

**GMA Supplier Audits for Food Excellence (SAFE)
Audit Checklist #8ACL53**

Supplier Information

Plant Name: American Natural Soy Processors, LLC
Address: 1510 South 2nd Street

City: Cherokee
State/Province: Iowa
Country: USA
Postal Code: 51012
Closest Major Airport *: Omaha, Nebraska

Parent Organization (if applicable)

Company Name: Clarkson Soy Products, LLC
Address: PO Box 80
 320 East South Street
P.O. Box:
City: Cerro Gordo
State/Province: Illinois
Country:
Postal Code:
Company Public Web Site: www.clarksonsoy.com

Plant Contact Information

Job Title/Position	Name	Telephone	Fax	Email Address
Plant Manager:	Sam Jennett	.	.	samj@americannaturalsoy.com
Quality Manager:	Nicolle Jennett	712-225-3500	712-225-1299	nicoles@americannaturalsoy.com
&nbsp;	Curtis Bennett	217-763-2861	217-763-2111	curtis.bennett@clarksongrain.com
&nbsp;	Rick Bucker	217-763-2861	217-763-2111	rick.bucker@clarksongrain.com

Current Audit Information

Type of Audit Performed: Food Protection

Is the facility required to be registered with the FDA? Yes

Is the facility registered with the FDA? Yes

External ID #:

Audit Date: Jan 14, 2011

Auditor Name: Larry Calahan

Length of Audit: 4 Days (3 days on-site and 1 day off-site writing report)

Supplier Personnel With Auditor: Quality Manager, Owner/Manager, Corporate Manager, Production Manager/Maintenance Supervisor, Night Production Supervisor and Quality Assurance Lab Director.

Exit Interview With: No exit interview was conducted.

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

Does this facility audit their supplier either through a first/second/third party audit?
Identify the auditing company that performs those audits: N/A
Products Produced: Non-GMO, Organic, Non-Refined, Refined Vegetable Oils and Lecithins
Processing Method: Physical Non-chemical Refining
Type of Primary Packaging: 55 Gallon Drums, 6 Gallon Pails, 8 lb. Buckets, Bulk Rail and Bulk Trailers, Totes
Sizes of Primary Packaging: See above
New Product(s) Offering: None
Channels of Trade: Brokerage for resale
Hours of Operation: Sunday evening through Friday evening
Months of Operation: 12 Months

Structure Size, Construction, and Design

Year Built: 1960
Year(s) Updated: 2000
Size of Facility: 34,000 sq. ft.
Number of Employees: 17
Property Size: 10 acres
Neighboring Land Use: There is a warehouse/freezer to the South, A construction company to the North, a corn field to the East and a cornfield across the highway to the West
Building Materials, Exterior Walls: Sheet Metal and Concrete
Building Material, Interior Walls: Steel, Concrete, Painted Plywood
Building Material, Floors: Concrete
Building Material, Exterior Roof: Steel
Building Material, Interior Ceiling: Insulated Sheet Metal
Areas of the Plant Excluded from the Audit: None

Past Audit Information

Dates of Previous NFPA-SAFE Audits: Sep 21, 2007
(up to 3 years)

Executive Summary - Part 1

Auditor Judgement Summary		Auditor Judgement					
Category	Section	Fully Meets	Substantially Meets	Partially Meets	Does Not Meet	Critical Failure	N / A
1.0 MANAGEMENT RESPONSIBILITY	1.1 Management Commitment and Review	✓					
2.0 FUNDAMENTALS	2.1 Infrastructure	✓					
	2.2 Cleaning / 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/Product Defense	✓					
	2.15 Monitoring and Calibration of Measurement and Test Equipment						✓
	2.16 Calibration of Laboratory Equipment						✓
	2.17 Traffic Control						✓
	2.18 Facility Maintenance Program	✓					
3.0 FOOD SAFETY & HACCP SYSTEMS	3.1 Hazard Prevention/HACCP	✓					
	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 & Testing	✓					
	4.4 Control of non conforming Materials	✓					
	4.5 Good Laboratory Practices	✓					
	4.6 Document Control and Record Retention	✓					
	4.7 Corrective and Preventive Action	✓					
	4.8 Continuous Improvement	✓					
	4.9 Customer / Consumer Communication	✓					
	4.10 Internal Self auditing	✓					
5.0 REGULATORY CONSIDERATION	5.1 Label Control	✓					
	5.2 Regulatory & Industry Compliance	✓					
	5.3 Management of the Regulatory Inspection Process	✓					

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

	AUDIT ITEM	OBSERVATION
1.1.1	A facility quality policy is documented and is communicated to all levels of the organization	<p>The facility has a quality policy. American Natural Soy, Inc has the goal of processing and supplying the highest quality products in the industry to our customer specifications.</p> <p>The Owner/Manager authorized the policy.</p> <p>The quality policy is covered in all new hire training, employee training and is posted on some bulletin boards in the plant.</p> <p>The Quality Manager and Owner/Manager was interviewed to determine their understanding of the policy and how it was communicated to all employees. They were very familiar with the content of the policy and understood why a quality policy is so important to a company. They also knew how the policy was communicated to employees and where it was posted in the plant.</p>
1.1.2	A quality manual is documented	<p>There is a quality manual at this facility.</p> <p>Facility Quality Manual</p> <ul style="list-style-type: none">1 Administrative Policies1.1 Management Commitment1.2 Food Defense1.3 Crisis Management1.4 Recall & Traceability1.5 Customer Communication1.6 Vendor Approval1.7 Label Control1.8 Chemical Control1.9 Regulatory Compliance Program1.10 Continuous Improvement1.11 Corrective Action Program1.12 Document Control and Record Keeping2 Prerequisite Programs2.1 GMPs2.2 GLPs2.3 Training Program2.4 Allergen Control Program2.5 Sanitation Program2.6 Sanitary Construction, Design, and Installation2.7 Maintenance Program2.8 Equipment Calibration2.9 Water Quality Program2.10 Environmental Testing2.11 Foreign Material Control2.12 Pest Control2.13 HACCP2.14 Verification

		<p>3 Material Control</p> <p>3.1 Incoming Material Program</p> <p>3.1.1 Raw Material</p> <p>3.1.2 Processing Aids</p> <p>3.1.3 Packaging</p> <p>3.1.4 New Equipment</p> <p>3.2 Storage Program</p> <p>3.3 Outgoing Product</p> <p>3.3.1 Inspecting & Testing</p> <p>3.3.2 Product Release</p> <p>3.3.3 Transport</p> <p>4 Plant Certifications</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 food defense.</p> <p>The Quality Manager reports directly to the company Owner/Manager and indirectly to a Corporate Technical Manager.</p> <p>The groups responsible for quality and food safety are given sufficient authority to protect product and the customers' interests. The Quality Manager reports directly to the Owner/Manager of the company.</p> <p>The Quality Manager was interviewed and was able to explain how the quality department is given sufficient authority and accountability to ensure that non-compliant product or product being held can only be released by the Quality Department.</p> <p>Qualified temporary replacements are identified when key food safety and quality personnel are absent from the workplace?</p>
1.1.4	Quality system effectiveness reviews are conducted routinely	<p>Proper quality system effectiveness reviews are performed by management. The plant has improved their system review process to include a full quality system review and summary report with follow up of deficiencies and corrective actions. A system to ensure that corrective actions are effective will also be part of the review process.</p> <p>The reviews will be conducted at least quarterly and the reviews of all quality policies are completed on an annual basis.</p> <p>The facility performs corrective actions based upon results of the quality system effectiveness reviews.</p> <p>The facility proactively utilizes data collected during quality system effectiveness reviews to effect improvements.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The facility has a quality policy. The Owner/Manager authorized the policy. There is a quality manual at this facility. The Quality Manager reports directly to the company Owner/Manager and indirectly to a Corporate Technical Manager. Proper quality system effectiveness reviews are performed by management. The facility performs corrective actions based upon results of the quality system effectiveness reviews. The facility proactively utilizes data collected during quality system effectiveness reviews to effect improvements.

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 overhead attachments, were in good to excellent condition. The plant appeared to be very well maintained and during the tour, no facility deficiencies were observed.</p> <p>The plant has drains only in the processing area and the drains are trough type design. The floors are sloped to facilitate drainage. The drains have removable grates that allow adequate cleaning. The drains were properly maintained and clean. The drains do not appear to have any product contamination issues.</p> <p>There were no observations of potential for product contamination observed from foreign materials, condensation, dust, rust, peeling paint, etc. coming from overhead equipment, pipes or surrounding structures.</p> <p>Equipment was positioned to allow proper sanitation and maintenance. There were no issues observed with regards to the placement of the equipment.</p> <p>. There is very limited space between the suspended ceilings and the roof so inspection and repair is not possible and is not a requirement.</p>
2.1.2	Exterior grounds and structures are maintained in a condition that protects against the contamination of food and facility	<p>. The weather did not permit a detailed inspection of the outside grounds. A drive around was conducted and no obvious deficiencies were observed.</p> <p>Grounds were graded and sloped in such a way as to drain water away from outdoor structures and prevent water accumulation.</p>
2.1.3	Appropriate environmental controls (controlled temperature air filtration humidity lighting etc) are in place	<p>A HEPA filter system is utilized in the packaging area for all lecithin products produced at this facility. All other filling/packaging areas have air exhaust systems without managed air filtration. Temperature controls are not required for this process. Finished product is stored and shipped at ambient temperatures.</p> <p>Environmental control systems utilized by this facility appear to be effective. The only environmental controls used in the facility is associated with the HEPA filtration system which is a small contained area. Temperature control is also not required for the product.</p> <p>Records indicate that the effectiveness of environmental control systems is verified by this facility. This is applicable to the HEPA filtration system only.</p> <p>. Filtered air is only used in the HEPA filtration area.</p> <p>. The only records maintained for air filtration is in the HEPA system and this is serviced by an outside contractor annually or as required by production.</p> <p>Lighting in the facility meets the plant's internal requirements and appears adequate to maintain product safety and facilitate cleaning. The facility does not have specified lighting standards. There were no under-illuminated areas observed during the plant tour.</p>

2.1.4	All food contact surfaces are made from materials appropriate to the application eg stainless steel food grade plastics etc	<p>A policy is in place to control the materials from which food-contact surfaces should be constructed. The plant policy requires the use of stainless steel or food grade material for all product-contact applications. The use of stainless steel for food-contact applications are approved by all regulatory agencies.</p> <p>All food contact surfaces observed during the plant tour were made of stainless steel.</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>The plant water is provided by the city of Cherokee, IA.</p> <p>The following on-site treatments are given potable water and/or food-contact water prior to use: The plant utilizes a sand filter for all incoming water that is effective to .5 microns.</p> <p>The plant utilizes analytical and microbiological testing information from the municipality and this information is available monthly.</p> <p>. The water is softened using a salt/brine regeneration system.</p> <p>Food-contact steam is used on-site and the type and use of boiler chemicals meet government regulations. The food contact steam (including organic products) is used for sparging but there are no residual treatment chemicals remaining in this steam at point of application. Other boiler treatment water has chemicals to manage the boiler operation and these chemicals are approved for food applications.</p> <p>Food-contact ice is not used at this location.</p> <p>Since the plant does not conduct any water testing, no plant water testing results were reviewed. Water testing results from the city did not indicate any violative levels of chemicals or microbiological contaminants.</p> <p>There is no food-contact compressed air used at this site.</p> <p>Other properly filtered food-contact gases are used in this facility for the following purposes: Liquid nitrogen is used to clear lines with a purge of nitrogen between production runs.</p> <p>The food contact gases are not used in the product so monitoring is not applicable.</p>
2.1.6	Procedures are in place to protect water systems from backflow	<p>All water systems are protected against backflow.</p> <p>Although this facility stated its backflow prevention devices are inspected on a recurring basis, there were no records to support this claim. There were no back-flow prevention records to review.</p> <p>During the GMA-SAFE Assessment of this facility, no 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>Restrooms, locker areas and dining/break areas were observed during the audit and were well maintained, clean and well managed in a sanitary manner. The restrooms and fixtures appeared to be regularly cleaned and sanitized and trash was not overflowing.</p> <p>Restrooms and locker rooms do not open directly into processing or packaging areas.</p> <p>. There are no restrooms located in the production area and all restrooms in the office</p>

	<p>and break rooms do not open in production areas. The requirement for self-closing doors do not apply for this facility.</p> <p>Restrooms and locker rooms have ventilation that exhausts to the exterior of the facility.</p> <p>Plumbed systems in restrooms, locker rooms and related facilities, including heated water, appear to be fully functional.</p> <p>Hand washing/sanitation stations are readily available where ever needed. Hand washing signs were properly posted in English.</p> <p>Hand washing signs are posted at points of use in restrooms, locker rooms, hand sanitizing stations, dining areas and other related locations. The signs are posted in English and are approximately 8.5 X 11 inches.</p> <p>The hand washing stations are not equipped with hands-free faucets but are equipped with the following: antibicrobial soap, warm water, paper towels and trash containers.</p>
SECTION JUDGMENT:	Fully Meets
SECTION SUMMARY:	<p>The plant appeared to be very well maintained and during the tour, no facility deficiencies were observed. The drains were properly maintained and clean. A HEPA filter system is utilized in the packaging area for all lecithin products produced at this facility. All other filling/packaging areas have air exhaust systems without managed air filtration. Environmental control systems utilized by this facility appear to be effective. Records indicate that the effectiveness of environmental control systems is verified by this facility. Lighting in the facility meets the plant's internal requirements and appears adequate to maintain product safety and facilitate cleaning. The plant policy requires the use of stainless steel or food grade material for all product-contact applications. All food contact surfaces observed during the plant tour were made of stainless steel. The following on-site treatments are given potable water and/or food-contact water prior to use: The plant utilizes a sand filter for all incoming water that is effective to .5 microns. Other boiler treatment water has chemicals to manage the boiler operation and these chemicals are approved for food applications. Food-contact ice is not used at this location. Since the plant does not conduct any water testing, no plant water testing results were reviewed. There is no food-contact compressed air used at this site. All water systems are protected against backflow. Restrooms and locker rooms have ventilation that exhausts to the exterior of the facility. Plumbed systems in restrooms, locker rooms and related facilities, including heated water, appear to be fully functional. Hand washing signs were properly posted in English. Hand washing signs are posted at points of use in restrooms, locker rooms, hand sanitizing stations, dining areas and other related locations.</p>
	Facility's Response to Auditor's Observations

Section 2.2 Cleaning / Sanitation		
	AUDIT ITEM	OBSERVATION
2.2.1	There is a written comprehensive plant and equipment sanitation program	<p>This facility has a documented cleaning and sanitation/housekeeping program.</p> <p>The cleaning programs for the facility and operations are either daily or scheduled and monitored with a Master Sanitation/Cleaning schedule which includes all non-daily cleaning that applies to all areas in the facility (including outside grounds). The</p>

		<p>cleaning schedule also includes drains, overheads, walls and dock doors.</p> <p>Cleaning and sanitation frequencies are included in the cleaning and sanitation program and those frequencies are met. The principle sanitation effort is daily or when a change-over of product is required. During the plant tour, non-daily cleaning programs appear to be effective.</p> <p>Facility cleaning and sanitation efforts appear effective.</p>
2.2.2	Maintenance of the facility and its equipment ensures safe manufacture of wholesome foods	<p>Equipment is designed, constructed and situated to facilitate easy cleaning.</p> <p>Based on the plant tour and review of the cleaning program, the equipment appears to be adequately cleaned and evaluated prior to production start-up.</p> <p>Examined welds and seams appeared to be of good to excellent quality.</p> <p>No "dead head" piping was observed that might harbor stagnant product.</p> <p>No open "dead end" sections or spaces of pipes, railings, bollards, etc. were observed.</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>The work instructions for CIP/ COP/ Manual procedures include the following: 1. designated cleaning areas for tools/utensils, 2. Specific chemicals to be used, 3. Concentration, 4. Frequencies, 5. rinsing procedures and recleaning procedures.</p> <p>The plant uses visual inspection of equipment and ATP testing at several locations to verify the effectiveness of the sanitation procedures.</p> <p>This facility utilizes clean-in-place (CIP) systems. The lecithin processing line utilizes a CIP cleaning system.</p> <p>Chemicals are added to the system to be cleaned using a CIP procedure and then circulated within the system. The concentration is controlled by the amount of cleaning chemical added to the system.</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 in the cleaning of food-contact surfaces. The plant program only includes brushes for food contact cleaning activities (inside of pipes). No issues were observed during the plant tour.</p> <p>The brushes are color coded white for food-contact use.</p> <p>The written SOP procedures include the information for use of brushes for white food-contact applications.</p> <p>The facility has specific locations designated for storage of controlled utensils. All utensils were properly stored during the plant tour.</p> <p>Brush usage and storage practices were acceptable and no storage or usage deficiencies were observed.</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>The plant conducts visual evaluations (pre-operative) and ATP testing to verify that</p>

		<p>cleaning is effective.</p> <p>All personnel who perform pre-operational testing are trained specifically for this purpose. The training program for people conducting pre-op inspections and ATP testing is a combination of initial 3rd party supplier training, on-the-job instruction and coaching by the Quality and Management staff;.</p> <p>Results from pre-operational inspection and/or testing are reviewed by management on a frequent basis. The owner/manager reviews all exception issues at least weekly to ensure compliance to the program.</p> <p>Documented corrective actions are carried out whenever cleaning/sanitation standards are not met.</p> <p>Appropriate personnel are identified for management of the cleaning/sanitation program. A production supervisor is assigned to manage the cleaning and sanitation program.</p> <p>The production supervisor (night shift) was interviewed to determine his understanding of cleaning procedures, inspection programs and reporting requirements. He was very familiar with policies and procedures.</p>
2.2.6	For water free (dry) processing zones effective procedures are in place to clean equipment and structures	<p>This facility has no water-free processing areas.</p> <p>.</p> <p>.</p> <p>Water is never used for cleaning in these dry zones.</p> <p>.</p> <p>.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		<p>This facility has a documented cleaning and sanitation/housekeeping program. Cleaning and sanitation frequencies are included in the cleaning and sanitation program and those frequencies are met. During the plant tour, non-daily cleaning programs appear to be effective. Facility cleaning and sanitation efforts appear effective. Equipment is designed, constructed and situated to facilitate easy cleaning. This facility follows documented work instructions for cleaning and sanitation. The work instructions for CIP/ COP/ Manual procedures include the following: 1. designated cleaning areas for tools/utensils, 2. Specific chemicals to be used, 3. Concentration, 4. Frequencies, 5. rinsing procedures and recleaning procedures. This facility utilizes clean-in-place (CIP) systems. The lecithin processing line utilizes a CIP cleaning system. The plant program only includes brushes for food contact cleaning activities (inside of pipes). The facility takes steps to monitor the effectiveness of cleaning methods. The plant conducts visual evaluations (pre-operative) and ATP testing to verify that cleaning is effective. Appropriate personnel are identified for management of the cleaning/sanitation program. A production supervisor is assigned to manage the cleaning and sanitation program.</p>
		Facility's Response to Auditor's Observations

Section 2.3 Pest Control		
	AUDIT ITEM	OBSERVATION
2.3.1	A functioning documented pest control program is in place	<p>This facility has a functioning, documented pest control program in place.</p> <p>The pest control program is managed solely by the following third-party pest control contractor(s): Presto-X.</p> <p>The plant does not conduct any pest control activities except checking select interior traps to ensure that no pests are left in the device between PCO checks.</p> <p>The facility's pest control program does not list targeted pests.</p> <p>During the GMA-SAFE Assessment, no evidence of current, uncontrolled pest activity was observed within or outside of the plant.</p> <p>The Owner/Manager is notified by the PCO if there are any issues as part of the PCO inspection.</p>
2.3.2	Building exterior is protected from entry by rodents and other pests	<p>There were no exterior structural issues observed that would permit entry of rodents and/or other pests. All interior walls and openings to the outside were inspected during the plant tour. One dock door did not fully close at the bottom (ice build-up) and allowed some light from the outside. This opening was the only deficiency noted during the plant tour.</p> <p>. Screens are used when openings (doors or windows) are used to provide ventilation in high heat periods.</p> <p>There is a complete vegetation-free zone adjacent to all production and storage buildings. The vegetation-free zone (crushed rock) is approx. 30 inches wide and is around the entire perimeter of the facility. Some areas of the plant have concrete instead of crushed rock.</p> <p>Building exteriors are free of pest harborage sites such as obsolete equipment, maintenance and building materials, pallets, etc. stored close to facility structures.</p> <p>The plant utilizes trash containers that are located outside. The trash is removed daily and consists of material that is dry and would not attract common pests. The trash area is well maintained and does not pose any potential risk of contamination to the products or facility. Trash control inside the plant is also well managed.</p> <p>All applicable waste and lab waste is disposed of according to governmental requirements.</p>
2.3.3	The pest control program addresses types of devices and the monitoring of those devices	<p>The plant uses the following pest control devices: Bait stations (outside only), Curiosity traps, Glue boards (when required), Pheromone devices (when needed) and ILTs with glue boards and electrocutors where appropriate. The current devices appear to be effective (appropriate for pest monitoring) and are securely deployed. The bait stations are tamper resistant.</p> <p>Those who service pest control traps and bait stations are required to examine the interior of all devices. The PCO verifies inspection of the device by opening the device and scanning the bar code.</p>

		<p>The interior curiosity traps are inspected every other week year around and the plant personnel inspect select curiosity traps between the PCO checks. The ILTs are checked every other week year around. The outside bait stations are inspected every other week except when the stations are covered with snow or ice. Compliance to the schedule appears to be good.</p> <p>The facility has a schematic indicating current placement of pest control devices; e.g., bait boxes, mechanical traps, glue boards, ILTs, pheromone stations, etc. The map is dated as follows: 12/3/10 and 1/11/11. No devices were missing or improperly deployed.</p> <p>Poison bait stations are used at the facility in the following manner to control pests: The plant uses 20 poison bait stations around the perimeter of the building and also on the fence line. The spacing for the bait stations are approx. 40-50 feet apart.</p> <p>The facility uses "curiosity traps" in its pest control program. The plant uses 76 curiosity traps for interior and exterior monitoring and control. The placement of the curiosity traps are approx. 20 ft. and devices are located on both sides of openings to the outside. Glue boards are only used when appropriate.</p> <p>All insect light traps (ILTs) are properly deployed by the facility to control flying insects. The plant utilizes 5 insect light units throughout the facility. The units are a combination of light/glue boards. The placement of the devices are appropriate and does not create attraction problems.</p> <p>. Pheromone traps are only used when necessary or appropriate. Pheromone devices are not shown on the facility map.</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>Pest control records were reviewed and corrective actions were documented and observed activities, trend reports were also current and available for review.</p> <p>A review of recent records shows that no area of the facility is found to have repetitive pest activity.</p>
2.3.5	Application of pesticides is performed by certified applicators a licensed pest control contractor or under direct supervision of the same	<p>The PCO is the only person applying pesticides.</p> <p>It was observed that the contracted pest control company's business license is current.</p> <p>The pest control company's certificate of insurance is current and has the following expiration date: The expiration date is 1/1/11.</p> <p>It was observed that all individual applicator licenses are current.</p> <p>. Since the plant employees do not apply pesticides, training of plant employees is not applicable.</p> <p>The following rodenticide usage is documented: Quintox. No other pesticides were reported.</p>

		Restricted Use Pesticides (RUPs) are not applied at this facility.
2.3.6	The facility maintains and executes written procedures for the application of pesticides	<p>Except for rodenticides, other pesticides are not used at this facility.</p> <p>Pesticide application records contain 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 for pest control are labeled accurately and stored securely	<p>No pesticides of any kind, including rodenticides, are stored at this facility.</p> <p>..</p> <p>..</p>
2.3.8	The facility formally audits contracted Pest Control Operator performance	This facility formally audits contracted Pest Control Operator performance by the following means: As part of the quality system audit, the Quality Manager conducts a formal review of the pest control program to ensure full compliance to the program and corrective actions of deficiencies.
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		<p>This facility has a functioning, documented pest control program in place. The pest control program is managed solely by the following third-party pest control contractor(s): Presto-X. The plant does not conduct any pest control activities except checking select interior traps to ensure that no pests are left in the device between PCO checks. The facility's pest control program does not list targeted pests. Trash control inside the plant is also well managed. The plant uses the following pest control devices: Bait stations (outside only), Curiosity traps, Glue boards (when required), Pheromone devices (when needed) and ILTs with glue boards and electrocutors where appropriate. The bait stations are tamper resistant. Those who service pest control traps and bait stations are required to examine the interior of all devices. The facility has a schematic indicating current placement of pest control devices; e.g., bait boxes, mechanical traps, glue boards, ILTs, pheromone stations, etc. The facility uses "curiosity traps" in its pest control program. The plant uses 76 curiosity traps for interior and exterior monitoring and control. All insect light traps (ILTs) are properly deployed by the facility to control flying insects. The plant utilizes 5 insect light units throughout the facility. Pheromone devices are not shown on the facility map. Deficiencies revealed by the facility pest control program are documented. Pest control records were reviewed and corrective actions were documented and observed activities, trend reports were also current and available for review. It was observed that the contracted pest control company's business license is current. Since the plant employees do not apply pesticides, training of plant employees is not applicable. Record retention for pesticide applications meets all regulatory requirements.</p>
		Facility's Response to Auditor's Observations

Section 2.4 Chemical Control		
	AUDIT ITEM	OBSERVATION
2.4.1	A chemical control program manages the use storage and handling of non food chemicals	There is a documented control program for managing non-food chemicals at this facility.

		<p>. Since this company is small and controls of purchasing are managed by the Owner/Manager, Control of purchasing of chemicals is tightly controlled. All chemicals must be reviewed and approved by the Owner/Manager before they are allowed in the facility.</p> <p>No uncontrolled non-food chemicals were observed in GMP zones.</p> <p>The facility enforces the following procedures for the purchase of non-food chemicals: Non-food chemicals are listed on an approved vendor list and cannot be purchased unless they are on the list. Non-food chemicals are stored in restricted areas and cleaning chemicals are stored in multiple locations. Caustic chemicals are closely monitored and kept in a secure area.</p> <p>Non-food chemicals are stored in a centralized area with limited access. Current storage practices appear to be adequate for this type of process.</p> <p>All primary and secondary chemical containers for non-food chemicals observed during the GMA-SAFE Assessment were accurately and legibly labeled.</p> <p>Personnel designated to cleaning functions have received training for the proper use and storage of non-food chemicals.</p>
2.4.2	Material Safety Data Sheets (MSDS) or non USA equivalent are available for all non food chemicals	<p>The following Material Safety Data Sheets (or non-USA equivalent) or applicable chemical documentation were requested during the GMA-SAFE Assessment and all were shown the auditor during the review: 1. the works Toilet Bowl Cleaner, 2. Adorn Toilet Bowl Cleaner, 3. Antibacterial Liquid Hand Soap. The plant was able to produce MSDS information for these chemicals in a short period of time (less than 5 minutes).</p> <p>The plant maintains several hard copies of MSDS data sheets and provides copies in the following areas: Front Office, Employee Break Room and Laboratory.</p> <p>Material Safety Data Sheets (or non-USA equivalent) include both pesticides and food-contact sanitation chemicals.</p> <p>During the GMA-SAFE Assessment, 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>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		<p>There is a documented control program for managing non-food chemicals at this facility. No uncontrolled non-food chemicals were observed in GMP zones. The facility enforces the following procedures for the purchase of non-food chemicals: Non-food chemicals are listed on an approved vendor list and cannot be purchased unless they are on the list. Non-food chemicals are stored in restricted areas and cleaning chemicals are stored in multiple locations. All primary and secondary chemical containers for non-food chemicals observed during the GMA-SAFE Assessment were accurately and legibly labeled. Material Safety Data Sheets (or non-USA equivalent) include both pesticides and food-contact sanitation chemicals.</p>
		Facility's Response to Auditor's Observations

Section 2.5 Personnel Practices	
AUDIT ITEM	OBSERVATION

2.5.1	The auditor was included in the facility's GMP program	. The auditor received GMP instructions prior to gaining access to the facility.
2.5.2	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 has the following policy with respect to the wearing of hair restraints: Hair restraints are required in the packaging area where product is exposed.</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>
2.5.3	The wearing of jewelry or other potential contaminants 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.) Excessive make-up is not listed in the plant policy.</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> <p>The facility does not have a policy that prohibits the excessive use of colognes, perfumes, and other odorants.</p>
2.5.4	Employees follow proper hygiene practices to prevent contamination	<p>The facility has the following written policy regarding personnel hygiene and hand sanitation practices: All employees, visitors and contractors are required to wash their hands when visiting the restrooms or entering the packaging area where product is exposed.</p> <p>During the GMA-SAFE Assessment, 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 need hand sanitizing stations in addition to wash sinks because of the processes it employs.</p> <p>Since hand sanitizing systems are not required for this type of process, hands-free systems are not applicable.</p> <p>.</p> <p>.</p>
2.5.5	Employee gloves used for food safety related purposes are maintained intact clean and sanitary	<p>This facility follows a written employee glove control policy/procedure for food safety related purposes. Only one employee in the clean room is required to wear and maintain clean gloves to prevent product contamination.</p> <p>The gloves are sterile latex.</p> <p>Procedures are in place to ensure gloves are clean, intact and sanitary.</p> <p>All employees observed during the GMA-SAFE Assessment of the facility properly complied with the glove policy.</p>
2.5.6	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 consumption policy.</p> <p>There are specific areas designated by management for the storage of personal effects</p>

		<p>and consumption of food and tobacco.</p> <p>Meals are not prepared at this facility.</p> <p>All employees, visitors and contractors observed during the GMA-SAFE Assessment of the facility properly adhered to the facility consumption policy.</p> <p>During the GMA-SAFE Assessment, no personal items were observed being improperly carried or stored.</p>
2.5.7	Product containers are only used for their intended purposes	Containers or finished product packages are not used for anything other than their intended purpose; e.g., not used as parts holders, stools, door stops, step ladders, etc.
2.5.8	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 to be reassigned to non-sensitive work or sent home.</p> <p>Personnel health procedures require employees with open wounds to be adequately protected, reassigned to non-sensitive work or sent home.</p> <p>Management personnel are trained to recognize and respond to employee health issues.</p> <p>All employees, visitors or contractors observed during the GMA-SAFE Assessment appeared to properly comply with the facility's personnel health policy.</p>
2.5.9	Uniforms footwear and outer apparel are designed or controlled in a manner to prevent risk from foreign materials	<p>This facility has a policy prohibiting the use of top pockets in uniforms or 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>The facility apparel policy prohibits tobacco use and/or food consumption while wearing uniforms or other outer clothing that will be taken back to production or packaging areas.</p> <p>Since employees in sensitive areas wear lab coats, a changing area is not needed.</p> <p>All employees, visitors or contractors observed during the GMA-SAFE Assessment appeared to properly comply with the facility's apparel policy.</p>
2.5.10	Uniforms and outer apparel are maintained in a clean manner	<p>. The facility has a policy regarding usage, storage, segregation, and cleanliness of uniforms, and outer apparel. Shoes are not covered in the cleanliness policy.</p> <p>The type of process or product at this facility does not require the use of different types of apparel.</p> <p>. The company only provides a lab coat for employees in the clean packaging area. No other uniforms are used or issued to employees. There is no policy addressing wearing clothing when away from the work area except lab coats are required in the clean packaging area.</p> <p>. Laundering of personal clothing and lab coats is the responsibility of the employee,</p>

	<p>who takes soiled clothing home and brings them back clean.</p> <p>There are restrictions for footwear in the food sensitive area and protective booties are required over the employees' shoes in the sensitive area. This applies to contractors and visitors also.</p> <p>During the GMA-SAFE Assessment, all employees, visitors and contractors observed near exposed food, ingredients, food packaging or food-contact surfaces wore appropriate, clean outer apparel.</p>
SECTION JUDGMENT:	Fully Meets
SECTION SUMMARY:	<p>All employees, visitors to the plant or contractors observed during the physical inspection of the facility properly adhered to the hair restraint policy. All employees, visitors to the plant and contractors observed during the physical inspection of the facility properly adhered to the jewelry policy. This facility follows a written employee glove control policy/procedure for food safety related purposes. All employees observed during the GMA-SAFE Assessment of the facility properly complied with the glove policy. The facility has a written consumption policy that prohibits eating, drinking and tobacco use in processing and packaging areas. All employees, visitors and contractors observed during the GMA-SAFE Assessment of the facility properly adhered to the facility consumption policy. All employees, visitors or contractors observed during the GMA-SAFE Assessment appeared to properly comply with the facility's personnel health policy. This facility has a policy prohibiting the use of top pockets in uniforms or other outer apparel. In addition to pockets, the facility policy prohibits carrying loose objects anywhere above the waist. Since employees in sensitive areas wear lab coats, a changing area is not needed. All employees, visitors or contractors observed during the GMA-SAFE Assessment appeared to properly comply with the facility's apparel policy. The facility has a policy regarding usage, storage, segregation, and cleanliness of uniforms, and outer apparel. During the GMA-SAFE Assessment, all employees, visitors and contractors observed near exposed food, ingredients, food packaging or food-contact surfaces wore appropriate, clean outer apparel.</p>
	Facility's Response to Auditor's Observations

Section 2.6 Training & Education	
AUDIT ITEM	OBSERVATION
2.6.1	<p>Training needs are assessed training is conducted and documented accordingly</p> <p>The facility provides food safety related training programs for its employees.</p> <p>The food safety related training program is documented.</p> <p>The food safety training includes the following topics: MSDS, HACCP, GMPs, Sanitation and Allergens.</p> <p>The training programs are required for all employees. Training is conducted in a classroom, individualized and computer based applications. Training is conducted for all new hires and refresher training is complete for each topic at least once per year.</p> <p>Training records are maintained in a central location in personnel files and on a computer data base to track training effectiveness.</p>

		<p>The plant uses some testing and supervisor sign-offs to document the effectiveness of the training.</p> <p>Training is provided in languages understood by all employees.</p> <p>Training includes documented job descriptions and work instructions for those engaged in food safety activities.</p>
2.6.2	Qualified personnel conduct food safety related training	<p>The Quality Manager provides food safety training and all other training is provided by a qualified management person or third party certified trainers.</p> <p>The qualifications for trainers are primarily determined by qualifications, experience or certifications depending on the type of training required.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The facility provides food safety related training programs for its employees. The food safety related training program is documented. The food safety training includes the following topics: MSDS, HACCP, GMPs, Sanitation and Allergens. The training programs are required for all employees. Training records are maintained in a central location in personnel files and on a computer data base to track training effectiveness.
		Facility's Response to Auditor's Observations

Section 2.7 Handling Storage & Delivery		
	AUDIT ITEM	OBSERVATION
2.7.1	Stored goods are protected from damage contamination and deterioration	<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.</p> <p>The inspection of storage areas is conducted daily.</p> <p>. The facility maintains on-site records for warehouse inspections, including corrective actions.</p> <p>The following records were reviewed, indicating an effective program for the inspection of storage sites:</p> <p>Storage areas inspected during the plant tour were very clean, orderly and well managed. No pest issues or potential contaminants were observed during the tour.</p> <p>Most goods and material are stored on pallets and away from walls.</p>
2.7.2	Temperature or humidity sensitive items are maintained under proper conditions to ensure proper food safety and maintain quality	<p>There are no temperature or humidity sensitive items stored by 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 both inbound and outbound carriers. They address the following: Mold, discoloration, odor, moisture.</p>

		<p>A review conducted during the GMA-SAFE Assessment of receiving records show established procedures are followed.</p> <p>Policies and procedures require the use of seals or locks on all 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.</p> <p>The following procedures are in place for handling inbound carriers arriving with broken or missing seals:</p> <p>Normally LTLs are not used at this facility.</p> <p>The facility follows a carrier back-haul policy that mandates what materials can be transported by company-owned vehicles on return trips. The policy include the following:</p> <p>The shipping and receiving areas are well designed and maintained to prevent possible product contamination.</p> <p>Carrier breakdown or unforeseen transit delays do not pose a threat for this type of product; therefore, no specific guidelines or policies are needed.</p>
2.7.4	Pallets are monitored for contamination sanitary and physical condition	<p>The pallet management program requires only new food grade pallets are used in the facility. The pallets are all heat treated.</p> <p>The plant only uses new heat treated pallets and they were observed during the plant tour and were in excellent condition.</p> <p>Slip sheets are not used by this facility.</p>
2.7.5	Bulk raw materials are protected against contamination during unloading and loading	<p>Bulk carriers are received and shipped from this facility. The following goods are received and shipped by bulk shipment: Incoming grain, incoming vegetable oil, outgoing meal and refined vegetable oil.</p> <p>The facility has documented procedures for unloading and loading of bulk carriers.</p> <p>Bulk unloading and/or loading activities observed during the GMA-SAFE Assessment appeared to conform fully to sanitary standards.</p> <p>The following food safety documentation for inbound and outbound carriers are required to have wash tags and COAs.</p> <p>The carriers provide transfer hoses and storage is not an issue.</p> <p>A record review showed the facility has complied with its bulk handling procedure.</p>
2.7.6	A schedule of inbound materials includes condition of storage and expiration date	<p>Shelf life is not an issue for raw materials received at this facility.</p> <p>The Owner/Manager was interviewed regarding acceptance procedures required by receiving and warehouse personnel. He was very familiar with policies and procedures.</p>

		<p>Raw materials are held in bulk trucks and transferred into storage tanks inside the plant. Since the raw materials are contained inside the bulk truck, transfer lines and storage tanks, there is little opportunity for deterioration or adulteration while awaiting final storage.</p> <p>There are no temperature sensitive items produced at this facility. Finished goods are stored in bulk tanks until the product is transferred to barrels or pails. There is little opportunity for deterioration or 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. Product shipped may be required to have at least xx% of remaining shelf-life. This requirement could be customer specific.</p> <p>The facility does not periodically validate product shelf life.</p> <p>. Shelf life requirements are dictated by the customer.</p> <p>The facility has a specific stock rotation program that includes the principles of "First In/First Out", "Oldest First", etc.</p> <p>The facility follows its stock rotation program.</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	<p>This facility does not accept returned goods.</p> <p>.</p> <p>.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		<p>The facility food safety program includes the protection or inspection of stored goods. 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. The facility maintains on-site records for warehouse inspections, including corrective actions. All ingredients and finished products are stored at ambient (uncontrolled) temperatures. There are inspection procedures in place for both inbound and outbound carriers. Policies and procedures require the use of seals or locks on all carriers. The pallet management program requires only new food grade pallets are used in the facility. Bulk carriers are received and shipped from this facility. The facility has documented procedures for unloading and loading of bulk carriers. The carriers provide transfer hoses and storage is not an issue. A record review showed the facility has complied with its bulk handling procedure. Raw materials are held in bulk trucks and transferred into storage tanks inside the plant. The facility has procedures and requirements regarding shelf life and the release status of finished goods. The facility does not periodically validate product shelf life. The facility follows its stock rotation program. This facility does not accept returned goods.</p>
		Facility's Response to Auditor's Observations

Section 2.8 Vendor Approval	
AUDIT ITEM	OBSERVATION

2.8.1	There is a Vendor Approval Process for ingredients food contact packaging and services affecting food safety and quality	<p>. Vendor approvals are handled by a specific broker or customer and the approved vendor program is managed by these outside companies. The vendor approval for processing aids or supplies have the following elements: Review, Evaluation, Testing if appropriate, approval and addition to a vendor approval list.</p> <p>The facility accepts all goods from approved vendors, regardless of the manufacturing location.</p> <p>New vendors are subject to increased scrutiny until they have demonstrated consistent compliance to specifications.</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>A recent shipment of an ingredient (Pure-Flo B-80) was verified as an approved supplier.</p>
2.8.3	A system for evaluation of vendor performance is in place	<p>The facility follows a program to evaluate ongoing vendor performance.</p> <p>The program for handling "out of compliance" issues with vendors would normally result in a rejected load that would be returned to the vendor.</p> <p>There have not been any 'out of compliance" issues in the last 12 months so records were not reviewed.</p> <p>The vendor performance procedure requires feedback to the vendor only when problems arise with their goods.</p> <p>.</p> <p>The facility does not purchase goods directly from growers; therefore, there is no need for Good Agricultural Practices (GAP) documentation.</p>
2.8.4	There are provisions for buying from "non approved" sources in the case of emergency situations	<p>The facility has a documented procedure regarding emergency or priority purchases from a non-approved vendor, including the following key elements: Approval would be determined and documented by the Quality Department.</p> <p>Although this facility has a procedure regarding emergency purchases from non-approved vendors, the facility has not required it within past twelve months.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		<p>The vendor approval for processing aids or supplies have the following elements: Review, Evaluation, Testing if appropriate, approval and addition to a vendor approval list. The facility accepts all goods from approved vendors, regardless of the manufacturing location. A comprehensive list of approved vendors is documented and up-to-date. The facility follows a program to evaluate ongoing vendor performance. The vendor performance procedure requires feedback to the vendor only when problems arise with their goods.</p>
		Facility's Response to Auditor's Observations

Section 2.9 Packaging Approval for Use		
	AUDIT ITEM	OBSERVATION
2.9.1		

Packaging materials are purchased according to written approved specifications	<p>Purchases of packaging materials are conform to written, approved specifications.</p> <p>The facility has a system to track and manage its Pure Food Guaranty program (or recognized program equivalent).</p> <p>The facility follows established procedures to inspect and release incoming packaging to inventory. The inspection procedure includes an inspection for condition and quantity and is then released for storage or use by production.</p> <p>. The plant process uses minimal packaging materials and partial containers are either stored in a cabinet after use or kept in the production area until all material is used.</p> <p>Packaging materials are stored separately from other materials that could cause possible contamination issues.</p>
SECTION JUDGMENT:	Fully Meets
SECTION SUMMARY:	Purchases of packaging materials are conform to written, approved specifications. The facility follows established procedures to inspect and release incoming packaging to inventory. Packaging materials are stored separately from other materials that could cause possible contamination issues.
	Facility's Response to Auditor's Observations

Section 2.10 Control of Materials		
	AUDIT ITEM	OBSERVATION
2.10.1	Incoming ingredients are tested and/or verified as conforming to written specifications	<p>Specifications and procedures identify acceptance criteria for incoming ingredients, including processing aids (if used).</p> <p>The specifications and work instructions are provided with hard copies in a manual in the lab.</p> <p>. Certificates of Analysis are not currently required for incoming ingredients or processing aids. COAs are required for finished goods depending on the customer requirements.</p> <p>Incoming ingredients are inspected for quality and condition and compliance to specifications. Once the inspection has been completed and no deficiencies are observed, the material is released for use by production.</p> <p>All material that is handled under the Organic claim is identity and integrity preserved throughout the process.</p>
2.10.2	A process for the modification of incoming material specifications is documented	<p>The facility has a procedure to coordinate and confirm specification changes with vendors.</p> <p>All specification changes by vendors are provided in writing by the appropriate vendor.</p> <p>There have been no specification changes in the last 12 months so record reviews were not conducted.</p>
2.10.3	Control procedures for reworked products are in place	The facility has policies and procedures that address the use of materials intended to be reworked.

	<p>The facility follows procedures that address the storage condition of materials designated to be reworked.</p> <p>The facility has procedures that address the identification and coding of materials designated to be reworked.</p> <p>. The amount of reworked material would be determined and controlled by the Quality Department.</p> <p>The facility maintains batch formulation records that detail the usage of reworked product.</p> <p>. The facility has natural breaks in the generation of rework material and this break satisfies a clean break requirement.</p> <p>There have not been any rework additions in the last 12 months so record reviews were not conducted.</p>
SECTION JUDGMENT:	Fully Meets
SECTION SUMMARY:	Specifications and procedures identify acceptance criteria for incoming ingredients, including processing aids (if used). The facility has a procedure to coordinate and confirm specification changes with vendors. The facility follows procedures that address the storage condition of materials designated to be reworked. The facility maintains batch formulation records that detail the usage of reworked product. The facility has natural breaks in the generation of rework material and this break satisfies a clean break requirement.
	Facility's Response to Auditor's Observations

Section 2.11 Sanitary Design		
	AUDIT ITEM	OBSERVATION
2.11.1	Sanitary design considerations are part of all new equipment approvals	<p>The facility has policies and procedures for the review and approval of equipment sanitary design before making a purchase.</p> <p>Procedures for the review of Sanitary design reference and/or utilize established industry standards. All equipment and utensils at ANS are designed, constructed, installed, operated and maintained so as not to pose a contamination threat to product and are made of FDA food grade materials.</p> <p>Current adherence to equipment design approval procedures could not be verified during the GMA-SAFE Assessment because no equipment purchases have been made within the last twelve months.</p>
2.11.2	Sanitary procedures are followed during equipment installation	<p>The facility has specific policies and procedures to ensure installation of equipment in a sanitary fashion.</p> <p>Since there have been no new equipment installations within the last twelve months, current adherence to approved equipment installation procedures could not be verified during the GMA-SAFE Assessment.</p>

2.11.3	Once installed sanitary design and proper installation of equipment is validated prior to first startup	<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 regular service.</p> <p>When criteria for approving newly installed equipment for regular service is not met, procedures require corrective actions before newly purchased equipment can be placed into service.</p> <p>No new equipment installations have occurred within the last twelve months. Therefore, no determination could be made during the GMA-SAFE Assessment regarding the facility's conformance to its corrective action policies.</p>
2.11.4	Subsequent modifications to equipment and surrounding structures do not compromise sanitary design	<p>Change control procedures for existing equipment or structures require verification of sanitary design and cleaning practices.</p> <p>The owner/manager is responsible for change control procedures.</p> <p>When changes have been made, old or obsolete equipment and piping appear to have been removed from the area.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The facility has policies and procedures for the review and approval of equipment sanitary design before making a purchase. The facility has specific policies and procedures to ensure installation of equipment in a sanitary fashion. When criteria for approving newly installed equipment for regular service is not met, procedures require corrective actions before newly purchased equipment can be placed into service. Change control procedures for existing equipment or structures require verification of sanitary design and cleaning practices.
		Facility's Response to Auditor's Observations

Section 2.12 Traceability and recall management		
	AUDIT ITEM	OBSERVATION
2.12.1	An effective recall management program is in place	<p>A formal recall management program is in place at this facility.</p> <p>This recall management program is documented.</p> <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>The recall management program assigns responsibilities to the following qualified individuals: The quality manager is responsible for the recall management program.</p> <p>In the event of a recall, emergency contact information is readily available to responsible individuals.</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	The facility requires all incoming goods (including bulk items, if any) to carry traceable coding.

		<p>Raw agricultural products are traceable to growing fields and/or collection sites?</p> <p>A recent material shipment was reviewed and it appears materials are properly coded to permit traceability.</p> <p>The plant does not receive incoming pallets with multiple lot codes so this requirement is not applicable.</p>
2.12.3	Inbound materials are coded by the facility when received	Even though vendors code materials sent to this location, the facility also applies its own code to these items.
2.12.4	Raw materials are traceable to finished products Finished goods are traceable through distribution to the first customer	<p>Finished product inventories are tracked using a manual system which allows tracking to the first level of distribution.</p> <p>The facility has the ability to trace raw materials all the way to finished product.</p> <p>The facility has the capability to maintain full traceability even where one lot code is commingled with others. A specific example follows. Since the plant is not able to keep individual bulk storage lots isolated for recall purposes, a recall might involve more than one lot of product associated with the commingled bulk ingredient.</p> <p>The facility has a process for traceability of reworked and/or repacked products, which is documented and followed.</p> <p>The facility has a process that can trace reworked/repacked product back to its original production lot.</p> <p>The finished product is coded as follows:</p> <p>The facility does not package finished goods into "Brite Stock".</p> <p>During the GMA-SAFE Assessment, coding for raw materials and finished products appeared correct, accurate and legible.</p>
2.12.5	The effectiveness of product traceability is tested regularly	<p>The facility conducts routine, periodic in-house traceability exercises (mock recalls) to track raw materials forward through to the first level of distribution. The plant conducts mock recalls once per year.</p> <p>Routine traceability exercises are executed by the facility from finished product back to its raw materials.</p> <p>The plant has a standard of 100% in 24 hours.</p> <p>Results of past in-house trace exercises are documented and self-assessments are performed.</p> <p>The last two mock recalls were conducted by a third party organic auditor and the information is not available to review.</p>
2.12.6	Traceability performance is challenged during the GMA SAFE Assessment	<p>A production lot of Organic Soy Lecithin (Lot# 16LS1-90-3540) was traced to the first level of distribution. The production lot total was nine 55 gallon units. The total amount was shipped to two customers.</p> <p>The plant was able to recover 100% of the material in a total time of 1 hour and 16 minutes.</p>

SECTION JUDGMENT:	Fully Meets
SECTION SUMMARY:	A formal recall management program is in place at this facility. This recall management program is documented. recall management documentation describes the scope of the program. The recall management program assigns responsibilities to the following qualified individuals: The quality manager is responsible for the recall management program. The facility has the ability to trace raw materials all the way to finished product. The facility has a process that can trace reworked/repacked product back to its original production lot. The finished product is coded as follows: The facility does not package finished goods into "Brite Stock". The facility conducts routine, periodic in-house traceability exercises (mock recalls) to track raw materials forward through to the first level of distribution. The plant conducts mock recalls once per year. Routine traceability exercises are executed by the facility from finished product back to its raw materials.
	Facility's Response to Auditor's Observations

Section 2.13 Crisis Management		
	AUDIT ITEM	OBSERVATION
2.13.1	The facility has a crisis management program (in addition to its recall management System)	<p>Besides a product recall program, the facility also has a documented crisis management program?</p> <p>The crises plan includes the following: Fire, Explosion, Tornado, and Power Outage.</p> <p>The owner/manager is responsible for the crisis management program.</p> <p>The facility's crisis management program includes emergency contact information and is available to those responsible for the program.</p> <p>The facility's crisis management program has not been tested or activated within the past twelve (12) months.</p> <p>. The plant has contingency plan for the majority of the product produced at this facility.</p> <p>The facility has procedures to inform customers when a crisis occurs that may affect their supply chain?</p>
	SECTION JUDGMENT:	Fully Meets
	SECTION SUMMARY:	Besides a product recall program, the facility also has a documented crisis management program? The Owner/Manager is responsible for the crisis management program.
		Facility's Response to Auditor's Observations

Section 2.14 Food/Product Defense		
	AUDIT ITEM	OBSERVATION
2.14.1	Documented procedures manage product/food defense (security) at the facility	<p>A product/food Defense Assessment has been conducted for this facility.</p> <p>The plant originally used the C-TPAT program for the initial assessment.</p> <p>Based upon this Assessment, the facility has developed a documented food (or product)</p>

		<p>defense plan.</p> <p>All aspects of the facility's food (or product) defense plan have been fully implemented.</p> <p>The owner/manager is responsible for coordinating the food defense program at the facility.</p> <p>The food (or product) defense plan requires the investigation and reporting of any security breach to the program leaders.</p>
2.14.2	The Food (or Product) Defense plan is effectively implemented	<p>The plant has an employee entrance that requires a code to access the facility and a camera inside the entrance to validate entry. Several offices and the lab are also locked and requires a code for entry.</p> <p>Non-employees must enter the main office which is locked after hours. The visitor or contractor must sign in and be escorted by a plant employ from this point.</p> <p>This facility wishes not to publish the exact means employed for its food (or product) defense. It requests the Reader to request this information directly from facility management.</p> <p>The facility performs background checks on all types of employees, whether full-time, part-time, temporary or seasonal.</p> <p>Based on the plant tour, document reviews and management interviews, compliance to the Food Defense Program is good.</p>
2.14.3	The Food (or Product) Defense plan is properly 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>This food (or product) defense communication/training has been fully implemented.</p> <p>The food defense training program is covered for all new employees and annual with refresher training.</p> <p>The instruction sheet which includes GMPs and other plant requirements are signed by the visitor or contractor before they are allowed to enter the facility.</p> <p>Food Defense instructions were provided to the auditor before gaining access to the facility.</p>
2.14.4	The Food (or Product) Defense plan is periodically assessed reviewed and when necessary updated	<p>Facility management periodically assess the food (or product) defense plan for areas of vulnerability, including premises, products and raw materials that are potentially at risk.</p> <p>The food defense review is conducted at least annually or when a incident occurs that would require a review.</p> <p>Corrective actions are implemented when management reviews reveal Food Defense vulnerabilities.</p>
SECTION JUDGMENT:		Fully Meets

SECTION JUDGMENT:	N / A
SECTION SUMMARY:	Since the kinds of raw materials and processed/finished product at this facility do not require special handling or segregation to prevent cross contamination, this section is not applicable.
	Facility's Response to Auditor's Observations

Section 2.18 Facility Maintenance Program		
	AUDIT ITEM	OBSERVATION
2.18.1	An effective Corrective and Preventive Maintenance Program is in place	<p>The facility has a documented corrective and preventive maintenance program.</p> <p>The corrective and preventive maintenance program is part computerized and part manual.</p> <p>The program includes procedures to address and track overdue/open work orders.</p> <p>The corrective and preventive maintenance program includes a complete list of food handling equipment.</p> <p>The program includes equipment maintenance frequencies.</p> <p>Priorities are established for the repair of critical equipment when food safety and quality issues are involved.</p> <p>The plant engineer is responsible for the maintenance and PM program.</p> <p>The corrective and preventive maintenance program provides specialized training for maintenance personnel.</p> <p>The production manager was interviewed to determine his understanding of the PM program. He was very familiar with policies and procedures.</p> <p>The corrective and preventive maintenance program includes parts inventory management.</p>
2.18.2	Appropriate maintenance records are kept	<p>Records are maintained for preventive, predictive, routine and emergency maintenance activities.</p> <p>The maintenance records are maintained for at least 5 years.</p>
2.18.3	The Corrective and Preventive Maintenance Program is designed 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 following individuals (titles/positions) are responsible for post-maintenance sanitation inspection of equipment: The night production Supervisor.</p> <p>Post-maintenance equipment inspections are completed and documented.</p>

		<p>Product is not typically purged from the line after emergency maintenance repairs in order to flush away any residual contamination.</p> <p>Maintenance areas are clean and maintained to prevent contamination to other areas of the facility.</p>
2.18.4	The maintenance program includes a policy for temporary repairs	<p>The corrective and preventive maintenance program includes a Temporary Repairs policy with the following key elements in place: Temporary repairs do not occur very often and if it did occur the repair would be completed after a production run or soon after the production run. A work order would be generated to document the process.</p> <p>The Temporary Repairs policy is documented.</p> <p>No temporary repairs were observed during the inspection of this facility.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The facility has a documented corrective and preventive maintenance program. The corrective and preventive maintenance program is part computerized and part manual. The corrective and preventive maintenance program includes a complete list of food handling equipment. The program includes equipment maintenance frequencies. The plant engineer is responsible for the maintenance and PM program. The corrective and preventive maintenance program provides specialized training for maintenance personnel. The corrective and preventive maintenance program includes parts inventory management. Records are maintained for preventive, predictive, routine and emergency maintenance activities. The Temporary Repairs policy is documented.
		Facility's Response to Auditor's Observations

3.0 FOOD SAFETY AND HACCP SYSTEMS

Section 3.1 Hazard Prevention/HACCP

AUDIT ITEM	OBSERVATION
3.1.1 HACCP or another 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 mandated Hazard Prevention program.</p> <p>The HACCP Plan is compliant with NACMCF.</p> <p>The HACCP Plan for Organic Soy Lecithin was reviewed during the audit.</p> <p>All products and/or processes are covered by the facility's HACCP/Hazard Prevention program.</p>
3.1.2 Designated individuals are 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 to evaluate the current HACCP/Hazard Prevention plans, typically with the following schedule: The teams meet annually or when changes occur.</p>

		<p>The Quality Manager is HACCP Certified (Food Science Degree and several HACCP courses and certifications), The Lab Director is also a Food Science/Microbiology graduate of Iowa State University and has had formal HACCP training,.</p> <p>At least one member of the Hazard Prevention team has completed a HACCP/Hazard Prevention training session. The Owner/Manager, Corporate Manager and Quality Manager has had HACCP training. The training was conducted by Iowa State University.</p> <p>The HACCP/Hazard Prevention program requires relative activities to be routinely reported to facility management.</p>
3.1.3	Appropriate preliminary hazard analyses were conducted prior to developing the HACCP/Hazard Prevention plan	<p>Documentation shows this facility has undergone a preliminary Hazard Analysis, determining controls for all identified risks.</p> <p>All HACCP/Hazard Prevention plans reviewed are fully supported by written Hazard Analyses.</p> <p>HACCP/Hazard Prevention plans include product descriptions, intended use and target customers (channels of trade).</p> <p>Process flow diagrams are current for all HACCP/Hazard Prevention plans.</p> <p>The Hazard Analysis plan considers both severity and likelihood of occurrence of risks identified in the formal Hazard Analyses.</p> <p>. The product is sold for further processing and the end user is not identified in the HACCP Plan.</p> <p>The Hazard Analysis plan takes into consideration potential end users, relevant microorganisms, physical and chemical contaminants and the potential for tampering/adulteration.</p>
3.1.4	The HACCP/Hazard Prevention plans include: CCPs critical limits monitoring activities corrective actions verification procedures and record keeping procedures	<p>The Organic Soy Lecithin HACCP Plan was reviewed.</p> <p>The plant HACCP Plan has no CCPs.</p> <p>.</p> <p>.</p> <p>.</p>
3.1.5	Hazard Prevention systems are correctly implemented according to facility HACCP/Hazard Prevention plans	<p>The HACCP Plan is reassessed at least annually.</p> <p>.</p> <p>.</p> <p>HACCP/Hazard Prevention plans in use are current and up-to-date. The HACCP Plan was reassessed on January 7, 2011 and August 2010.</p> <p>All copies of the HACCP/Hazard Prevention plans are signed by authorized</p>

		individuals.
3.1.6	Personnel demonstrate knowledge and take specified actions regarding procedures identified in the HACCP/Hazard Prevention plan	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The facility has a documented Hazard Prevention program. The Hazard Prevention program is HACCP based. The HACCP Plan is compliant with NACMCF. The facility has a multidisciplinary HACCP/Hazard Prevention team assigned overall responsibility for the Hazard Prevention program. At least one member of the Hazard Prevention team has completed a HACCP/Hazard Prevention training session. All HACCP/Hazard Prevention plans reviewed are fully supported by written Hazard Analyses. Process flow diagrams are current for all HACCP/Hazard Prevention plans. The Organic Soy Lecithin HACCP Plan was reviewed. The plant HACCP Plan has no CCPs. HACCP/Hazard Prevention plans in use are current and up-to-date.
		Facility's Response to Auditor's Observations

Section 3.2 Microbiological Testing		
	AUDIT ITEM	OBSERVATION
3.2.1	A microbiological testing program is in place where applicable	<p>Microbiological testing is conducted for product made at this facility.</p> <p>The facility does not have a microbiological testing program that monitors sanitation efforts.</p> <p>There is no microbiological testing program for environmental monitoring.</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 the following microbiological testing at this facility: The finished product (Lecithin Only) has the following tests conducted: TPC, Yeast & Mold, Coliform, generic E. coli, Staph Aureus, and Salmonella. Some products are only tested if required by customers.</p>

		<p>All microorganisms important for this type of product/process are monitored.</p> <p>Rapid microbiological testing is not performed for product manufactured at this location.</p> <p>.</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>A COA for a shipment of Lecithin was reviewed and compliance to specifications was acceptable.</p>
3.2.3	Appropriate environmental testing is conducted	<p>Environmental micro testing is not a requirement for this type of process or product.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p>
3.2.4	Timely actions are taken based upon microbiological testing results	<p>Microbiological results are used to determine product disposition.</p> <p>Environmental microbiological results are not used to determine product disposition.</p> <p>The following example shows corrective actions for out-of-standard ingredient or product results are documented: The document of corrective action was not available at this facility to review.</p> <p>Corrective actions for out-of-standard ingredient or product results are documented.</p> <p>All finished products and raw materials are held until microbiological test results are available and verified as acceptable.</p> <p>COA test results were reviewed and compliance to specifications were acceptable.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		<p>Microbiological testing is conducted for product made at this facility. There is no microbiological testing program for environmental monitoring. No microbiological tests are conducted with raw materials at this facility. Rapid microbiological testing is not performed for product manufactured at this location. Acceptance limits for microbiological test results of in-process and finished products are used to determine product acceptability. Microbiological results are used to determine product disposition. COA test results were reviewed and compliance to specifications were acceptable.</p>
		Facility's Response to Auditor's Observations

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

AUDIT ITEM		OBSERVATION
3.3.1	Analytical testing is conducted as part of the food safety or regulatory compliance program	No analytical testing is conducted by this facility as part of its facility's food safety or regulatory compliance program.
3.3.2	Appropriate decisions are made based upon food safety related analytical testing results	
SECTION JUDGMENT:		N / A
SECTION SUMMARY:		Since no analytical testing is required as part of the facility's food safety or regulatory compliance program, this section is not applicable.
		Facility's Response to Auditor's Observations

Section 3.4 Food Allergens and Chemical Sensitivities		
AUDIT ITEM		OBSERVATION
3.4.1	Food allergens and sensitizing chemicals are identified and managed at the facility	<p>This facility uses or stores materials recognized by the country of origin or destination, or by the customer, as food allergens or chemical sensitizing agents.</p> <p>The following allergens or sensitizing ingredients are used at this facility: Soy.</p> <p>The allergen plan includes the following: Management review, Corrective actions, Documentation of incidents and follow-through to determine if corrective actions are effective.</p> <p>The facility's allergen control procedure lists all allergens and sensitizing agents for colors, lubricants, processing aids, and packaging used in the plant.</p> <p>Procedures require determining whether new ingredients and materials are allergen and sensitizer free.</p> <p>The facility provides allergen-specific training to personnel working with or handling allergens.</p>
3.4.2	Procedures are in place to prevent cross contact of products by undeclared allergens and sensitizing agents	<p>The following protective measures and/or corrective actions are taken to protect other products from allergens/sensitizers during product changeover or equipment cleaning:</p> <p>There are documented procedures for the control of allergen/sensitizers used in the facility.</p> <p>Precautions are followed to prevent inadvertent cross-contact by allergens and</p>

		<p>sensitizing agents from receiving through shipping. Change-over procedures and scheduling requirements are developed to control cross contamination issues.</p> <p>Ingredients and products containing allergens and sensitizing agents are managed differently than non-allergenic goods. Since Soy is the only allergen used in the facility, scheduling and changeover procedures appear adequate to control and manage the program.</p> <p>. Equipment and people are not dedicated but procedures are in place to manage changeovers and proper scheduling to control any possible cross contamination.</p> <p>All appropriate measures are employed to prevent allergen/sensitizer cross-contact issues.</p> <p>The facility conducts post-cleaning tests of shared equipment to verify absence of allergens.</p> <p>Any cross-contact issue related to allergen or sensitizing agents would be retained and disposition would be determined by the Quality Department.</p> <p>Review of facility records showed that corrective actions for suspected cross-contact with undeclared allergens are documented.</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>Procedures are in place that ensure all allergens and sensitizing agents are correctly displayed on product labels in accordance with regulatory requirements.</p> <p>Allergen labeling procedures are documented and were verified during the GMA-SAFE Assessment.</p> <p>The facility does not use "May contain" or similar label statements as a warning against inadvertent use of allergens/sensitizers.</p>
3.4.4	Rework procedures are in place to prevent the cross contact of products with an undeclared allergen	<p>. Rework is not used in this process.</p> <p>.</p> <p>.</p> <p>.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		<p>The following allergens or sensitizing ingredients are used at this facility: Soy. The facility's allergen control procedure lists all allergens and sensitizing agents for colors, lubricants, processing aids, and packaging used in the plant. The facility provides allergen-specific training to personnel working with or handling allergens. Ingredients and products containing allergens and sensitizing agents are managed differently than non-allergenic goods. All appropriate measures are employed to prevent allergen/sensitizer cross-contact issues. Review of facility records showed that corrective actions for suspected cross-contact with undeclared allergens are documented. Allergen labeling procedures are documented and were verified during the GMA-SAFE Assessment.</p>
		Facility's Response to Auditor's Observations

Section 3.5 Foreign Material Control

	AUDIT ITEM	OBSERVATION
3.5.1	Protective measures are taken to eliminate contamination from foreign (extraneous) material	<p>The facility has documented procedures and work instructions regarding the control of foreign materials.</p> <p>In-house procedures address foreign material that may be inherent to the process</p> <p>This facility makes use of the following foreign materials control devices: Screens, bag filters, muliti-stage filters.</p> <p>The following areas use screens and filters: Refined Oil and Lecithin Process.</p> <p>Foreign material control devices are monitored at prescribed frequencies.</p> <p>Corrective action is taken if a foreign material control device is found to be missing or nonfunctional.</p> <p>.</p> <p>Pre-operational and post-maintenance inspections of foreign material control devices, including corrective actions, are documented.</p> <p>Specialized training to employees who monitor or handle foreign material control devices is provided by the facility.</p> <p>Documentation relating to foreign material control devices indicated devices are properly employed, maintained and monitored.</p> <p>If a foreign material is detected by a detection device, the product would be retained back to the last acceptable check. The Quality Department determines the disposition of the material that is retained.</p> <p>Metal detection, /X-ray and other foreign material detection devices are not used at this site.</p> <p>The facility monitors foreign material control devices for integrity and functionality.</p> <p>Pre-operational or post-maintenance inspections target equipment for any metal-to-metal contact points, missing nuts or bolts and equipment wear.</p> <p>The process is contained in vessels and pipes and hand-held cutting tools.</p> <p>Wooden pallets are used in the plant but there are no dumping operations which could cause possible wood contamination issues.</p>
3.5.2	Foreign material hold policies are in place and followed	<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>.</p> <p>.</p> <p>The Quality Manager was interviewed about policies and procedures related to hold</p>

		<p>procedures and records. She was very familiar with the program and responsibilities related to monitoring and controlling product on hold.</p>
3.5.3	<p>Effective procedures are in place for the prevention of contamination from glass ceramics and brittle plastic contamination</p>	<p>The facility has a documented glass/ceramics/brittle plastic control procedure.</p> <p>Documented work instructions for managing glass/ceramics/brittle plastic are provided by the facility.</p> <p>These instructions include procedures for inspection and start-up approval for a processing line following breakage incidents.</p> <p>Accountabilities for line start-up following a breakage incident are defined. The Quality Department or Supervisor is accountable for line start-up following a breakage incident.</p> <p>The Quality Manager was interviewed to determine her understanding of the glass/brittle plastic program. She was very familiar with the plant program and was able to explain the policy and procedures that are required.</p> <p>The following items are included in the policy: Lighting, forklift lenses, site glasses, temperature gauges.</p> <p>Glass if permitted in offices and the laboratory.</p> <p>When glass must be used in processing areas, the facility has special procedures to prevent glass contamination.</p> <p>The facility does inspect and inventory glass/ceramics/brittle plastics in the processing and packaging area.</p> <p>Based on the plant tour and interviews of management personnel, compliance to the plant's glass/ceramics/brittle plastic policy is good.</p> <p>There are no records of breakage and no records were reviewed.</p> <p>Lights are properly shielded as required.</p>
3.5.4	<p>Procedures ensure food grade lubricants are used where necessary</p>	<p>Documented procedures exist regarding the use and control of food grade lubricants and similar materials.</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>Lubricants are controlled by the maintenance department. The plant has only food-grade lubricants.</p> <p>During the Assessment, non-food grade lubricants were not observed being applied in a manner inconsistent with the labeling.</p> <p>Exposed food or food-contact surfaces beneath lubricated mechanisms are properly protected.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The facility has documented procedures and work instructions regarding the control of

foreign materials. In-house procedures address foreign material that may be inherent to the process. This facility makes use of the following foreign materials control devices: Screens, bag filters, muliti-stage filters. Foreign material control devices are monitored at prescribed frequencies. Pre-operational and post-maintenance inspections of foreign material control devices, including corrective actions, are documented. Documentation relating to foreign material control devices indicated devices are properly employed, maintained and monitored. The facility monitors foreign material control devices for integrity and functionality. The facility has a documented glass/ceramics/brittle plastic control procedure. Documented work instructions for managing glass/ceramics/brittle plastic are provided by the facility. When glass must be used in processing areas, the facility has special procedures to prevent glass contamination. Documented procedures exist regarding the use and control of food grade lubricants and similar materials. The plant has only food-grade lubricants. Exposed food or food-contact surfaces beneath lubricated mechanisms are properly protected.

Facility's Response to Auditor's Observations

4.0 MANUFACTURING QUALITY SYSTEMS

Section 4.1 Conformance to Customer Specifications

AUDIT ITEM		OBSERVATION
4.1.1	Customer specific standards are evaluated and controlled	<p>There are documented procedures for accepting customer orders, requests 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 has a policy to contact its customers whenever specifications cannot be met. The Lab Director would make the contact.</p> <p>A review of recent change control documentation indicates the supplier notifies its customer when changes are made that may affect customer product quality, machinability, compliance with customer specifications or adherence to regulations.</p> <p>. Customer guidelines are followed prior to the disposal/destruction of customers' trademarked, non-compliant goods.</p> <p>Specifications are available in the Laboratory and are available to people that need the information.</p> <p>There are no formulations or recipes for this type product. Specifications are maintained by the Quality Department.</p> <p>Versions of specifications in use during the GMA-SAFE Assessment were verified to be the most current and up-to-date.</p> <p>Specifications take under consideration quality, safety and regulatory issues.</p>
4.1.2	If co manufacturers are used procedures are in place to monitor their production	<p>This facility does not use co-manufacturers to produce any portion of its customers' product.</p> <p>.</p>

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SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		There are documented procedures for accepting customer orders, requests and specifications. A review of recent change control documentation indicates the supplier notifies its customer when changes are made that may affect customer product quality, machinability, compliance with customer specifications or adherence to regulations. Specifications are maintained by the Quality Department.
		Facility's Response to Auditor's Observations

Section 4.2 Process Control		
	AUDIT ITEM	OBSERVATION
4.2.1	Process control procedures are in place to ensure conformance to specifications	<p>The facility conducts volume/weight control activities that monitor and adjust finished product in order to assure conformance to specifications.</p> <p>The facility conducts process control activities that monitor and adjust ongoing processes in order to assure conformance to specifications. The following checks are conducted: weight, temperature, color, moisture, organoleptic, Acetone insolubility.</p> <p>The facility provides training for individuals who monitor process control activities.</p> <p>Process control systems convey out-of-control situations to appropriate operators whenever critical systems are automated.</p>
4.2.2	Current procedures are available for operators for all prescribed process and quality checks	<p>The most current, documented processing and quality procedures/checks are readily accessible to operators.</p> <p>Operators observed during the GMA-SAFE Assessment appeared to follow the documented processing and quality procedures provided them.</p>
4.2.3	Statistical process controls are utilized	<p>No study to determine the usefulness of Statistical Process Control (SPC) techniques has been made at this site.</p> <p>.</p> <p>.</p> <p>.</p> <p>.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The facility conducts process control activities that monitor and adjust ongoing processes in order to assure conformance to specifications. The facility provides training for individuals who monitor process control activities. Process control systems convey out-of-control situations to appropriate operators whenever critical systems are automated.
		Facility's Response to Auditor's Observations

Section 4.3 Inspection & Testing		
	AUDIT ITEM	OBSERVATION
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 Lab Director verifies whether product complies with specifications.</p> <p>The following organoleptic evaluations are performed on finished goods: Flavor, color, aroma.</p> <p>Finished product samples are set aside in compliance with the retained sample program. A small amount of product (several ounces) is retained for 5 years at ambient temperatures.</p>
4.3.2	Finished goods records are available that show evidence of inspection and test results	<p>The following inspection records are maintained by the facility: Product Quality, Specification Compliance, COAs, Lab Analysis, In-process checks.</p> <p>Lab analysis and COA analysis records were reviewed and compliance with specifications is acceptable.</p>
4.3.3	Finished goods records are reviewed before product is released to customers	<p>The facility executes a positive release system for finished goods, under the following criteria: The positive release program requires complete analysis and verification of compliance to specification before releasing to the customer.</p> <p>Product is not released until inspection records are reviewed by the following individuals (title/position): The Lab Director is authorized to review and release products.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		This facility has a finished goods inspection program that ensures conformance to internal or customer specifications. The Lab Director verifies whether product complies with specifications. Finished product samples are set aside in compliance with the retained sample program. Lab analysis and COA analysis records were reviewed and compliance with specifications is acceptable.
		Facility's Response to Auditor's Observations

Section 4.4 Control of non conforming Materials		
	AUDIT ITEM	OBSERVATION
4.4.1	Non conforming materials are segregated and controlled against inadvertent shipment	<p>Non-conformance procedures at this facility are fully documented. The quality department places product on hold and the Quality Department is the only department that can release the product. The product is held physically and hold tags are placed on the loads.</p> <p>This facility utilizes the following non-conformance "Hold" procedure to identify, segregate, control and manage the disposition of non-conforming materials:</p> <p>Non-conformance procedures apply to raw materials, work-in-progress, and finished products.</p>

		<p>Only specifically authorized personnel are allowed to release held materials back to distribution. The Quality Department or Lab Director are authorized to release product on hold.</p> <p>Procedures are followed to verify quality and safety of materials prior to release for sale or reuse.</p> <p>The facility follows specific corrective actions to minimize or eliminate any recurrence of events that have resulted in a "Hold" decision.</p> <p>Employee interviews and record reviews indicate the facility complies with its product hold procedure. The Quality Manager and Lab Director were interviewed and compliance to the hold program is acceptable.</p> <p>The Hold Tags are used to communicate non-conformance product to appropriate personnel.</p> <p>The Quality Manger was interviewed regarding her understanding of non-conformance requirements. She was very familiar with the policies and procedures for non-conformance issues.</p> <p>Third party audits and in-house self audits are used to challenge the non-conformance program.</p> <p>Procedures exist to communicate information to customers regarding non-conforming finished goods prior to shipment.</p> <p>During the Inspection, no evidence was observed that non-conforming materials were inadvertently released to production or shipped to customers/consumers.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		Non-conformance procedures at this facility are fully documented. The quality department places product on hold and the Quality Department is the only department that can release the product. This facility utilizes the following non-conformance "Hold" procedure to identify, segregate, control and manage the disposition of non-conforming materials: Non-conformance procedures apply to raw materials, work-in-progress, and finished products. The Quality Department or Lab Director are authorized to release product on hold.
		Facility's Response to Auditor's Observations

Section 4.5 Good Laboratory Practices		
	AUDIT ITEM	OBSERVATION
4.5.1	Analytical and/or microbiological testing are performed in a suitable laboratory	<p>In-house laboratories are used for product testing purposes.</p> <p>The lab is located in a separate room from production and access is controlled with a locked door. The only microbiological testing done is Total Plate Count on 3M Petri-film and pour plates.</p> <p>The following testing is performed by contract laboratories: The contract lab conducts the following tests: Total Plate Count, E. coli, Coliform, Staph A., Salmonella, Y&M and Listeria species. The outside lab is Key Labs, Decatur, IL.</p>

		<p>The lab is considered an expert for Lecithin analyticals. The lab is also a certified lab.</p> <p>Steps are taken by the facility to verify that contract laboratories also conduct self-validation procedures.</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 in-house lab is capable of conducting physical, analytical and limited microbiological tests.</p> <p>In-house laboratories follow recognized/official methodologies for all tests. The lab follows AOAC and BAM 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>Cross-check records were reviewed and the Quality Manager was interviewed regarding the program and compliance to customer requirements. The Quality Manager was familiar with the program and results.</p> <p>Some or all products made at this facility are exported outside the country of origin.</p> <p>No records were available since the export documents and requirements are handled by the corporate offices.</p>
4.5.3	Laboratory methods are validated for accuracy and analyst proficiency is periodically verified	<p>Laboratory methods are validated by the facility regarding accuracy and reproducibility.</p> <p>The facility conducts periodic testing to confirm that test methods are accurate at the stated limit of detection and that quantitative methods are accurate throughout the desired range of measurements. Documented procedures were followed as required.</p> <p>Lab validation records were reviewed and compliance to the program appears to be acceptable.</p> <p>The plant conducts in-house testing programs to ensure that in-house analysts are capable of performing laboratory procedures with accuracy and precision.</p> <p>Analyst proficiency reports were examined, and they verified that in-house analysts were capable of properly performing their duties.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		In-house laboratories are used for product testing purposes. The outside lab is Key Labs, Decatur, IL. The lab is also a certified lab. The facility verifies that contract laboratories follow approved methods for required analyses. The in-house lab is capable of conducting physical, analytical and limited microbiological tests. In-house laboratories follow recognized/official methodologies for all tests. The lab follows AOAC and BAM methods. An up-to-date laboratory manual with testing procedures is available at this facility. The plant conducts in-house testing programs to ensure that in-house analysts are capable of performing laboratory procedures with accuracy and precision.

Facility's Response to Auditor's Observations

Section 4.6 Document Control and Record Retention

AUDIT ITEM	OBSERVATION
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 system to manage and control all food safety and quality related documentation, data and records.</p> <p>The Quality department is responsible for creating food safety and quality documents and transmitting the documents to personnel in the facility. The Quality Department is also responsible for any changes to the documents and removal of obsolete documents.</p> <p>The Quality Department is the only department to issue quality and food safety documentation.</p> <p>The Quality Department manages customer specifications to ensure confidentiality.</p> <p>Food safety and quality related documentation are not maintained electronically by this facility.</p> <p>.</p> <p>.</p> <p>.</p> <p>The records are retained for 5 years.</p> <p>During the GMA-SAFE Assessment it was noted that work instructions, procedures, batch records, etc. are not current or up-to-date. Several work instructions were reviewed and all were current and up-to-date.</p> <p>Records indicate that essential documents are signed, authorized and dated by the appropriate personnel.</p>
4.6.2 Food safety and quality related records are legible and correct Proper error correction procedures are followed	<p>Records reviewed during the GMA-SAFE Assessment were legible and appeared 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, authorized signatures, etc.</p> <p>Food safety and quality related records are signed and dated by the reviewer.</p> <p>Food safety and quality data or records are reviewed weekly or daily if critical.</p>
SECTION JUDGMENT:	Fully Meets
SECTION SUMMARY:	The Quality department is responsible for creating food safety and quality documents and transmitting the documents to personnel in the facility. The Quality Department is the only department to issue quality and food safety documentation. Food safety and quality related records are signed and dated by the reviewer. Food safety and quality data or records are reviewed weekly or daily if critical.
	Facility's Response to Auditor's Observations

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Section 4.7 Corrective and Preventive Action		
	AUDIT ITEM	OBSERVATION
4.7.1	An effective corrective and preventive action process is in place	<p>The facility follows a pre-determined, documented approach or program for corrective and preventive actions.</p> <p>The corrective and preventive action process includes 1) identification of the issue, 2) investigation of the root cause, 3) timely corrective action, and 4) follow-up to confirm implementation and effectiveness.</p> <p>. This supplier maintains corrective and preventive action records.</p> <p>The facility collects and analyzes information or data that would help it prevent future product failures.</p> <p>The internal audit review process is used to review corrective and preventive actions and follow up action. These meetings are documented.</p> <p>Based on document reviews and interviews with the Quality Manager and Owner/Manager, compliance to the corrective and preventive action program is good. Procedures have been established and procedures are followed to investigate incidents and document corrective actions and ensure that the follow-up is conducted in a timely fashion.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The facility follows a pre-determined, documented approach or program for corrective and preventive actions. This supplier maintains corrective and preventive action records. The internal audit review process is used to review corrective and preventive actions and follow up action.
		Facility's Response to Auditor's Observations

Section 4.8 Continuous Improvement		
	AUDIT ITEM	OBSERVATION
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 reevaluates and improves current practices before issues arise.</p> <p>The underlying goals of the program are to review Key Performance Indicators to improve plant results. The Key Performance Indicators are as follows: Out of Specification Product, Customer Complaints, Yields, Cost per Pound, Labor Cost per Pound, Production rates. Trend and raw data is used to review and improve processes and plant results. Product or process improvements include the following: 1. Review data and use plant or outside resources to improve the process.</p> <p>Due to the size of the facility, only a limited number of people meet on a recurring basis to work on continuous improvement projects.</p> <p>Management reviews and makes decisions based upon recommendations regarding continuous improvement opportunities.</p>

	A recent automation of the Lecithin system improved up-time and efficiencies.
SECTION JUDGMENT:	Fully Meets
SECTION SUMMARY:	The underlying goals of the program are to review Key Performance Indicators to improve plant results. Product or process improvements include the following: 1. Review data and use plant or outside resources to improve the process.
	Facility's Response to Auditor's Observations

Section 4.9 Customer / Consumer Communication		
AUDIT ITEM	OBSERVATION	
4.9.1 Procedures manage customer/consumer compliments complaints suggestions and inquiries in a timely manner	<p>Customer/consumer communications are managed at the facility, handling all compliments, complaints, suggestions and inquiries.</p> <p>Customer/consumer communication procedures for the facility are documented.</p> <p>The goal is to respond in a minimum of 24 hours and to ensure that the problem does not repeat. The goal is also to ensure that future complaints of the same nature does not repeat.</p> <p>From a review of communications during the GMA-SAFE Assessment, it was confirmed that customer/consumer communication procedures are followed.</p> <p>Customer/consumer communication procedures assign responsibility to the following individuals for managing customer compliments, complaints, suggestions and inquiries: The Quality Manager is responsible for handling and managing customer communications.</p> <p>Employees who manage the customer/consumer communications program have received relevant training.</p> <p>This facility has an up-to-date listing of customer contacts from which it can discuss customer/consumer issues.</p> <p>The following example(s) indicate customer/consumer complaints, suggestions and inquiries reviewed during the GMA-SAFE Assessment are processed in a timely manner: Customer complaint letters were not available to review. Most communications are verbal and are handled immediately.</p>	
SECTION JUDGMENT:	Fully Meets	
SECTION SUMMARY:	Customer/consumer communications are managed at the facility, handling all compliments, complaints, suggestions and inquiries. Customer/consumer communication procedures for the facility are documented. Customer/consumer communication procedures assign responsibility to the following individuals for managing customer compliments, complaints, suggestions and inquiries: The Quality Manager is responsible for handling and managing customer communications.	
	Facility's Response to Auditor's Observations	

Section 4.10 Internal Self auditing

AUDIT ITEM		OBSERVATION
4.10.1	A documented internal audit program ensures ongoing compliance with quality and food safety standards	<p>The facility has a self-auditing program to ensure ongoing compliance with quality and safety standards.</p> <p>The internal self-auditing program is documented.</p> <p>Internal audits adhere to written procedures, standards and/or checklists.</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 plant conducts Quality System audits, GMP audits and Housekeeping.</p>
4.10.2	The internal 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 assigned to manage the internal audit program.</p> <p>The Quality Manager has formal education, in-house and third-party training.</p> <p>Internal auditors who appear on inspection reports and perform internal audits have received the following specialized training:</p> <p>Auditors are independent of the areas they audit.</p>
4.10.3	The internal audit process is effectively implemented	<p>Reports are issued detailing the findings from internal audits.</p> <p>After reviewing internal audit records, it was indicated that corrective actions are responded to within a reasonable amount of time. Records of internal audits were not available to review.</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. The management team would review at least weekly.</p> <p>Based on a review of the audit program, training records and corrective action follow-up reports, compliance to the internal audit program is good.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The internal self-auditing program is documented. Internal audits adhere to written procedures, standards and/or checklists. The plant conducts Quality System audits, GMP audits and Housekeeping. There are accountable individuals assigned to manage the internal audit program. The Quality Manager is assigned to manage the internal audit program. Reports are issued detailing the findings from internal audits. Records of internal audits were not available to review.
		Facility's Response to Auditor's Observations

5.0 REGULATORY CONSIDERATIONS		
Section 5.1 Label Control		
AUDIT ITEM		OBSERVATION
5.1.1	There is a documented process with procedures to develop review and	This facility applies both labels printed on-site and pre-printed labels.

	approve labels	<p>There is a documented label pre-approval process at this facility.</p> <p>The facility verifies that all labels comply with regulatory requirements.</p> <p>Labels are created on-site using a customer's template. The only communication that occurs with the facility is when changes are needed to the template.</p> <p>Since all labels are created by the customer, accurate nutritional information is the customer's responsibility.</p> <p>Some labels would include Kosher, Halal, Organic, Non-GMO, Expeller Pressed, Cold Pressed.</p>
5.1.2	Labels are verified before application as appropriate for the product being run	<p>Labels used on line during the GMA-SAFE Assessment matched the product and formulation that was being produced at the time of the GMA-SAFE Assessment.</p> <p>Labels are not pre-checked using UPC/bar code scanners or similar devices.</p> <p>Labels are generated on line and excess labels are removed before a new product is started.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		This facility applies both labels printed on-site and pre-printed labels. The facility verifies that all labels comply with regulatory requirements. Labels are created on-site using a customer's template. Labels are generated on line and excess labels are removed before a new product is started.
		Facility's Response to Auditor's Observations

Section 5.2 Regulatory & Industry Compliance		
	AUDIT ITEM	OBSERVATION
5.2.1	Products processes training and records comply with applicable local state and federal regulations	<p>FDA, USDA (for Organic), State of Iowa govern production at this facility.</p> <p>The Quality Manager is responsible to ensure compliance to all regulations.</p> <p>The Owner/Manager and Quality Manager is responsible for ensuring compliance to applicable local, state and federal regulations.</p> <p>Products manufactured at this facility do not require the services of a Process Authority.</p> <p>Training records showing employee training in GMP and Housekeeping were reviewed and verified as complete and current.</p> <p>Records of regulatory review from city and state officials did not indicate any deficiencies that required correction or follow-up. Compliance to regulatory requirements appear to be acceptable.</p>
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		FDA, USDA (for Organic), State of Iowa govern production at this facility. The Owner/Manager and Quality Manager is responsible for ensuring compliance to applicable local, state and federal regulations.

	Facility's Response to Auditor's Observations

Section 5.3 Management of the Regulatory Inspection Process

AUDIT ITEM	OBSERVATION
5.3.1 Management and training for the regulatory inspection process is in place	<p>The facility has pre-established procedures for handling regulatory inspections when they occur.</p> <p>Procedures for handling regulatory inspections are documented.</p> <p>The facility requires the following steps to be followed when handling regulatory inspections: 1. Ask for and verify credentials, 2. Accompany the inspector, 3. Take notes, 4. Prohibit photography, 5. Take duplicate samples and copies of any documents.</p> <p>There is an up-to-date 24-hour contact list with regards to personnel who manage the regulatory process. The list is easily accessible personnel regardless of time or day of week.</p> <p>Personnel responsible for managing regulatory compliance and/or visiting regulatory inspectors are provided specific training for this purpose. The training is provided annually.</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.</p> <p>The plant has not had a regulatory visit in the last 12 months so no review of records was completed.</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.</p> <p>Since no records were reviewed, verification that procedures were followed could not be accomplished.</p>

SECTION JUDGMENT: Fully Meets

SECTION SUMMARY: The facility has pre-established procedures for handling regulatory inspections when they occur. Procedures for handling regulatory inspections are documented. Personnel responsible for managing regulatory compliance and/or visiting regulatory inspectors are provided specific training for this purpose. The customer is notified by the facility when a regulator evaluates that customer's product. Customers are notified when a regulator is given copies of documents/records pertaining to that customer's product.

	Facility's Response to Auditor's Observations