, third party accreditation and food safety and regulatory audit reports.</p> <p>The facility only accepts products/ingredients from approved vendor at specific manufacturing locations.</p>
2.8.2	An "Approved Vendor List" is utilized for ingredients food contact packaging and services affecting food safety and quality	<p>A comprehensive list of approved vendors is documented and up-to-date.</p> <p>The supplier of a delivery of corn was identified from receiving records and verified against the approved vendor list. There was evidence in the vendor approval system that this supplier was fully approved. Records were reviewed which included the suppliers Identity Preservation Certificate issued by SGS (Issue date: December 9, 2005) and a continuing guarantee which contained specific questions relating to the absence of genetically modified organisms and presence of allergens.</p>
2.8.3	A system for evaluation of vendor performance is in place	<p>The facility follows a program to evaluate vendor performance.</p> <p>Out of compliance situations with suppliers requires the initiation of a "Complaint Report". A "Complaint Report" details the date of the incident, raw material, lot number, quantity and description of the problem. Documented corrective actions are provided by the supplier before the report is closed out.</p> <p>Corrective action records were reviewed during the audit and they revealed that a corrective action was taken in response to an identified issue.</p> <p>The vendor performance procedure requires routine feedback to the supplier, whether or not issues arise.</p> <p>A complaint report (foreign body - piece of plastic) dated April 18, 2006 for a delivery of corn was reviewed with a satisfactory response of corrective actions implemented by the supplier noted on April 27, 2006. Subsequent deliveries confirmed that corrective actions implemented by the supplier were acceptable.</p>
2.8.4	There are provisions for buying from "non approved" sources in the case of emergency situations	<p>The facility does not allow purchases from non-approved vendors for any reason.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>The vendor approval program includes an evaluation of the vendor's food safety program based on the risk of the raw material. The supplier of a delivery of corn was identified from receiving records and verified against the approved vendor list. There was evidence in the vendor approval system that this supplier was fully approved. Out of compliance situations with suppliers requires the initiation of a "Complaint Report". A "Complaint Report" details the date of the incident, raw material, lot number, quantity and description of the problem. Corrective action records were reviewed during the audit and they revealed corrective actions were taken in response to identified issues.</p>

**Facility's Response to Auditor's Observations**

**Section 2.9 Packaging Approval for Use**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
2.9.1	Packaging materials are purchased according to written approved specifications	<p>Purchases of packaging materials are based upon written, approved specifications.</p> <p>The facility has a system to track and manage the Pure Food Guaranty program (or recognized program equivalent). Packaging must comply with European legislation for Plastics and Articles in Contact with Food (Legislation (EC 2002/72) including 21 CFR 177-1520 and 21 CFR 184 - 1191).</p> <p>The facility follows established procedures to inspect and release incoming packaging to inventory. Packaging must meet applicable specifications and be purchased from an approved vendor.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		Packaging must comply with European legislation for Plastics and Articles in Contact with Food (Legislation (EC 2002/72) including 21 CFR 177-1520 and 21 CFR 184 - 1191). The facility follows established procedures to manage and release incoming packaging to inventory. Packaging must meet applicable specifications and be purchased from an approved vendor.

**Facility's Response to Auditor's Observations**

**Section 2.10 Control of Materials**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
2.10.1	Incoming materials are verified as conforming to written specifications	<p>Specifications and procedures identify acceptance criteria for incoming ingredients.</p> <p>Process employees have a copy of the raw material specification available for corn bits via the Achiever computer system at the computer terminal in the laboratory/process control room. All quality management system procedures are available through this mechanism. A basic receiving specification through a contract is provided to Seretram to cover raw materials which are received under Seretram's control. Such raw materials however, are of a low food safety risk and Best Company Mills has historical knowledge of these vendors.</p> <p>The facility requires Certificates of Analysis (or equivalent) to be checked against the ingredient specifications upon receipt of goods.</p> <p>Raw materials are checked against required specification criteria. Raw material is only received if the quality and condition is satisfactory. The Quality Manager is informed if there are any deviations to the specification requirements. Records reviewed indicated that inspection and release procedures for incoming ingredients were followed.</p>
2.10.2	A process to change or modify incoming material specifications is documented	<p>The facility has a procedure to coordinate and confirm specification changes with vendors.</p> <p>All specification changes are approved in writing by the appropriate vendor.</p> <p>The facility has made no specification changes within the last twelve months.</p>
2.10.3	There are control procedures for rework products	<p>The facility has policies and procedures that address the use of materials intended for rework. There is a procedure for rework or "re-feed" at this facility which denotes the handling and traceability of product(s) intended for rework (FAB 300-3 Rev 0, 5 Apr 04).</p> <p>The facility follows procedures that address the storage condition of materials intended for rework.</p> <p>The facility has procedures that address the identification and coding of materials intended for rework.</p> <p>The facility has guidelines that dictate the amount of rework permitted in the final formula. Dependent upon the quality attributes of the re-feed product, re-feed is usually added back to finished product in a continuous flow at a rate of approximately 5%. The percentage of re-feed is controlled by the speed of the conveyor belt. Re-feed product can only be added back to the finished product stream post bed dryer and pre-metal detection/packing. There is no re-feed back at the "mixing bowl" stage.</p> <p>The facility maintains batch formulation records that detail the usage of reworked product.</p> <p>Periodic breaks in re-feed cycles are not applicable as unique batches of re-feed product are blended until the batch is finished. The facility does not operate a continual re-feed system as part of its manufacturing process.</p> <p>Re-feed records were reviewed for product that was packed on May 9, 2006 which followed documented procedures.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>

**SECTION SUMMARY:**

Raw materials are checked against required specification criteria. Raw material is only received if the quality and condition is satisfactory. The Quality Manager is informed if there are any deviations to the specification requirements. Records reviewed indicated that inspection and release procedures for incoming ingredients were followed. There is a procedure for rework or "re-feed" at this facility which denotes the handling and traceability for product(s) intended for rework (FAB 300-3 Rev 0, 5 Apr 04). Re-feed records were reviewed for product being packed on May 9, 2006 which followed documented procedures.

**Facility's Response to Auditor's Observations**

**Section 2.11 Sanitary Design**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
2.11.1	The design of new equipment is approved following sanitary considerations	<p>The facility has specific policies and procedures for approval of equipment before purchase.</p> <p>The facility has a documented procedure to review sanitary design considerations of equipment prior to purchase.</p> <p>Procedures for the review of Sanitary design reference and/or utilize established industry standards. The facility has a documented procedure to review sanitary design considerations prior to purchase. Sanitary design is verified prior to purchase following set guidelines issued by Best Company Mills.</p> <p>Equipment which comes into contact with food must be suitable for food use. Stainless steel grade used for food contact surfaces is corrosion resistant Grade 316. Conveyor belts must also be suitable for food use.</p> <p>Recent purchasing records were reviewed and they verified that approval procedures for equipment design are followed. Records for the replacement of the hopper in the sheeting area on May 2, 2006 were reviewed and noted to have followed established approval procedures.</p>
2.11.2	Equipment installation is approved to ensure sanitary operating conditions	<p>The facility has specific policies and procedures to approve the sanitary installation of equipment.</p> <p>Recent records were reviewed and they verified that approval procedures for equipment installation are followed.</p>
2.11.3	Newly installed equipment is challenged to verify proper sanitary design prior to use	<p>The facility has specific policies and procedures to challenge and verify the proper sanitary design and installation of newly purchased equipment before being placed into service.</p> <p>If sanitary operating criteria for newly installed equipment are not met, procedures require corrective actions before newly purchased equipment is placed into service.</p> <p>Recent corrective action records show that established procedures are followed when less than acceptable challenge results are found.</p>
2.11.4	Modifications to existing structure and equipment do not compromise sanitary design	<p>This facility has a documented change control procedure regarding type, construction and minimum requirements when existing structures and equipment are altered. The Engineer Manager is responsible for the change control program where any new equipment required or changes to existing equipment would follow standard procedures for approval and commissioning of new equipment in liaison with the Quality Manager.</p> <p>When changes are made, old or obsolete equipment and piping are removed.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		The facility has a documented procedure to review sanitary design considerations prior to purchase. Sanitary design is verified prior to purchase following set guidelines issued by Best Company Mills. Equipment which comes into contact with food must be suitable for food use. Records for the replacement of the hopper in the sheeting area on May 2, 2006 were reviewed and noted to have followed established approval procedures. The Engineer Manager is responsible for the change control program. When changes are made to the facility, old or obsolete equipment and piping are removed.





**Section 2.12 Traceability and Recall Management**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
2.12.1	An effective recall management program is documented	<p>Recall management documentation describes the scope of the program.</p> <p>Specific procedures to be followed during an actual recall are included in the documentation.</p> <p>Emergency contact information is available from recall management documentation.</p> <p>The recall management program outlines individual responsibilities. The Operations Director for the whole facility (including Seretram) is responsible for the recall management program along with Best Company Mills Operations Manager.</p> <p>Activity records are kept concerning the recall management program.</p>
2.12.2	Vendors provide a means of traceability for incoming goods and materials	<p>The facility requires all incoming goods (including bulk items, if any) to be coded by vendors.</p> <p>A recent material shipment was reviewed and it indicated materials are properly coded to permit traceability.</p> <p>The facility does not have a policy regarding multiple lot codes on incoming pallets or shipments.</p>
2.12.3	Inbound materials are coded by the facility when received	<p>The facility does not assign any internal identification code to received material.</p>

<p>2.12.4</p>	<p>Raw materials are traceable into finished products Finished goods are traceable through distribution to the first customer</p>	<p>All finished product has a unique pallet identification number in the format of bar codes which are assigned by Seretram SAP's computerized stock inventory system and forwarded to the packing area. The unique pallet identification number corresponds to the date of production, product description, product code, lot number, best before end date and quantity. Pallets of finished product are first entered onto Best's 'K-Roll' computerized system where they await positive release. Once a positive release for a lot code is available, the unique pallet identification is released onto the SAP system at Seretram who is responsible for finished product and transportation.</p> <p>The facility has the ability to trace raw materials into finished product.</p> <p>. Raw material corn bits are stored in 2 silos with an approximate individual capacity of 85 tons. Corn consumption is recorded in real time on the "Track.exe" system. The silos are run empty prior to refilling however there is a small possibility of an overlap between 2 different deliveries of corn. Therefore, Best Company Mills has estimated (based on silo commissioning information), that there is a 10 ton possible overlap between deliveries. During a recall situation, a 10 ton quantity from the previous batch and subsequent delivery batch would be considered part of the recall as a security measure.</p> <p>The facility has a process for traceability of reworked and/or repacked products, which is documented and practiced.</p> <p>The facility has a process which can trace rework/repack product back to its original production lot.</p> <p>Finished products are labeled with a bar code label which contains details relating to the product description, product article code, lot number, date of production, best before end date and quantity. The bar code labels are printed at the point of packing and applied to the surface of the finished product. The unique lot number is an encrypted code (e.g. 138687) which corresponds to the production date on the SAP system.</p> <p>During the audit, coding for raw materials and finished products appeared correct, accurate and legible.</p>
<p>2.12.5</p>	<p>The effectiveness of product traceability is tested regularly</p>	<p>The facility conducts routine internal mock recalls for raw material forward.</p> <p>Routine internal mock recalls are executed by the facility for lot code backward.</p> <p>Lot code forward traceability exercises are routinely carried out by this facility.</p> <p>The facility's expectations for the percentage recovery and elapsed time taken to conduct the traceability exercise are established at 100% within a 4 hour period which was documented on the Mock Recall Evaluation Form.</p> <p>The facility last conducted a traceability/recall exercise on May 4, 2006 on a delivery of raw material corn (45,630kg) which went to produce 210 totes of finished product on 2 production date codes. Finished product was shipped to one customer between March 13 - 17, 2006 with 6 totes not shipped and destined for re-feed. This exercise was conducted within 3.25 hours and traced 100% of product. The trace exercise conducted previous to this was successfully carried out on May 5, 2005 and accounted for 100% of the raw material corn delivery within 2 hours.</p> <p>Results of the past trace exercises are documented and self-assessments are performed.</p>

2.12.6	Traceability performance is challenged during the audit report	<p>A drum of fully refined Palmoleine in use with lot code 153210 was selected during the audit of the process facilities for a traceability exercise. A quantity of 6,992kg (38 x 184kg drums) of Palmoleine was received on February 8, 2006 from an approved supplier. The process department commenced use of this lot code on March 26, 2006 and was still using up to May 9, 2006. Manual mixing records were obtained which verified the start of use dates. A date code within this period (March 22, 2006) was picked at random and traced forward to establish the quantity of finished product produced. The facility manufactures only one finished product - Bugles Half Product (Product code 700 604 0000). Finished product manufactured on this date with finished product lot number 138687 came to 112 totes (24,569kg in total) that were shipped on 4 different loads to 2 customers. There was no re-feed product packed as part of this batch and no stock was on hold. SAP stock inventory system showed that all stock had been shipped from Best Company Mills.</p> <p>The results of the exercise revealed 100% of product was traced within a one hour period.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>The Operations Director for the whole facility (including Seretram) is responsible for the recall management program along with Best Company Mills Operations Manager. Finished products are labeled with a bar code label which contains details relating to the product description, product article code, lot number, date of production, best before end date and quantity. The bar code labels are printed at the point of packing and applied to the surface of the finished product. The unique lot number is an encrypted code (e.g. 138687) which corresponds to the production date on the SAP system. The facility's expectations for the percentage recovery and elapsed time taken to conduct the traceability exercise are established at 100% within a 4 hour period which were documented on the Mock Recall Evaluation Form. The results of the mock recall exercise conducted during the audit revealed 100% of product was traced within a one hour period.</p>

**Facility's Response to Auditor's Observations**

**Section 2.13 Crisis Management**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
2.13.1	The facility has a crisis management program in addition to product recalls	<p>The facility has a documented crisis management program in addition to product recalls.</p> <p>In addition to the Best Company Mills Crisis Response Plan Booklet, there is a Crisis Resource Manual (dated March 2002). This is held by the Operations Director at Seretram. The crises identified include issues associated with fire, flood, security, a business continuity threat, an environmental issue, product safety/integrity, human safety, chemical incident and a financial threat.</p> <p>The Operations Director at Seretram is identified as the Crisis Coordinator and is responsible for managing any crisis across the whole facility.</p> <p>The facility's crisis management program includes emergency contact information.</p> <p>The facility's crisis management program has been tested/activated within the past 12 months. A crisis management simulation was prompted by Best Company Mills Group on June 4, 2004. The crisis involved a fire in the production facility. All personnel were evacuated and accounted for in the time frame noted in the procedures. The simulation was handled by the Crisis Coordinator and the rest of the facility crisis team. The test was considered successful.</p> <p>The facility has a contingency plan to continue to supply its customers in the event of a prolonged interruption. There is a business continuity plan (BCP) which explains different scenarios of interruption to the business. Each manufacturing site within the Best Company Mills Group is responsible for ensuring a "BCP" is in place. This Best Company Mills location has the possibility to divert production to 2 sister sites who manufacture the same product if there was a prolonged interruption.</p> <p>Procedures are in place to inform customers that a crisis has occurred that may affect the supply chain.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		The facility has a documented crisis management program beyond product recalls. The crises identified include issues associated with fire, flood, security, a business continuity threat, an environmental issue, product safety/integrity, human safety, chemical incident and a financial threat. The Operations Director at Seretram is identified as the Crisis Coordinator and is responsible for managing any crisis across the whole facility. There is a business continuity plan (BCP) which explains different scenarios of interruption to the business. Each manufacturing site within the Best Company Mills Group is responsible for ensuring a "BCP" is in place.

**Facility's Response to Auditor's Observations**

**Section 2.14 Food Defense**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
2.14.1	A documented policy/plan manages Food Defense (security) at the facility	<p>A Food Defense assessment has been conducted for the facility.</p> <p>The facility's Food Defense policy/plan is documented.</p> <p>The facility has performed a food defense assessment using the local government policies and procedures.</p> <p>.</p> <p>The Operations Manager at Best Company Mills is responsible for the food defense program.</p> <p>The Food Defense policy or plan requires the investigation and reporting of any security breaches to the program leader.</p>
2.14.2	The Food Defense policy/plan is fully implemented	<p>The Food Defense policy or plan has been fully implemented at this facility.</p> <p>Employees have been issued a main entry door swipe card which they use to enter the facility. The card is returned and deactivated if the employee leaves the Company.</p> <p>There is a door bell which delivery drivers for raw material corn use to advise process employees that they have arrived. Deliveries of other raw materials are received at Seretram. Truck drivers are required to stay in their vehicles while raw corn is unloaded.</p> <p>Protective clothing has the name of the employee stitched on it. Only employees from Seretram who receive raw materials and collect finished products from the warehouse are permitted entry to Best Company Mills areas of the facility. Visitors and contractors have an appointment booked before arriving on site where they are received by their host. Visitors who do not have an appointment cannot gain access to the facility until they are challenged by Senior Management. The main entrance door is locked by a swipe card system. There is an external perimeter fence which surrounds the whole facility. Security guards are present and inspect the facility externally and internally. Additional lighting has also been installed in external areas. A wire seal was put on a door in the warehouse to prevent unauthorized entry.</p> <p>The facility does not perform background checks on full-time employees. Local employment legislation prevents background checks being performed on prospective or current employees.</p> <p>The facility does not perform background checks on part-time employees.</p> <p>This facility does not use temporary employees.</p> <p>This facility does not use seasonal employees.</p> <p>Observations made during the audit revealed that Food Defense activities were consistent with the current policy/plan.</p>

2.14.3	The Food Defense plan is communicated and training is conducted	<p>The facility Food Defense coordinator and facility Food Defense team have not received training in Food Defense.</p> <p>The facility has a Food Defense communication/training program for its employees.</p> <p>The employee Food Defense communication/training has been fully implemented.</p> <p>Internal food defense training has been provided to employees and is subsequently refreshed during regular production shut down periods or annually, as required.</p> <p>The facility visitor policy explains the GMP procedures to the visitor/contractor with particular reference to medical health and personal hygiene. A sign in policy is in place for all visitors and evidence was available that this sign in procedure is effective (i.e. pest contractor sign in on April 20, 2006).</p> <p>Food Defense instructions were provided to the auditor before access to the facility.</p> <p>The auditor received GMP instructions prior to gaining access to the facility. Additionally, this audit was required to sign in as the policy stated.</p>
2.14.4	The Food Defense plan is periodically assessed reviewed and updated	<p>Facility management assesses the Food Defense policy/plan for areas of vulnerability, including premises, products and raw materials that are potentially at risk. There is a GMP audit conducted by the Operations Manager, Engineering Manager and Quality Manager which includes facility security.</p> <p>The Food Defense policy/plan is audited monthly.</p> <p>Corrective actions are implemented when management assessments reveal Food Defense vulnerabilities. Corrective actions as a result of the last food defense audit (February 7, 2006) have been implemented and there is a continual improvement program to consider the installation of additional lighting in external areas.</p>
<b>SECTION JUDGMENT:</b>		<b>Substantially Meets</b>
<b>SECTION SUMMARY:</b>		<p>The facility has performed a food defense assessment using the local government policies and procedures. The Operations Manager at Best Company Mills is responsible for the food defense program. Employees have been issued a main entry door swipe card which they use to enter the facility. The card is returned and deactivated if the employee leaves the Company. Local employment legislation prevents background checks being performed on prospective or current employees. Internal food defense training has been provided to employees and is subsequently refreshed during regular production shut down periods or annually, as required. There is a GMP audit conducted by the Operations Manager, Engineering Manager and Quality Manager includes facility security. The food defense coordinator and/or facility food defense team have not received specialized training in food defense.</p>

**Facility's Response to Auditor's Observations**

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ISSUE: the Food Defense Coordinator and his team have not received specialized training.

DETERMINATION OF CAUSE: Because help was received from local law enforcement officials while setting up our Food Defense plan, it was determined that formal instruction was not required. However, it is clear that food-plant-specific training is indeed necessary.

CORRECTIVE ACTIONS: In March, we will be sending our key Operations Management, including the Food Defense Coordinator, to a two-day training class jointly taught by our Trade Association and the US FDA. In turn, the Food Defense Coordinator will train the other members of the security team. Based upon what is learned, we will make what ever improvements possible. Any changes requiring capital approval will be submitted to the Directors in October.

VERIFICATION: Current policies and guidelines will be rewritten to reflect the changes mentioned above. This document will be available for the next SAFE audit. If our customer desires, it can send a SAFE auditor or its own representative to review the documented changes. However, we cannot allow our written program to leave these premises.



**Section 2.15 Calibration Measuring and Test Equipment**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
2.15.1	A system for processing equipment calibration is in place	<p>The facility has a documented calibration program for processing equipment.</p> <p>The processing equipment calibration program includes a list of process equipment requiring calibration. The facility has not identified any process equipment as critical in nature.</p> <p>The program includes calibration frequencies for each piece of equipment on the list.</p> <p>The calibration program describes persons/positions responsible for calibration.</p> <p>The facility has an equipment identification system. Each piece of equipment contains a serial number that is maintained in a computer data base.</p> <p>Calibrations are performed both in house and by approved external contractors. For example ELCOWA is responsible for calibrating the metal detector and the weigh scales are calibrated by Mettler Toledo.</p> <p>The program does include documented instructions for calibrating process equipment in-house.</p> <p>Calibration records were reviewed for the stamped weight (20kg) which is used to verify the weighing equipment on a weekly basis. Such external calibration is conducted every 3 years by Rack Entrepot with the last external calibration conducted on November 13, 2003. Elcowa calibrated the CCP metal detector on May 20, 2006 (annual). The calibration schedule for the metal detector on the mixer (metal detector identification: VAB 12864-03) was incorrect and did not correspond to its calibration certificate.</p> <p>Processing equipment is calibrated against certified or other acceptable industry standards. Process Equipment is traceable to national and international standards however it was not available for the calibration weight used by Mettler when they conducted the last calibration for the bag line weighing equipment (serial no. 656605) on June 27, 2005.</p> <p>Facility personnel responsible for calibrating processing equipment receive specialized training.</p> <p>The facility has documented corrective action procedures when processing equipment is found to be out-of-calibration. There were no examples of corrective action to review for equipment found out of calibration.</p> <p>.</p> <p>When a piece of equipment is identified as out-of-calibration, the product is placed on hold since the last satisfactory verification check or last calibration. A deviation record would be completed by the Quality Manager who is responsible for the disposition of any product when any prescribed measuring devices are found to be operating outside of its specified limits.</p>

<p>2.15.2</p>	<p>A system for laboratory equipment calibration is in place</p>	<p>The facility has a documented calibration program for laboratory equipment.</p> <p>The laboratory equipment calibration program includes a list of process equipment requiring calibration. The facility has not identified any laboratory equipment as critical in nature.</p> <p>The program includes calibration frequencies for each piece of equipment on the list.</p> <p>The calibration program describes persons/positions responsible for calibration.</p> <p>The facility has an equipment identification system. Each piece of equipment contains a serial number that is maintained in a computer data base.</p> <p>Moisture analyzers are calibrated externally on an annual basis by Arizona Company with the last calibration conducted on January 18, 2006 (e.g. serial number 27567). Moisture analyzers are verified internally on a weekly basis by in-house personnel.</p> <p>. The program does include documented instructions for calibrating laboratory equipment in-house.</p> <p>Internal verification of the moisture analyzers was last conducted on May 3, 2006. Records indicated that the performance was satisfactory.</p> <p>Laboratory equipment is not calibrated against certified or other acceptable industry standards.</p> <p>Facility personnel responsible for calibrating laboratory equipment receive specialized training.</p> <p>The facility has documented corrective action procedures when laboratory equipment is found to be out-of-calibration. There have been no instances where the moisture analyzers were found to be outside of calibration. Best Company Mills has 3 moisture analyzers, therefore, if one analyzer was outside of calibration, moisture results could be cross checked against the other analyzers until calibration of the defective unit could be arranged.</p> <p>.</p> <p>When a piece of equipment is identified as out-of-calibration, the product is placed on hold since the last satisfactory verification check or last calibration. A deviation record would be completed by the Quality Manager who is responsible for the disposition of any product when any prescribed measuring devices are found to be operating outside of its specified limits.</p>
<p><b>SECTION JUDGMENT:</b></p>		<p><b>Substantially Meets</b></p>
<p><b>SECTION SUMMARY:</b></p>		<p>The facility has a documented calibration program for processing and laboratory equipment. There were no processing or laboratory equipment identified as critical in nature. Each piece of equipment contains a serial number that is maintained in a computer data base. Calibrations are performed both in house and by approved external contractors. When a piece of equipment is identified as out-of-calibration, the product is placed on hold since the last satisfactory verification check or last calibration. A deviation record would be completed by the Quality Manager who is responsible for the disposition of any product when any prescribed measuring devices are found to be operating outside of its specified limits. Laboratory equipment is not calibrated against recognized industry standards. Process Equipment is traceable to national and international standards however it was not available for the calibration weight used by Mettler when they conducted the last calibration for the bag line weighing equipment (serial no. 656605) on June 27, 2005.</p>

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ISSUE: Calibration documentation for Mettler balances were not shown to the SAFE auditor when requested.

DETERMINATION OF CAUSE: The documents in question were misfiled.

CORRECTIVE ACTIONS: The documents in question were found and returned to their correct folder. Those responsible for misplacing the document have been retrained. We have reviewed our Document Control Procedures and made changes that will reduce the possibility of a recurrence.

VERIFICATION: Upon request, a copy of the new procedures along with a copy of the misplaced Mettler balance calibration record will be sent to the SAFE auditor and/or our customer.



**Section 2.16 Traffic Control**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
2.16.1	Segregation of raw from processed/finished product is sufficient to prevent cross contamination	The kinds of raw materials and processed/finished product do not require physical segregation to prevent cross-contamination.
2.16.2	Control measures are in place to reduce the potential of cross contamination	Foot baths are not required by the type of process or product manufactured at this facility.
<b>SECTION JUDGMENT:</b>		<b>Not Applicable / Auditable</b>
<b>SECTION SUMMARY:</b>		The kinds of raw materials and processed/finished products made at this facility do not require physical segregation to prevent cross-contamination.

**Facility's Response to Auditor's Observations**

**Section 2.17 Maintenance**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
2.17.1	A corrective and preventive maintenance program is in place and is effective	<p>The facility has a documented corrective and preventive maintenance program.</p> <p>The corrective and preventive maintenance program is computer operated.</p> <p>The maintenance program includes procedures to address and track overdue/open work orders.</p> <p>The corrective and preventive maintenance program includes a list of food handling equipment.</p> <p>The maintenance program includes a schedule of maintenance frequencies.</p> <p>The corrective and preventive maintenance program provides for the training for maintenance personnel.</p> <p>The corrective and preventive maintenance program includes parts inventory management.</p> <p>The Engineer Manager is responsible for overseeing the corrective and preventive maintenance program.</p> <p>Priorities are established for the repair of critical equipment regarding safety related issues i.e., personnel and food.</p> <p>A process team leader was questioned on the corrective and preventive maintenance program. He was able to explain the program and all documentation associated with it.</p>
2.17.2	The maintenance program includes maintenance records	<p>Records are maintained for preventive, predictive, routine and emergency maintenance activities.</p> <p>Maintenance documents are retained as part of the quality management system records retention policy which is 5 years.</p>
2.17.3	The maintenance program is structured to prevent contamination from maintenance activities	<p>The maintenance program requires reconciliation of all tools after repairs and prior to start-up.</p> <p>The reconciliation of all machine parts is required by the maintenance program after repairs and prior to start-up.</p> <p>The corrective and preventive maintenance program requires post-maintenance sanitation inspection of equipment. The Engineering Manager, Process Team Leader and the Quality Manager are responsible for overseeing post maintenance equipment inspections.</p> <p>Post-maintenance equipment inspections are documented.</p> <p>Tools/part carts are cleaned and/or dedicated to prevent contamination of the processing area.</p> <p>A purge process is performed after certain emergency maintenance repairs to flush away any residual contamination.</p>

2.17.4	The maintenance program includes a policy for temporary repairs	<p>The corrective and preventive maintenance program includes a Temporary Repairs policy indicating if and when such repairs are permitted. Procedures for temporary repairs are documented in a temporary repairs policy (MAINT 100) which specifies any repair tape used must be dated. Cables or plastic ties may only be used if the repair is urgent and only as a temporary measure until a permanent fix is accomplished through the work order system.</p> <p>The Temporary Repairs policy is documented.</p> <p>No temporary repairs observed during the audit of the facility.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>The facility has a documented corrective and preventive maintenance program. The Engineer Manager is responsible for overseeing the corrective and preventive maintenance program. All equipment which requires maintenance, either managed internally or externally, is listed by area and scheduled to prevent any risk to the food safety of the product. Records are maintained for all maintenance activities. Maintenance records are retained as part of the quality management system records retention policy which is 5 years. Post-maintenance equipment inspections are documented. The Engineering Manager, Process Team Leader and the Quality Manager are responsible for overseeing post maintenance equipment inspections. The corrective and preventive maintenance program includes a Temporary Repairs policy indicating if and when such repairs are permitted. Procedures for temporary repairs are documented in a temporary repairs policy (MAINT 100) which specifies any repair tape used must be dated. No temporary repairs were observed during the physical inspection of the facility.</p>

**Facility's Response to Auditor's Observations**

### 3.0 FOOD SAFETY AND HACCP SYSTEMS

#### Section 3.1 HACCP/Food Safety

	AUDIT ITEM	OBSERVATION
3.1.1	A HACCP/Hazard Prevention plan is documented for each product/process	<p>The facility has a documented Hazard Prevention program.</p> <p>The Hazard Prevention program is HACCP based.</p> <p>This facility does not operate under a government regulated HACCP/Hazard Prevention program.</p> <p>There is only one product manufactured at this facility which is "Bugles Half Product". There is only one process flow and a corresponding HACCP plan to cover the process from raw material receipt through to finished product.</p> <p>All products or processes are covered under the HACCP/Hazard Prevention program.</p>
3.1.2	A team is in place and responsible for developing modifying the Hazard Prevention program and implementing and maintaining the Hazard Prevention system	<p>The facility has a multidisciplinary HACCP/Hazard Prevention team assigned overall responsibility for the Hazard Prevention program.</p> <p>The HACCP/Hazard Prevention team meets on a regular basis. HACCP review meetings are conducted on an annual basis.</p> <p>All HACCP team members have a Certificate in HACCP Principles which includes the Operations Manager, Engineering Manager and Quality Manager. All team leaders and process employees have been trained to a comprehensive internal HACCP program.</p> <p>At least one member of the Hazard Prevention team has completed a HACCP/Hazard Prevention training session. The HACCP Team Leader (Quality Manager) has received external training in HACCP principles from the local university in September 2002.</p>
3.1.3	HACCP/Hazard Prevention preliminary steps and hazard analyses were conducted prior to developing the HACCP/Hazard Prevention plan	<p>The HACCP/Hazard Prevention plans comply with Codex.</p> <p>The HACCP/Hazard Prevention plans include product descriptions, intended uses and target customers (channels of trade). The target customers are national and international food processing companies.</p> <p>Process flow diagrams are current for all HACCP/Hazard Prevention plans.</p> <p>All HACCP/Hazard Prevention plans reviewed are supported by a written Hazard Analysis.</p> <p>The Hazard Analysis considered both severity and likelihood of occurrence.</p>

<p>3.1.4</p>	<p>The HACCP plans include: CCPs critical limits monitoring activities corrective actions verification procedures and record keeping procedures</p>	<p>The HACCP process flow and HACCP plan for "Bugles Half Product" was reviewed during the audit.</p> <p>The HACCP risk analysis has determined there is only one CCP which is the final metal detection step post drying. Critical limits for this CCP is absence of metal. Monitoring of the CCP is conducted according to the metal detection procedure (FAB 100-2 &amp; FAB 100-1) which is a verification check before, every 2 hours during and at the end of production. The metal detector sensitivity is checked using test pieces containing metal spheres of 1.5mm Ferrous and 2.0 Stainless Steel. There is no non-ferrous test piece used as there is a series of magnets and sieves on each raw material and the production equipment are made of stainless steel. Corrective action if a CCP was outside of its critical limits is to notify the Quality Manager when product is rejected. The Quality Manager will determine the cause, assess risk, reject, rework or release product. Monitoring checks are documented on the CCP monitoring sheet (FAB 100-11). If calibration fails or verification fails or if test piece is not rejected, hold product since last good calibration and determine the cause, assess the risk, reject, rework or release product. The CCP is verified by the Quality Manager on a daily basis. Monthly trend analysis is conducted as part of the key performance indicator program.</p> <p>.</p> <p>.</p> <p>.</p> <p>The facility conducts audits or reviews of the HACCP/Hazard Prevention procedures. Semi-annual reviews of HACCP/Hazard Prevention procedures are conducted by the Quality Manager.</p> <p>The facility has validated all critical control limits. The critical control limit was validated by the manufacturer of the metal detection equipment.</p> <p>The HACCP/Hazard Prevention plan is assessed annually or in response to changes or new information that could affect the validity of the HACCP plan.</p>
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3.1.5	Hazard prevention systems are correctly implemented according to facility HACCP/Hazard Prevention plans	<p>The HACCP/Hazard Prevention plans in use are current and up-to-date. The HACCP plan for Bugles Half Product (DIR 410-6) is dated July 25, 2005 and is current.</p> <p>All copies of the HACCP/Hazard Prevention plans are signed by authorized individuals. The HACCP plan is signed and authorized by the Quality Manager and the Operations Manager.</p> <p>The monitoring procedures indicated in the HACCP/Hazard Prevention plans were conducted and recorded as required.</p> <p>The corrective action procedures indicated in the HACCP/Hazard Prevention plans were conducted and recorded as required.</p> <p>The verification procedures indicated in the HACCP/Hazard Prevention plans were conducted and recorded as required.</p> <p>Reviews of CCP monitoring, corrective action and records verification are conducted by personnel trained in HACCP/Hazard Prevention.</p> <p>In-house reviews of CCP monitoring, corrective actions and record verification are documented as specified by HACCP/Hazard Prevention plans.</p> <p>HACCP/Hazard Prevention records were readily available per facility requirements.</p> <p>There are no recurring deficiencies noted in the HACCP/Hazard Prevention system.</p>
3.1.6	Personnel demonstrate knowledge and take specified actions regarding procedures identified in the HACCP/Hazard Prevention plan that are under their area of responsibility	<p>A process employee was challenged on the CCP for metal detection and was able to conduct a routine challenge during the facility inspection. The employee was able to explain the corrective action process if the metal detector failed during a routine test including action taken if there was a metal detector positive alert. The process employee was aware of who has responsibility for managing the HACCP system. A process team leader was also able to explain the functions of HACCP and why it is important to food safety.</p> <p>No specialized training is provided for HACCP/Hazard Prevention operators.</p> <p>The audit revealed no apparent deficiencies in training, knowledge and execution of the HACCP/Hazard Prevention plans.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>The facility has a documented Hazard Prevention program. The Hazard Prevention program is HACCP based. All products or processes are covered under the HACCP/Hazard Prevention program. This facility does not operate under a government regulated HACCP/Hazard Prevention program. The facility has a multidisciplinary HACCP/Hazard Prevention team assigned overall responsibility for the Hazard Prevention program. The HACCP/Hazard Prevention plans comply with CODEX. The HACCP process flow and HACCP plan for "Bugles Half Product" was reviewed during the audit. The HACCP/Hazard Prevention plan is assessed annually or in response to changes or new information that could affect the validity of the HACCP plan. The HACCP plan for Bugles Half Product (DIR 410-6) is dated July 25, 2005 and is current.</p>

**Facility's Response to Auditor's Observations**

**Section 3.2 Microbiological Testing**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
3.2.1	Microbiological testing is in place where applicable	<p>The facility has a microbiological testing program for sanitation. Such surface swabs are analyzed for Salmonella and Listeria according to the schedule. 5 locations are swabbed on a 3 month rotating basis.</p> <p>There is a microbiological testing program for environmental monitoring. Air plates are collected on a quarterly basis to determine mold levels in the plant's environment. These samples are collected in the finished product, packaging area.</p> <p>No microbiological tests are conducted with raw materials at this facility.</p> <p>The facility does not have a microbiological testing program for work-in-progress.</p> <p>Finished product undergoes microbiological testing at this facility. Due to the nature (low water activity) of the finished product, there is a limited risk of microbiological growth. Therefore, finished product is sampled every three months for total viable count, coliforms, Salmonella and yeasts and molds.</p> <p>Rapid tests are not used for any microbiological analysis.</p>
3.2.2	Microbiological testing follows approved standards procedures and methodologies	<p>Acceptance limits for microbiological test results of in-process and finished products are used to determine product acceptability.</p> <p>Microbiological results of a finished "Bugles Half Product" were reviewed (April 5, 2006). All results were within their specified limits.</p> <p>The program includes actions to take when out-of-standard microbiological results are found. A deviation report would be completed if any results were found to be outside of the normal specification range.</p> <p>Corrective actions for out-of-standard ingredient or product results are documented. There were no out of specification results available to verify during the audit but the procedures for handling results of out of specification product was clearly explained by the Quality Manager.</p>
3.2.3	Appropriate environmental testing is conducted	<p>. Although there are documented procedures that the facility should take if mold counts are high on air plates; there were no samples noted that were outside of the acceptable range.</p> <p>. Although this is covered in the company's policy, there was no way for this auditor to verify the process.</p> <p>In-house record reviews have found no trends and/or recurring environmental positives.</p> <p>A program is established requiring follow-up environmental swabs or other testing be done for isolated positives to verify effectiveness of the corrective action.</p> <p>.</p> <p>Finished product is not tested in response to targeted positive environmental results.</p>

3.2.4	Appropriate decisions are made based upon microbiological testing results	<p>Microbiological results are not used to determine product disposition. The microbiological sampling plan on finished product is only used as an indicator of background microbiological levels. The product has a low moisture and water activity content and is subject to further heat treatment by the customer.</p> <p>Environmental microbiological results are not used to determine product disposition.</p> <p>Finished products and raw materials are never held pending acceptable microbiological results.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>The facility has a microbiological testing program for sanitation and finished product. Due to the nature (low water activity) of the finished product, there is a limited risk of microbiological growth. Therefore, finished product is sampled every three months for total viable count, coliforms, Salmonella and yeasts and molds. There were no out of specification results available to verify during the audit but the procedures for handling results of out of specification product was clearly explained. Microbiological results are not used to determine product disposition. The microbiological sampling plan on finished product is only used as an indicator of background microbiological levels. The product has a low moisture and water activity content and is subject to further heat treatment by the customer.</p>

**Facility's Response to Auditor's Observations**

**Section 3.3 Analytical Testing for Food Safety and/or Regulatory Compliance**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
3.3.1	Analytical testing is conducted as part of the Food Safety program	No analytical testing is conducted by this facility as part of its facility's Food Safety program.
3.3.2	Appropriate decisions are made based upon food safety related analytical testing results	
<b>SECTION JUDGMENT:</b>		<b>Not Applicable / Auditable</b>
<b>SECTION SUMMARY:</b>		No analytical testing is conducted by this facility as part of its Food Safety program.

**Facility's Response to Auditor's Observations**

**Section 3.4 Food Allergens and Chemical Sensitivities**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
3.4.1	Food allergens and sensitizing chemicals are identified and managed at the facility	<p>This facility neither uses nor stores recognized food allergens.</p> <p>.</p> <p>.</p> <p>.</p> <p>The facility provides allergen-specific training to personnel working with or handling allergens. Allergen training is provided to employees at this facility and covers products an employee may bring into the facility (e.g., lunches and snacks purchased through vending machines).</p>
3.4.2	Procedures are in place to prevent cross contamination of products by undeclared allergens and sensitizing agents	<p>.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p>
3.4.3	Labeling and packaging procedures exist to ensure that only correct labels are used Labels are verified to be correct relative to the appropriate allergens	<p>.</p> <p>.</p> <p>.</p>
3.4.4	Rework procedures are in place to prevent the cross contact of products with an undeclared allergen	<p>.</p> <p>.</p> <p>.</p> <p>.</p>
<b>SECTION JUDGMENT:</b>		<b>Not Applicable / Auditable</b>
<b>SECTION SUMMARY:</b>		Although this facility neither uses nor stores recognized food allergens/sensitizers; it does provide training to their employees covering allergen items an employee may bring into the facility or buy through a vending machine.





**Section 3.5 Foreign Material Control**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
3.5.1	Procedures or devices are in place for foreign material control	<p>The facility has documented procedures and work instructions regarding the control of foreign materials.</p> <p>Foreign material control devices at Best Company Mills are stringent with various mechanisms present at every raw material decanting stage (e.g. magnets, in line sieves, in line metal detectors and end of line metal detectors).</p> <p>The magnets, in line metal detector and rotary sieve are present at the exit of the corn silos. The sugar hopper has a static sieve with an in line metal detector. The Sodium Bicarbonate and Salt has a static sieve and a magnet. The monoglyceride emulsifier has a static sieve with a magnet. Palmoleine oil is pumped through a stainless steel strainer. Culinary steam passes through a 150 micron stainless steel filter. The formed and dried product passes over a 2 stage sieve. An end of line metal detector with an auto reject mechanism is present after the bed dryer and pre-packing and checked against 1.5mm ferrous and 2.0mm stainless steel test piece according to set frequencies.</p> <p>Foreign material control devices are monitored at prescribed frequencies.</p> <p>Specialized training to employees who monitor or handle foreign material control devices is provided by the facility.</p> <p>Work instructions with regards to calibration of metal detector and/or X-ray equipment include the frequency of test, the test piece size and requirements for an acceptable test. The in-line metal detectors are checked against 2mm ferrous, 2.0mm magnetic stainless steel and 2.5mm non magnetic stainless steel test pieces on a daily basis. The end of line metal detector is checked according to the metal detection verification procedure (FAB 100-1). This is described in the HACCP section of this report.</p> <p>A process employee questioned during the audit was able to explain the mechanisms of ensuring the magnets, sieves and metal detectors performed correctly and corrective action taken when a test piece is rejected. Procedures and records for documenting such checks were reviewed and revealed they were done in accordance with written documentation.</p> <p>The facility monitors foreign material control devices for integrity and functionality.</p> <p>Pre-operational/post-maintenance inspections target equipment for any metal-to-metal contact points, missing nuts or bolts and equipment wear.</p> <p>Pre-operational and post-maintenance inspections of foreign material control devices are documented and include corrective actions.</p> <p>There is no wood permitted in the facility with exception of the warehouse. Any wooden pallets storing raw materials are fully wrapped in plastic before they are taken to the weighing and mixing areas.</p>

3.5.2	Corrective action is taken if a foreign material control device (including metal detector/x ray) is found to be nonfunctional	<p>Corrective action is taken if a foreign material control device is found to be missing or nonfunctional.</p> <p>The facility has product hold procedures that define what leads to a "HOLD" and the scope/amount of product to be held.</p> <p>Product hold procedures define acceptable methods for re-inspection and sensitivity of the equipment used to release product.</p> <p>A process employee was able to explain the corrective action and hold procedures if the metal detector (CCP) failed to reject the test pieces during verification checks. There were no incidences to review of failed/rejected test pieces during verification checks.</p>
3.5.3	Effective procedures are in place for the prevention of glass/brittle plastic contamination breakage and handling	<p>The facility has a documented glass/brittle plastic control procedure.</p> <p>Glass and hard plastic procedure (FAB 160) outlines the glass/plastic control procedures for this facility and actions required in the event of breakage.</p> <p>All items of hard plastic such as hopper inspection windows, gauge dials, process control panels, forklift truck lenses, overhead light diffusers including ultra violet light tubes in electric fly killer units are included in the glass/plastic control policy.</p> <p>Documented work instructions for managing glass/brittle plastic are provided by the facility.</p> <p>Inspection and approval procedures for line start-up following a breakage incident are defined.</p> <p>Glass/brittle plastic control procedures identify areas where usage of glass utensils is permitted.</p> <p>. This facility does not need to maintain a highly audited "glass free zone" because they do not package products in glass containers, this item is N/A.</p> <p>Overhead lights in mixing and processing area are all covered with plastic diffusers. Halogen lights in the warehouse have glass covers due to the high temperature generated, however the risk of breakage is minimal as the lights are well above the pallet racking system.</p> <p>. If some type of glass breakage did occur, the Quality Manager is responsible for ensuring the procedures are fully adhered to, but again this facility does not package product in glass containers.</p> <p>Based on observations, employees were knowledgeable of the glass/plastic control procedures and records to fill out if a glass breakage incident does occur.</p> <p>A process employee and a team leader were questioned regarding the glass/hard plastic breakage procedure and provided satisfactory answers regarding steps to take if a glass breakage incident occurs.</p> <p>.</p>

3.5.4	Lubricants used are food grade where necessary	<p>Documented procedures exist regarding the use and control of food grade lubricants.</p> <p>There is documented evidence that lubricants used near exposed food or food-contact surfaces are food grade, and are used according to labeled instructions.</p> <p>Cleaning chemicals and lubricants are all stored in their original containers in designated areas on plastic spillage containment pallets.</p> <p>During the audit, non-food grade lubricants did not appear to be applied inappropriately.</p> <p>Exposed food or food-contact surfaces beneath lubricated mechanisms are properly protected by drip pans.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>The facility has documented procedures and work instructions regarding the control of foreign materials. Foreign material control devices at Best Company Mills are stringent with various mechanisms present at every raw material decanting stage (e.g. magnets, in line sieves, in line metal detectors and end of line metal detectors). The facility monitors foreign material control devices for integrity and functionality. Pre-operational/post-maintenance inspections target equipment for any metal-to-metal contact points, missing nuts or bolts and equipment wear. Corrective action is taken if a foreign material control device is found to be missing or nonfunctional. The facility has a glass/hard plastic breakage policy. Accountabilities for line start-up are defined. The Quality Manager is responsible for ensuring the procedures are fully adhered to. All chemicals and lubricants used on site must be approved and food grade. Lubricants are all stored in their original containers in designated areas on plastic spillage containment pallets.</p>

**Facility's Response to Auditor's Observations**

**4.0 MANUFACTURING QUALITY SYSTEMS**

**Section 4.1 Conformance to Customer Specifications**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
4.1.1	Customer specific standards are evaluated and controlled	<p>There are documented procedures for accepting customer orders and specifications.</p> <p>The facility verifies whether it has the capability, required test methods, equipment and trained analysts to produce product that will conform to customer specifications?</p> <p>The facility contacts its customers whenever specifications cannot be met. The facility ensures that it meets all customer requirements and addresses any conformance issues as they arise. Finished product is not permitted to be shipped unless it meets the finished product specification.</p> <p>There is only one product produced at this facility with one product specification. All quality parameters and product characteristics are available to process employees through the computerized MQIS (Manufacturing Quality Inspection System).</p> <p>.</p> <p>Versions of specifications in use during the audit were verified to be the most current and up-to-date.</p>
4.1.2	Co manufacturers are managed and steps are taken to ensure conformance to customer specifications	<p>This facility does not use any co-manufacturers to produce products for its customers.</p> <p>.</p> <p>.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>There are documented procedures for accepting customer orders and specifications. The facility ensures that it meets all customer requirements and addresses any conformance issues as they arise. Finished product is not permitted to be shipped unless it meets the finished product specification. There is only one product produced at this facility with one product specification. All quality parameters and product characteristics are available to process employees through the computerized MQIS (Manufacturing Quality Inspection System). This facility does not use any co-manufacturers to produce products for customers.</p>

**Facility's Response to Auditor's Observations**

**Section 4.2 Process Control**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
4.2.1	Process control procedures are in place to ensure conformance to specifications	Control activities conducted during the processing phase are not required, due to the type of process or product at this facility.
4.2.2	Current procedures are available for operators for all prescribed process and quality checks	.
4.2.3	Statistical process controls are utilized	Statistical Process Control is not utilized at this facility. . . .
<b>SECTION JUDGMENT:</b>		<b>Not Applicable / Auditable</b>
<b>SECTION SUMMARY:</b>		Control activities conducted during the processing phase are not required, due to the type of product or process at this facility.

**Facility's Response to Auditor's Observations**

**Section 4.3 Inspection & Test**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
4.3.1	Finished products are inspected and tested to ensure conformance to internal and/or customer requirements	<p>This facility has a finished goods inspection program that ensures conformance to internal or customer specifications.</p> <p>Results from finished goods inspections are reviewed to determine whether products comply with internal or customer standards.</p> <p>The Quality Manager is responsible for ensuring finished product complies with the finished product specification and customer requirements.</p> <p>Organoleptic evaluations are performed on finished goods. Visual checks are conducted on finished product for quality defects such as misshapes, flats and strings every 2 hours. A sample of finished product is also fried according to set guidelines and compared against an "optimum" library sample. Assessment includes an evaluation of color, texture, taste, odor including solubility. Scoring is marked on a 1 (lowest score) - 9 (highest) scale with comments available to help scoring. The evaluation against the library sample is conducted daily by an assessment panel.</p> <p>There is no sample retention program in place as all finished product is subject to positive release.</p>
4.3.2	Finished goods records are available to show evidence of inspection and test results	<p>All process and quality data is maintained on the respective computer systems for all production runs which can be retrieved by conducting a search with set date or within a given time frame. Finished product inspection records including shipping and delivery notes were available for product with lot number 138687.</p> <p>Finished goods inspection records for the trace exercise selected during the audit (production date: March 22, 2006) indicated that all results were within specification and retrievable for review from the record storage system.</p>
4.3.3	Finished goods records are reviewed before product release to customers	<p>The facility executes a positive release system for finished goods. The positive release system (COA) details physical attributes such as moisture, density, clusters and trim strips on raw product. Bulk density, goodness index score, flats, breakages, clusters, trim strips, cooker char, split/peelback, doubles and misalignment results are recorded for the product in a fried state. Results reviewed for April 2, 2006 were within specification.</p> <p>Inspection of paper records are reviewed on a daily basis by Senior Management. The process team leader is responsible for highlighting any out of specification results for the Quality Manager. The Quality Manager reviews the checks conducted on CCP/foreign body controls through paper records. The Quality Manager has remote access to the MQIS system either at the facility or away from the facility through a password control access feature. The Quality Manager or Operations Manager is responsible for releasing finished goods.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		<p>The Quality Manager is responsible for ensuring finished product complies with the finished product specification and customer requirements. There is no sample retention program in place as all finished product is subject to positive release. The Quality Manager or the Operations Manager reviews finished product inspection records pending release. Inspection records are reviewed on a daily basis by Senior Management. The process team leader is responsible for highlighting any out of specification results to the Quality Manager. The Quality Manager reviews the checks conducted on CCP/foreign body controls through manual records. The Quality Manager or Operations Manager is responsible for releasing finished goods.</p>



**Section 4.4 Control of non conforming Materials**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
4.4.1	Non conforming product is segregated and controlled against inadvertent shipment	<p>This facility has a product non-conformance ("Hold") procedure to identify, segregate, control and manage the disposition of non-conforming materials. A process team leader is responsible for ensuring non-conforming product is put on hold. The Quality Manager is the only person authorized to release product on hold. There are 3 color coded labels used to identify product with a deviation issue. Red label indicates a product is blocked/held, an orange label indicates product is destined for rework (re-feed) and green indicates that previously held product is released. There is a special non-conforming product storage area in the warehouse for finished product/raw materials. A non-conforming area also exists for packaging. There was a pallet of cardboard tote boxes which were present in the packaging non-conformance area however there was no indication on the pallet of the hold number or reason for non-conformance (although records were available elsewhere). Finished product is blocked on Best Company Mills "K-Roll" computer system with a corresponding alpha code. This blocked product is only transferred onto Seretram's SAP system when the product has been released by the Quality Manager.</p> <p>Non-conformance procedures at this facility are fully documented.</p> <p>Product non-conformance procedures apply to raw materials, work-in-progress, and finished products.</p> <p>This facility is not permitted to ship non-conforming product. Therefore, no customer communication procedures are required.</p> <p>.</p> <p>A process employee was asked to clarify the deviation procedure during the facility audit. The employee explained that a deviation record would be completed which highlights the deviation, product concerned, time including an investigation and documentation of corrective/preventive actions. Blocked non-conforming product is then stored in the designated quality area within the warehouse. Answers provided correlated with the procedure.</p> <p>No instances of non-conforming materials inadvertently released to production or shipped to the customer were noted during the audit.</p> <p>Only specifically authorized personnel are allowed to release held product back to distribution. The Quality Manager is authorized to release product, block product or destroy non-conforming product.</p> <p>There were no methods used to audit or challenge the product non-conformance program.</p>
<b>SECTION JUDGMENT:</b>		<b>Substantially Meets</b>
<b>SECTION SUMMARY:</b>		<p>A process team leader is responsible for ensuring non-conforming product is put on hold. The Quality Manager is the only person authorized to release product on hold. The site does not ship product to customers outside of the product specification. All products must conform to pre-determined parameters. No instances of non-conforming materials inadvertently released to production or shipped to the customer were noted. There was a pallet of cardboard tote boxes which were present in the packaging non-conformance area however there was no indication on the pallet of the hold number or reason for non-conformance (although records were available elsewhere).</p>

**Facility's Response to Auditor's Observations**

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ISSUE: Unmarked tote boxes found in packaging "hold" area.

DETERMINATION OF CAUSE: The material in question were actually spent totes destined for recycling. They should have been stored near the recycling room, but were mistakenly placed in our "hold" area.

CORRECTIVE ACTIONS: Within one hour of being notified, the materials were moved to their proper location.

VERIFICATION: QC has been asked to inventory all materials in the "hold" area on a daily basis, reporting any discrepancies to the Ops Manager. Also, when such materials are collected, the Processing Department Supervisor is responsible to ensure the bundling and marking of any refuse container. Fork lift drivers have been instructed not to carry out any materials unless clearly marked.



**Section 4.5 Good Laboratory Practices**

Section 4.5 Good Laboratory Practices	
AUDIT ITEM	OBSERVATION
4.5.1 Analytical and microbiological testing are performed in a suitable laboratory	<p>No analytical or microbiological testing is performed at this facility. Quality checks are only conducted at the facility including a check for moisture content. No chemicals or hazardous material is used in the process/control laboratory.</p> <p>.</p> <p>Some or all analytical and microbiological testing is performed by contracted laboratories. Eurofins conducts pesticide analysis and Eurofins Genescan conducts GMO analysis. Microbiological analysis for water, product and surface/environmental swabs is conducted by Laboratoires des Pyrenees.</p> <p>Best Company Mills follows an approval process which ensures the laboratory is accredited to ISO 17025. The site also checks if the laboratory conducts any proficiency testing including any other external accreditations.</p> <p>The facility verifies that contract laboratories follow approved methods for required analyses.</p>
4.5.2 Laboratory procedures follow recognized and/or official methodology for all tests for which such standards exists	<p>The facility conducts quality testing only.</p> <p>. The in-house laboratory follows procedures defined by Best Company Mills and/or customer prescribed methods.</p> <p>An up-to-date laboratory manual with testing procedures is available at this facility.</p> <p>The facility verifies that internal and/or customer-specified methods are used.</p> <p>The quality manager described which tests are performed and which tests are conducted on behalf of customer requirements.</p> <p>Best Company Mills obtains guidance from the customer relating to the receiving country's product testing requirements. There is also a person responsible at Seretram for exporting conditions i.e. Customs /Health Certificate requirements.</p> <p>Laboratory procedures used in the facility had references to officially approved methodologies. Moisture is analyzed by following the official method NF EN ISO 12880 (X33-005).</p>
4.5.3 Laboratory methods are validated for accuracy and analyst proficiency is verified periodically	<p>** Laboratory methods are not validated for accuracy or reproducibility.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p> <p>Steps are taken by the facility to verify that contract laboratories also conduct self-validation procedures.</p>
<b>SECTION JUDGMENT:</b>	<b>Partially Meets</b>

<b>SECTION SUMMARY:</b>	Quality checks are only conducted at the facility including a check for moisture content. No chemicals or hazardous material is used in the process/control laboratory. Eurofins conducts pesticide analysis and Eurofins Genescan conducts GMO analysis. Microbiological analysis for water, product and surface/environmental swabs is conducted by Laboratoires des Pyrenees. Best Company Mills follows an approval process which ensures the laboratory is accredited to ISO 17025. Currently, for the moisture quality test this facility is performing there is no validation concerning the accuracy or reproducibility by the different technicians.
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**Facility's Response to Auditor's Observations**

**ISSUE:** Moisture testing is not periodically validated.  
**DETERMINATION OF CAUSE:** This validation testing has not been done in the past because it was felt that the test equipment was self-standardizing. However, the auditor pointed out that even though the equipment is self-standardizing, individual technicians could make mistakes by adding the wrong sample size, misreading the dial indicator, etc.  
**CORRECTIVE ACTIONS:** In February, we began a quarterly program with our sister facility to cross-check each technician's results from samples with known moisture content.  
**VERIFICATION:** These quarterly cross-checks are reviewed by the corporate Technical Services Director. Any deviation from statistical norms result in instrument recalibration and technician retraining.

**Section 4.6 Document Control and Record Keeping**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
4.6.1	Systems are in place for managing and controlling food safety and quality related documentation data and records	<p>The facility employs a formal system to manage and control all food safety and quality related documentation, data and records.</p> <p>All policies/procedures and recording documents are electronic and available to all users through the Achiever computer system. New documents are listed with a document type, document category, document reference, revision, issue date, author, owner and approved by details. Any amendments to set documents must be requested and authorized prior to change and electronic replacement. There is an "audience" list of users which facilitates the notification of any updates or removal of obsoletes.</p> <p>The Quality Manager or Operations Manager is approved to authorize and issue documentation relating to quality/food safety.</p> <p>Documents containing sensitive information relating to customer confidentiality are not released by Best Company Mills. Other documents/procedures which do not contain sensitive details are signed as an uncontrolled copy with the date and signature of the Quality Manager.</p> <p>All quality management system data is backed up with Seretram's server on a daily basis. Best Company Mills also has a fire/flood proof safe on site where backup tapes may be stored. Computer terminals can only be accessed through password entry controls.</p> <p>There is documented records retention policy whereby records associated to traceability are retained for 7 years. CCP's and HACCP records are retained for 5 years along with all other quality management system documentation e.g. complaints, deviations, internal audits and specifications etc.</p> <p>Foreign body verification check records (e.g. magnet checks) were reviewed during the audit and were noted to be current, complete and up-to-date.</p> <p>Magnet, sieve checks, metal detection records and mixing ingredient records were reviewed during the audit and were noted to be signed, dated and authorized by appropriate personnel.</p> <p>Electronic records are maintained. Electronic Food Safety/Quality records are password protected to monitor access.</p> <p>It was determined during the audit that the facility ensures Quality system documentation is captured electronically and is accurately maintained.</p> <p>Electronic record requirements include security measures, signatures, and audit trails.</p>
4.6.2	Food safety and quality related records are legible and correct Proper procedures are utilized for making corrections	<p>Records reviewed during the audit were legible and accurate.</p> <p>The facility follows proper procedures for making corrections to records; i.e., ink only, no "white-out" or erasures, no pre- or post-entering of data, false signatures, etc.</p> <p>Food safety and quality related records are signed and dated by the reviewer to verify the review process.</p> <p>All production and quality records are checked at least daily or earlier if required, by the Quality Manager or the Operations Manager.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>

**SECTION SUMMARY:**

The facility has a system to manage and control all quality-related documentation, data and records. The Company follows the requirements for document control based on ISO 9001:2000. The Quality Manager or Operations Manager is approved to authorize and issue documentation relating to quality/food safety. There is documented records retention policy whereby records associated to traceability are retained for 7 years. CCP's and HACCP records are retained for 5 years along with all other quality management system documentation e.g. complaints, deviations, internal audits and specifications etc. It was determined during the audit that the facility ensures Quality system documentation is captured electronically and is accurately maintained. Electronic record requirements include security measures, signatures, and audit trails. All records reviewed during the audit were legible and accurate. Raw and finished goods are released by authorized personnel only. All production and quality records are checked at least daily or earlier if required, by the Quality Manager or the Operations Manager.

**Facility's Response to Auditor's Observations**

**Section 4.7 Corrective and Preventive Action**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
4.7.1	The corrective and preventive action process is defined and includes: identification of the issue investigation of root cause timely corrective action and follow up to confirm implementation and effectiveness	<p>The facility has a systematic approach or program for corrective and preventive actions.</p> <p>There are documented procedures for managing corrective and preventive actions.</p> <p>The corrective and preventive action process includes identification of the issue, investigation of root cause, corrective actions and follow-up to verify that the steps implemented are effective.</p> <p>This supplier maintains corrective and preventive action logs.</p> <p>The facility collects and analyzes information or data that would help it prevent future product failures.</p> <p>Corrective and preventive actions are reviewed as part of the management review process according to the ISO 9001:2000 requirement. The last management review meeting was conducted on March 23, 2006 where a review of such actions was part of the agenda and the minutes.</p> <p>An issue relating to the base seal of food contact plastic bags was noted with a corrective action notice being forwarded to the packaging supplier on November 3, 2005. A corrective action response was received from the supplier on December 23, 2005 who had documented that an improvement to the bag sealing process within the supplier's facility had been made. Best Company Mills has had no further issues with bags to date.</p>
	<b>SECTION JUDGMENT:</b>	<b>Fully Meets</b>
	<b>SECTION SUMMARY:</b>	<p>The facility has a systematic approach or program for corrective and preventive actions. There are documented procedures for managing corrective and preventive actions. This supplier maintains corrective and preventive action logs. The facility collects and analyzes information or data that would help it prevent future product failures. An issue relating to the base seal of food contact plastic bags was noted with a corrective action notice being forwarded to the packaging supplier on November 3, 2005. A corrective action response was received from the supplier on December 23, 2005 who had documented that corrections to the bag sealing process had been made.</p>

**Facility's Response to Auditor's Observations**

**Section 4.8 Continuous Improvement**

<b>Section 4.8 Continuous Improvement</b>	
<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
4.8.1 A systematic proactive approach examines and improves current practices before issues arise	<p>The facility has a continuous improvement program in place that examines and improves current practices before issues arise.</p> <p>There are several key performance indicators set by Best Company Mills which measures the efficiency of the quality management system, monitors corrective actions and highlights areas for improvement. KPI's are set as measurable targets for all areas of the business; for example, KPI's are based on first time quality, number of complaints, results of audits (internal and external), shut down time periods for maintenance, corrective actions including number of health &amp; safety incidents.</p> <p>Due to the size of the facility, a limited number of people work on improvement projects and meet on a recurring basis. Depending on the issue, Best Company Mills tries to select one management employee, one hourly employee from the area where the issue has been identified and one hourly appointment from a different part of the plant to provide an outsiders perspective of the issue.</p> <p>There is a formal management review of all continuous improvement opportunities. The Quality Manager, Operations Manager and Engineering Manager review the continuous improvement program through formal management reviews. The Quality Manager also presents data on complaints and key achievements at the monthly Best Company Mills Group European Quality Meetings.</p> <p>Best Company Mills has been reviewing and investigating the need to implement a central vacuum system in processing (i.e. weighing/mixing area) so that the areas can be vacuumed on a regular basis. This latest project was a huge investment for the Company. The central vacuum system is only just fully operational and has taken approximately one year to commission.</p>
<b>SECTION JUDGMENT:</b>	<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>	The facility has a continuous improvement program in place. There are several key performance indicators set by Best Company Mills which measures the efficiency of the quality management system, monitors corrective actions and highlights areas for improvement. KPI's are set as measurable targets for all areas of the business; for example, KPI's are based on first time quality, number of complaints, results of audits (internal and external), shut down time periods for maintenance, corrective actions including number of health & safety incidents. The Quality Manager, Operations Manager and Engineering Manager review the continuous improvement program through formal management reviews.

**Facility's Response to Auditor's Observations**

**Section 4.9 Customer/Consumer Complaints**

Section 4.9 Customer/Consumer Complaints	
AUDIT ITEM	OBSERVATION
4.9.1 Procedures manage customer/consumer complaints suggestions and inquiries in a timely manner	<p>. Customer communications are managed at the facility, handling all complaints, suggestions and inquiries.</p> <p>. Customer communication procedures for the facility are documented.</p> <p>. From a review of communications during the audit, it was confirmed that customer communication procedures are followed.</p> <p>. Customer communication procedures define accountability for managing the complaints. Customer complaints can be received either directly by the Quality Manager at the facility or via the Corporate Group.</p> <p>. Employees who manage the customer communications program have received training.</p> <p>. This facility has an up-to-date list of customer contacts with whom it can discuss issues.</p> <p>The facility does not have any key measurements for success noted in handling and resolving customer complaints.</p> <p>. Customer complaints, suggestions and inquiries reviewed during the audit indicate they are processed in a timely manner. Twenty customer complaints were reviewed during the audit. The majority of the complaints were due to obliterated coding information. The complaints were investigated and the customers were provided a response within 5 days. The ink-jet code dater was replaced with a laser-jet machine. The complaints have been reduced to one in the last six months.</p>
<b>SECTION JUDGMENT:</b>	<b>Substantially Meets</b>
<b>SECTION SUMMARY:</b>	Customer complaints can be received either directly by the Quality Manager at the facility or via the Corporate Group. Twenty customer complaints were reviewed during the audit. The majority of the complaints were due to obliterated coding information. The complaints were investigated and the customers were provided a response within 5 days. The ink-jet code dater was replaced with a laser-jet machine. The complaints have been reduced to one in the last six months. The facility does not have any key measurements for success noted in handling and resolving customer complaints.

**Facility's Response to Auditor's Observations**

ISSUE: The auditor claims our customer communication program does not include "key measurements for success".

RESPONSE: Our customer communication program indeed includes key measurements for success (called "Goals for Customer Feedback"). They were in the binder given the auditor during his document review process. They are easily found in the inside cover of our Customer Communications Manual. They must not have been pointed out to the auditor during his visit.

CORRECTIVE ACTIONS: Our audit coordinator who accompanies auditors during their visits will ensure this information is presented to all future auditors.

VERIFICATION: A copy of these goals is available to the SAFE auditor and our customer upon request.



**Section 4.10 Internal Auditing**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
4.10.1	A documented internal audit program ensures ongoing compliance with quality and food safety standards	<p>The facility has a documented internal auditing program to ensure ongoing compliance with quality and safety standards.</p> <p>Both a facility audit schedule and an up-to-date audit log are kept as part of the internal audit program</p> <p>The facility performs a quality system audit twice a year and GMP/Hygiene audits monthly.</p>
4.10.2	The audit process is managed and conducted by trained qualified individuals	<p>There are accountable individuals assigned to manage the internal audit program. The quality manager is responsible for managing the internal audit program.</p> <p>Both the Quality Manager and the Engineer Manager has received specific internal auditor training at Socotec (external company) on January 22, 2004.</p> <p>The auditors who appear on inspection reports and perform internal audits have received specialized training. Documented qualifications exist for internal auditors either through external training courses or through in-house training from Best Company Mills Group personnel.</p> <p>Auditors are independent of the areas they audit.</p>
4.10.3	The audit process is effectively implemented	<p>Internal audits adhere to written procedures, standards and/or checklists.</p> <p>Reports are issued detailing the findings from internal audits.</p> <p>After reviewing records it was indicated that corrective actions are responded to within a reasonable amount of time. An internal audit of sanitation was conducted by an auditor from Seretram on September 1, 2005 and was closed out on September 20, 2005.</p> <p>Established procedures verify corrective actions taken after an internal audit are done promptly and correctly.</p> <p>Results of the internal audits are periodically reviewed with the management team. Records demonstrated that the management reviews occur at the frequency established by the facility. Management reviews are conducted monthly where the results of internal audits forms are an integral part of the meeting.</p> <p>This auditor went to the specific sites identified in the inspection report and determined that corrective actions were performed as stated in the closed out work orders.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		The facility has a documented internal auditing program. The Quality Manager is responsible for managing the internal audit system at Best Company Mills. Auditors are independent of the areas they audit. Internal audits adhere to written procedures, standards and/or checklists. Reports are issued detailing the findings from internal audits. Management reviews are conducted monthly where the results of internal audits are an integral part of the meeting. This auditor went to the specific sites identified in the inspection report and determined that corrective actions were performed as stated in the closed out work orders.

**Facility's Response to Auditor's Observations**

**5.0 REGULATORY CONSIDERATIONS****Section 5.1 Labeling Approval**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
5.1.1	There is a documented process and procedure to develop review and approve labels	<p>There is a documented label approval process at this facility.</p> <p>The facility verifies that all labels comply with regulatory requirements.</p> <p>The facility obtains and verifies nutritional information for labels.</p> <p>This facility does make label and/or health claims regarding special processes or products. All certifications were up-to-date. All products are Kosher approved. Kosher Passover Certification was issued by the Federation of Synagogues on September 5, 2005 and is valid until August 1, 2006. The Company only uses corn from non-GMO sources. There is no reference to any special claims relating to "GMO-free" on the finished product label as the product is destined for further manufacturing.</p> <p>All labels are developed on-site using the facility's own specifications.</p>
5.1.2	Labels are verified before use as appropriate for the product being run	<p>Labels used on line during the audit matched the product and formulation that was being produced at the time of the audit.</p> <p>Labels are not pre-checked using UPC/bar code scanners or similar devices.</p> <p>All labels are automatically printed from the label machine at the point of weighing the final product. There is no procedure required for changeover.</p> <p>The facility does not package finished goods into "Brite Stock".</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		There is a documented label approval process at this facility. The facility verifies that all labels comply with regulatory requirements. This facility does make claims with regards to Kosher certification. All certifications were up-to-date. All labels are developed on-site using the facility's own specifications. Labels being used on line matched the product and formulation that was being produced at the time of the physical inspection.

**Facility's Response to Auditor's Observations**

**Section 5.2 Regulatory & Industry Compliance**

<b>AUDIT ITEM</b>		<b>OBSERVATION</b>
5.2.1	Facility products processes training and records comply with applicable local state and federal regulations	<p>The facility operates within all European food hygiene regulations and French National legislation. The facility also complies with regulations associated with genetically modified food and feed e.g. EC 1829/2003.</p> <p>The facility is a member of a French Trade Association "L'Alliance 7" who forwards regular periodicals and any new regulations or information relating to the industry to Best Company Mills. Regulatory updates are also disseminated from Best Company Mills QA Director and the Best Company Mills Group is a member of Campden &amp; Chorleywood Food Research Association.</p> <p>The Quality Manager is responsible for ensuring all regulatory requirements are complied with.</p> <p>Due to the products produced at this facility, the facility does not need the services of a Process Authority.</p> <p>Training has been provided and records exist for process employees regarding current regulatory requirements.</p> <p>There has been no recent visit by the regulatory authority to verify any non-compliance issues.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>
<b>SECTION SUMMARY:</b>		The facility operates within all European food hygiene regulations and French National legislation. The facility also complies with regulations associated to genetically modified food and feed e.g. EC 1829/2003. The facility is a member of a French Trade Association "L'Alliance 7" who forwards regular periodicals and any new regulations or information relating to industry issues. The Quality Manager is responsible for ensuring all regulatory requirements are complied with. There has been no recent visit by the regulatory authority to verify any non-compliance issues.

**Facility's Response to Auditor's Observations**

**Section 5.3 Management of the Regulatory Inspection Process**

	<b>AUDIT ITEM</b>	<b>OBSERVATION</b>
5.3.1	Management and training for the regulatory inspection process is in place	<p>There are documented procedures for handling regulatory inspections when they occur.</p> <p>Regulatory authorities are received and accompanied around the facility by the Quality Manager or other Senior Manager ensuring that any procedures or documentation are available for review as requested. Duplicate copies of any documents or samples are taken as a reference by Best Company Mills. Photographs are prohibited due to facility confidentiality. There is a procedure in place to ensure regulatory inspections procedures are followed (DIR 900, Revision 2 19th April 2006) although there has not been a need to use the procedure to date. The facility has not received a regulatory visit since it was commissioned for production in 2002.</p> <p>There is an up-to-date list with regards to personnel who manage the regulatory process. External contacts for the Group are obtained from the Corporate Crisis Booklet dated January 2006 which is issued by the Group quarterly.</p> <p>The regulatory inspection procedure includes 24-hour contact information with mobile numbers for the management staff. The names and numbers on this list appeared to be up-to-date.</p> <p>Personnel responsible for managing regulatory compliance and/or accompanying regulatory inspectors are provided specific training for this purpose. Guidelines for handling regulatory visits are disseminated from Best Company Mills Group and form the basis for training of management on site.</p>
5.3.2	Customers are notified if their product is not in regulatory compliance	Customers are notified if their product is determined to be out of regulatory compliance.
5.3.3	Duplicate samples are retained when a regulatory sample is taken	<p>Facility procedures require duplicates to be taken when regulators take samples.</p> <p>The facility retains and segregates affected lots while it awaits test results from the regulator.</p> <p>The customer is notified by the facility when a regulator evaluates that customer's product. The Quality Manager is responsible to notify the customer if their product was sampled/reviewed by a regulator.</p> <p>There has been no regulatory inspection on site to date; therefore, there are no records available for review.</p>
5.3.4	Duplicate copies of documents given to regulatory authorities concerning a customer's product are made	<p>Customers are notified when a regulator is given copies of documents/records pertaining to that customer's product. The Quality Manager is responsible to notify the customer if the regulator is given copies of their records/specifications.</p> <p>There has been no regulatory inspection on site to date; therefore, there are no records available for review.</p>
<b>SECTION JUDGMENT:</b>		<b>Fully Meets</b>

**SECTION SUMMARY:**

Regulatory authorities are received and accompanied around the facility by the Quality Manager or other Senior Manager ensuring that any procedures or documentation are available for review as requested. Duplicate copies of any documents or samples are taken as a reference by Best Company Mills. Photographs are prohibited due to facility confidentiality. There is a procedure in place to ensure regulatory inspections procedures are followed (DIR 900, Revision 2 19th April 2006) although there has not been a need to use the procedure to date. The facility has not received a regulatory visit since it was commissioned for production in 2002. There is an up-to-date list with regards to personnel who manage the regulatory process. External contacts for the Group are obtained from the Corporate Crisis Booklet dated January 2006 which is issued by the Group quarterly. +++

**Facility's Response to Auditor's Observations**