Audit Report Global Standard Food Safety Issue 9

1. Audit Summary			
Company name	**Amalgamated Sugar Company**	Site code	8747948
Site name	Amalgamated Sugar Company-Nyssa		
Scope of audit	The mixing of molasses and granulated sugar to produce light and dark brown sugar packaged into bags and granulated sugar packed into totes, bulk railcars and trucks.		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit start date	2023-07-18	Audit finish date	2023-07-19
Re-audit due date	2024-10-09	Head office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose a module	Choose an item		
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit programme	Unannounced – mandatory 1 in 3 years
Previous audit grade	AA		Previous audit date	2022-09-21	
Certificate issue date	2023-08-17		Certificate expiry date	2024-11-20	
Number of non-conformities			Fundamental	0	
			Critical	0	
			Major	0	

2. Audit Results

	Minor	5

3. Company Details

Site address	105 East Main Street Nyssa, Oregon 97913		
Country	United States	Site telephone number	+2083836594
Commercial representative name	Kelly Malone	Email	kmalone@natsugar.com
Technical representative name	Lacey Messing	Email	LMessing@natsugar.com

4. Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3

Shift pattern	2 shifts, 5 days per week; 10 hrs./day; 7 am-5 pm & 5 pm-3 am	
Seasonal site	No	
Seasonal opening times (Start/end date)	Click or tap to enter a date.	Click or tap to enter a date.
Other certificates held	Kosher	
Outsourced processes	No	

4. Company Profile

Outsourced process description	N/A
Regions exported to	North America Choose a region Choose a region Choose a region Choose a region Choose a region
Company registration number	11281255704
Major changes since last BRCGS audit	Ongoing construction and renovation of facility; removed in-line metal detector on brown sugar line (in-process).

Company Description

Part of the Amalgamated Sugar Coop., the facility was built in the 1939 as a sugar mill but now only receives granulated sugar from Amalgamated sister facilities and produces light and dark brown sugar. The plant is 6,039 sq. mts. including a granulated sugar warehouse.

Sugar destined for brown sugar production is received mostly in bulk form and is stored in 5 silos. Molasses is received from tankers and is stored in 2 tanks, one for dark and one for light molasses (mix of invert sugar and molasses). Molasses is sprayed on the milled sugar, metal detected and packaged into bulk bags or retail sized bags with all products ambient shelf stable. Granulated sugar is also out loaded into bulk tankers.

The plant has 50 workers and operates 2 shifts 5 days per week, but during the 3-month Winter busy season, two 12-hour shifts, 6 days per week are operated with approximately 108,428,000 lbs. of sugar shipped per year.

The facility tour began 20 min. after arrival at site.

5. Product Characteristics

Product categories	15 - Dried food and ingredients Category Category Category Category Category Category Category
Finished product safety rationale	Low Aw: 0.22-granulated sugar; .59-Light Brown; .65-Dark Brown

High care	No	High risk	No	Ambient high care	No

5. Product Characteristics	
Justification for area	Based on factory zones as defined in appendix 2 of the standard, the facility is identified low risk/low care because all products have low Aw and are shelf stable.
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	None
Product recalls in last 12 months	No
Products in production at the time of the audit	Light Brown Sugar into 2 lb. retail bags; Bulk 50 lb. bags light Brown Sugar.

6. Audit Duration Details			
Total audit duration	18 man hours	Duration of production facility inspection	6 man hours
Reasons for deviation from typical or expected audit duration	Light Brown Sugar into 2 lb. retail bags; Bulk 50 lb. bags light Brown Sugar		
Combined audits	None		
Next audit type selected	Announced		

Present at audit
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)

Name	Job title	Opening meeting	Site inspection	Procedure review	Closing meeting
Bill Hardin	Assist. Warehouse Manager	X	X	X	X
Destiny Reeves	Warehouse Manager	X			X
Kelly Malone	QA Manager	X	X	X	X
Lacey Messing	Food Safety & Quality Professional	X	X	X	X
Jeremy Adamson	NSM Director of QA	Remote		Remote	Remote

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/Unannounced	Pass/Fail
2020-10	BRCGS	Announced	Pass
2021-09	BRCGS	Announced	Pass
2022-09	BRCGS	Announced	Pass

Document control			
CB Report number	US/F6H/614116		
Template name	F908 Food Safety Audit Report Template		
Standard issue	9	*Template issue date*	2022-12-16
Directory allocation	Food	*Version*	1.1

Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements			
Clause	Detail	Critical or Major	Re-audit date

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
4.6.3	An equipment commissioning procedure is not in place to control new equipment installation along with the movement of static equipment.	Discussed the process over with the QA Manager and we will create a SOP on the evaluation for equipment, new or static.	Completed the SOP and the QA Manager reviewed and signed off.	The Policy- Change Management has been used for equipment updates and the Capital Projects with the review of specifications, drawings and SDS information.	2023-08-09	MB
4.9.1.1	Food grade items on shelf in chemical storage building was not labelled as such. Non-food grade items were segregated on separate storage rack.	The next day added labels to the shelves to identify food grade vs non-food grade. At the time of inspection, no commingling was found.	Will follow up during the internal audits to confirm the shelves are properly labelled. See attached internal audit 4 date scheduled with reminder.	The chemical storage has been known food grade on the one side vs non-food grade on the other shelf.	2023-08-09	MB
4.10.3.4	It was noted that the rejection mechanism of product suspected of containing metal on the retail line is not being tested along with the detector itself. The line uses a compressed air blast to reject bags into a secured container.	Spoke to the employee to change up his confirmation of rejecting the brown bag, see metal detector test training. Remove the test card from the retail bag before the air rejects the bag and allow the bag to be rejected into the rejected box.	Will verify metal detector test every month for 6 months during the monthly inspection. See attached WHS-WI-018 Retail Brown Line Metal Detector Test R 1. After the 6 months change to inspect metal detector testing every quarter. Employee during original test was verified on with	The employee tested the metal detector with a test card. The metal detector detected but the employee pulled the test card and retail bag prior to it fully rejecting with the air rejection.	2023-08-09	MB

Minor						
			the work instruction on 7.26.23.			
4.11.1	Appropriate cleaning conditions observed in the different areas in the facility such as processing areas, however cobwebs and were observed on a wall of the B warehouse along with general dust and dirt on the shipping receiving dock.	Cleaned the cobwebs. Before and After photos were taken.	Added “remove cobwebs, dust and dirt” to the weekly cleaning schedule and will monitor during the monthly inspection, see question # 12.	Webs, dirt and dust was sometimes not noticed because of the use of doors during monthly inspections. Other areas were not noted for cleaning during the inspections.	2023-08-09	MB
7.1.6	Training records for various employees were examined and were found to be accurate and timely, however, several training sign-up sheets did not have the subject, trainer or duration of training.	Updated the form to include the subject, trainer, date and duration.	The June Toolbox Meeting was completed and will follow up for next month’s toolbox meeting sign in sheet.	Food Safety & Quality Professional did not update the form to include the subject, trainer and duration. See attached May Toolbox Meeting Notes.	2023-08-09	MB

Comments on non-conformities
Click or tap here to enter text.

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Lead auditor		
Auditor number	**First name**	**Second name**
21335	Mark	Bacola

Audit team				Attendance (YYYY/MM/DD, 24hr: MM)			Presence	
First name	Second name	Auditor number	Role	Audit Date	Start time	End time	Remote or physical	Professional recognition number
Mark	Bacola	21335	Lead Auditor	2023/07/18	09:30	18:30	Physical	
Mark	Bacola	21335	Lead Auditor	2023/07/19	09:00	18:00	Physical	

1. Senior management commitment

Product Safety and Quality Culture Plan

The company's senior management has demonstrated that they are fully committed to the implementation of the requirements of the Global Standard for Food Safety. This includes the provision of adequate resources, effective communication, systems of review and actions to be taken to effect continual improvement.

The Commitment to Food Safety and Quality 08/10/2002, was signed by the Warehouse/Terminal Manager, FSQP and QA Manager and is displayed at the site entrance and lunchroom and is included within the staff QA handbook. Management communicates the commitment via annual training and during new hire orientation.

Opportunities for improvement have been identified, implemented and are fully documented. Continual Improvement Measures and Food Safety Objectives, 1.3, 22/06/14. Amalgamated Sugar has been strongly promoting food safety and quality culture throughout their plants and offices.

Activities having an impact on food safety culture have been defined and articulated along with SOPs and plans regarding such activities. Parameters for the measurement of activities and their success have been defined along with timescales and to pinpoint potential deficiencies to foster continual improvement.

Strengths and weaknesses have been analysed along with methods to improve awareness and employee involvement using a Food Safety Culture Survey conducted annually.

Quality culture and quality goals and objectives have been set by the company based on the results of an employee survey and Management observations. Promotional events have been held to support the program such as audit result sharing, sharing customer complaints, outstanding worker awards along with daily meetings regarding quality related subjects and is articulated in the program.

Success of the plan is measured by paperwork correctness, worker participation from all departments, effectiveness of completed activities, training completion, customer complaints, regulatory actions and physical observations.

Food Safety and Legality Objectives

Food Safety Goals 2022:

Maintain a successful shipment rate of 99.5%,
Maintain a successful shipment rate of 99.9% for food safety related issues (site level),
Reduce total cost of complaints per shipment by 3% compared to prior 3 years,
Reduce customer complaint trending compared to the same quarter of the previous year, and for the year ending averages,
Complaint response 100%,
BRCGS-certified facilities will maintain an "A" grade,
Master sanitation schedules with completion rate of 85%,
Preventive maintenance inspections with completion rate of 80%,
Reduce the number of incidents by 3%,
Reduce the number of unplanned equipment repairs by 3%,
Meeting all internal facility inspection criteria.

Goals for 2022 were met.

2023 YTD objectives are being generally being met.

Success of the plan is measured by paperwork correctness, worker participation from all departments, effectiveness of completed activities, training completion, customer complaints, regulatory actions and physical observations. If goals are not achieved, a root cause analysis shall be performed

Management Review

The last full Annual Management Review was performed 22/08/09 with major agenda items discussed including Goals, Internal Audits, Customer Complaints, Customer Audit, Non-Conformances, HACCP, Food Defense, Food Safety Culture, Continuous Improvement, Resources and open agenda items with all managers attending the meeting.

Quarterly Scorecard Audits are also performed with the last dated 23/06/17 with continuing improvement goals graded. All goals for the 1nd quarter have been met per the scorecard.

Customer complaints along with internal non-conformities are monitored on a monthly/quarterly basis and discussed at their Monthly Management Meetings. Monthly toolbox meetings are held to involve employees in decision making and to take suggestions.

Regular Meetings

Documented monthly meetings are held where HACCP, sanitation, audits, culture plans, non-conforming products, training, continuous improvement, action items, goals, complaints including root cause, updated documents (SOPs & Training Docs.) and maintenance are on the agenda along with other plant issues such as maintenance, open projects and safety issues and other pertinent items; the last meeting is dated 23/08/17.

Confidential Reporting System

A complaint/whistleblower 800 phone number has been instituted and employees have been informed of the method to make complaints or where employees can express their feelings about food safety issues freely. Corporate HR will contact the relevant Manager responsible for the item and is given the complaint or comment to review and the feedback is submitted to Senior Management; there have been no reports

Legal Compliance

The Director of Quality Assurance keeps apprised of changes to regulations and technical information via emails from regulatory agencies and industry groups containing timely information; Technical, Regulatory and Industry Updates, 3.3, 19/04/08.

Management Participation

Various upper managers attended the audit and were involved in the process. Discussions with top management during the audit along with their attendance during the opening & closing meetings indicate a commitment to the quality and safety of the products supplied.

Previous Non-Conformities

The 4 CAs from previous audit have been corrected with no repeats.

Organisational Structure, Responsibilities, and Management Authority

A Corporate and local Organization Chart is maintained and shows the management team and responsibilities including key job functions. The structure in the facility has 1 department head; alternates to cover absence of key positions relating to food safety, legality, and quality in the facility, are described; Nyssa Organizational Chart, 08.1-DI-001, 20/09/11.

Job descriptions for the positions on-site are present and were examined as part of the audit and were examined as part of the audit; all were found to be complete and accurate Job Descriptions and Additional Food Safety Responsibilities, 3.5-01, 22/09/20. Sugar Warehouse Manager and Mechanical Supervisor were reviewed.

Employees are cross trained in various activities.

Staff are aware of their responsibilities and are trained to report any food safety issues.

The site has genuine electronic copy of the BRCGS Food Standard Issue 9.

Logo is not used. Consultants are not used.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
1.1.13	Logo not being used.
1.2.4	Consultants are not used.

2. The Food Safety Plan – HACCP

HACCP Team

The HACCP Team includes the Warehouse Manager, Food Safety and Quality Professional (team Leader), Assist. Warehouse Supervisor, Warehouse Foreman, Warehouse Maintenance Lead and Quality Assurance Manager.

The HACCP Team leader has 4 years with the company and is a PCQI along with HACCP training by SAI Global dated 16/02. Training certificates are on file for the HACCP team from AIB and for PCQI trained personnel along with internal trainings conducted annually.

The HACCP Team Leader as well as the other team members have a good understanding of HACCP principles based on the responses provided during the audit when interviewed. HACCP Training for all employees is provided during the year using presentations and specialized training for CCP monitors.

Pre-Requisite Programs

The factory has documented pre-requisite programs such as sanitation, pest control, staff training, purchasing, GMP, equipment PM, environmental testing programs, allergens, complaint handling, and facility GMP and internal audits.

Based on an inspection of the facility, it appears they have implemented the pre-requisite programs effectively.

Scope of HACCP

The scope of the plan and all applicable criteria are well documented; Nyssa Facility Food Safety Plan, FSP-08-Nyssa, 23/05/05. The intended use of the items is for the general public except individuals with allergen sensitivities for the ingredients. Product uses are for further processing by customers including bakeries, creameries and confectioners and retail customers.

Product descriptions are available with relevant product and packaging information along with shelf life.

The intended use of the items is for the general public along with vulnerable individuals, except individuals with allergen sensitivities for the ingredients and are sold to retail.

Rework is not performed, however, product that is not compliant can be re-melted by a sister facility

Process Flow Diagrams

Bulk sugar and syrup are received in bulk form, inspected, run by magnet/filter and moved into storage tanks. Sugar is then run through another magnet and an in-line metal detector and moved to the enrobing line where syrup is filtered again and sprayed onto the sugar and packaged with metal detection used prior to loading for bulk sugar and after packaging and these are considered a CCP.

The 1 HACCP study include all processes and products with a flow diagram present and confirmed dated 22/12/15 for the Granulated Sugar and Brown Sugar.

Hazard Analysis

Hazard analysis includes the evaluation of Biological, Chemical (including Radiological) and Physical risks using a decision tree; those identified as of concern were physical contaminants mainly in the form of metal and foreign material. Risk assessments are documented for the raw materials and processing steps considering the probability and severity. Codex decision tree used and documented in the HACCP Plan.

FDA Compliance policy guidelines 555.425, food adulteration involving hard or sharp materials. FDA Regulation on cGMP, FDA Foodborne Pathogenic Microorganisms and Natural Toxin Handbook, FDA 2013, Hazard Analysis and Risk Based Preventative Controls for Human Food, CFR 117. Justification was determined using customer requirements, industry, manufacturer's standards and governmental regulations. Hazards are mainly foreign material and contamination.

Justification was determined using customer requirements, industry, manufacturer's standards and governmental regulations. Hazards are mainly foreign material and contamination.

All granular sugar received by rail car or tanker truck is passed through screens and magnets and is stored for distribution or brown sugar production.

Based on the risk assessment, the only CCP identified is Metal Detection for granular sugar and brown sugar.

Critical Control Points, limits and controls

CCP #1-3 Metal Detection: Critical Limits (retail bags): 1.5 Fe, 1.8 NF, 2.0 SS and 2.0 AL.; Bulk Bags (industrial): 1.8 Fe, 2.0 Non-Fe, 2.5 SS and 2.0 Al. All shipped granulated and brown sugar product passes through an operating metal detector; functionality of metal detector was checked during audit. Corrective actions include putting the product on hold and evaluating.

Screens and magnets are used for Granulated Sugar and are not considered a CCP.

Filters used for the Molasses upon receipt and prior to spraying are 100 microns and are changed weekly; they are to be intact with no damage or excessive material. Corrective actions include putting the product on hold and re-filtering.

If a deviation occurs, the product must be placed on hold since and wait for disposition from the QA department.

Validation, Verification, and Review

Justification was determined using customer requirements, industry and manufacturer's standards and governmental regulations with hazards assessed as being foreign material and contamination.

Verification and validation of CCPs and the HACCP plan is performed annually during the review using customer complaints, CCP records, historical data and published literature.

The plant validates critical limits when changes occur, during historical data review and by using product non-conformances, complaints and during the annual HACCP review meeting. The validation of pre-requisite programs for specific hazard controls will occur if there are changes or there are new plans.

The HACCP plan was last reviewed 23/05/05 and shall be reviewed when changes are made to the process or on an annual basis at a minimum.

Records were reviewed during the vertical audit

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual, 3.2 Document control, 3.3 Record completion and maintenance

Food Safety and Quality Manual

The Quality Manual with department specific work instructions is available on the password protected, backed-up, company intranet with hard copies also available. Documents reviewed during the audit were noted to be legible, unambiguous, in appropriate languages and appropriately detailed to enable their correct application by the staff.

Corporate Food Safety and Quality Assurance Manual, 2022; Nyssa Facility Food Safety Plan, FSP-08-Nyssa, 23/05/05.

Changing rights only to the Director of Quality Assurance Manager and Senior Quality Specialist.

Document Control

A system is in place to maintain the most current document version. Document Control: Creation, Approval, and Implementation, 2.1, 19/04/08.

Staff is trained in document control annually with the manual provided on the company intranet and hard copies using BASICSAFE software. An updated list of documents and forms is present in the database; Register of Standardized Policies, 22/09/20; Corporate Register (SOPs), 22/09/20 and Corporate Register (Records), 22/09/20 were confirmed during the audit. Terminal Policies, Procedures and Records Index were reviewed.

Record Completion and Maintenance

Director of QA is responsible for maintaining corporate documents and records in the password protected, backed-up, company intranet with hard copies also available.

The Terminal Manager is responsible for maintaining the site-specific documents and records with documents retained for 6 years; shelf life is generally 18 months for brown sugar with granulated sugar 5 years; Record Completion and Retention, 2.2, 21/04/22.

Records examined during the mock recall were observed to be legible and in good condition. All procedures and SOPs are fully documented in the password protected, backed-up, company intranet with hard copies also available.

Staff is trained in document control annually.

3.4 Internal audits

Audits are performed annually covering all aspects of the FSQM per the Internal Auditing and Facility Inspections, 8.3, 19/04/08. An audit schedule for 2023 has been prepared with procedures calling for the internal audits to be performed throughout the year quarterly.

The internal auditor was trained externally in HACCP and Internal auditing dated 13/01/13 and is independent from the facility being audited.

Corrective actions for the internal audits are documented on the audit form.

Auditor reviewed the records of the corporate internal audit performed 23/03/22 with sections 3 & 4 of the standard reviewed, Q2. Corrective actions were required for some of the reviewed sections, CAs were reviewed for the deficiencies noted in the section reviews with a CA followed through.

Corporate audits are also performed annually for corporate policies with documentation present.

Internal Auditing and Facility Inspections SOP also describes the monthly facility inspection procedures for all areas of the facility. Corrective actions for the GMP audits are documented on the check sheet used for auditing. Follow-ups and conformation of corrective actions are noted in the Database.

GMP auditors are chosen based on experience and training and on-going food safety training, generally the FSQS conducts inspections. Nyssa Self Inspection Form is used to audit the facility and includes deficiencies and comments.

Audits from 23/04/25 were reviewed including corrective actions. Findings of site audits are shared with the team during management meetings and are subject to formal corrective actions.

In addition, daily pre-operational inspections are conducted in various areas to ensure that maintenance and cleaning conditions are appropriate when the facility is shut down; Brown Line Pre-Operational Inspection, 08-181-REC-004, 19/12/17.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Documented procedures based on a Materials Risk Assessment for Granulated Sugar, 23/02/22, Cane Molasses, 23/02/22, Coating Syrup, 23/02/22, Bags Polyethylene, 23/02/22, Flexible Intermediate Bulk Container (FIBC) Totes, 22/02/22 and for the acceptance and testing of raw materials per Supplier Approval, 5.18, 21/04/22. The sugar, syrup, molasses and packaging have been deemed low risk.

The documented corporate procedures for approving suppliers of goods and services require a questionnaire to be filled out by the supplier and by supplying a GMP or GFSI 3rd party audits if possible. On-going evaluation of each supplier is carried out based on risk but not less than every 3 years. Approval records were examined as part of the vertical audit for sugar and additives.

The Supplier Approval Program states that unapproved suppliers (spot purchases) are allowed. Brokers are not used.

An up-to-date list of approved suppliers is available for review; Approved Supplier Registry 2023, 10.13-REG-02, 23/06/25. 100% of the granulated raw sugar is supplied by an Amalgamated sister facility, all GFSI approved facilities.

Traceability programs with suppliers are verified by GFSI audits for ingredient suppliers.

Suppliers examined during the audit:

1-International Molasses Corp.- BRCGS certified 23/03/28.
2-Amalgamated Sugar-supplier of raw sugar from sister facilities, all SQF certified.
3-Hood Packaging-Poly Bags-SQF certified 23/03/08.

The procedure describes that unapproved supplier (spot purchases) are allowed under certain circumstances and must be risk assessed and approved by upper management per the plan.

Approval records were examined as part of the vertical audit.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

COAs and CLOGs are obtained for the ingredients that are used and all material are inspected and tested as required upon receipt; Receiving Bulk Shipment Initial & Final Inspection, 6.4-REC-04, 19/12/04; Incoming Packaging & Palletizing Inspection, 10.9-REC-01, 19/07/19; Unloading Railcar Checklist, 10.9.2.3-REC-01, 18/01/10 among other SOPs.

Inspections are conducted on all trucks and railcars when raw materials are received including conditions and seal numbers. Sampling of dry bulk sugar is performed for all deliveries to compare with specs. and to look for unsafe product. Samples are held for each delivery for 6 months.

The information was reviewed for raw material and packaging materials included as part of the vertical audit with no issues noted.

3.5.3 Management of suppliers of services

Contracts and specifications for services are maintained for the limited number of service providers were examined and found to be current and correct. Services are:

Data Storage-BasicSafe
Waste Removal-Ontario Sanitation
Pest Control-Sprague
Laundry-Cintas

Services are evaluated periodically and if the evaluation is satisfactory, the contract is renewed.

Exceptions to the supplier approval program are generally not allowed following the Supplier Control Program.

3.5.4 Management of Outsourced processing

N/A

3.6 Specifications

Raw material and finished product specifications include Product Description, Product Specification, Relevant Analytical and Micro Specifications, Storage and Shelf-Life information. Data sheets are provided in company format for finished product specifications; Specification Management, 6.1, 19/04/08.

Specifications were reviewed for raw materials, Fine Granulated Sugar Bulk, 23/02/10; Medium Brown Cane Sugar Molasses, 22/09/03; 25 lb. Poly Bags, 22/09/12 and finished products, Brown Sugar, 21/07/29 and Dark Brown Sugar, 21/07/29.

All were found to be correct with specifications reviewed every 3 years.

3.7 Corrective and preventive actions

Defined procedures are in place to record, investigate, analyze and correct the cause of non-conformities against standards, specifications and procedures which are critical to product safety, legality, and quality.

Corrections and Corrective/Preventative Actions & Root Cause, 1.4, 22/06/14 describes the methods for applying corrective actions. A computer aided program (BasicSafe) is used to follow and close out corrective actions.

The procedure describes the methods for collecting and analyzing data to determine the root cause, develop corrective actions, assign responsibility and to document the effectiveness of the corrective action taken.

Examples of completed CAPAs were available and reviewed during the audit. Corrective actions are recorded for product non-conformances and internal audits, regulatory actions, external audits and any other source in BasicSafe.

There have been 35 CAs YTD including all audits performed. Reviewed CAPAs involving internal audits re: internal scorecard goals (sanitation, equipment, customer satisfaction).

3.8 Control of non-conforming product

Procedures describe activities required in the case of non-conforming product. Activities include putting the product on hold and providing evidence of conformance to the specification.

Non-Conforming Product or Materials, 7.2, 22/08/02, describes the procedures for releasing product and controlling non-conforming product. The Terminal Manager has the final authority for disposition along corporate QA.

Product is blocked form shipping by the computerized inventory control system. All non-conforming products are identified using the appropriate tag and segregated if possible.

All employees interviewed had a good understanding of the procedure to notify management in case of any non-conforming product or material.

Dry products can be remelted and processed in another facility and there has been no product destroyed.

3.9 Traceability

Traceability exercises are conducted per the Traceability, 4.4, 21/04/22, at least 2 times per year via a computerized tracking system. Procedures defines methods of controlling traceability of finished goods, semi-finished goods, raw material and packaging; Mock Trace of Product, WHS-REC-004, 12/05/15.

Most raw materials and all finished products are coded using a lot number consisting of 7 digits for packaged and bulk finished products coded using a lot number consisting of 9-10 digits; AN, year, Julian date, sequential load number.

Traceability exercises are generally conducted along with mock recalls, including the information one step behind and one step ahead with exercises completed at least annually.

Personnel interviewed can describe the lot tracking methods effectively. Records reviewed during the audit were current and completed per the plan.

Suppliers are required to state the details and a copy of their last traceability exercise on an initial questioner and every 3 years per their vendor approval program or through GFSI audits.

The facility conducted the last Traceability exercise 23/07/17 on 50 lb Poly Bags, received 22/10/28, Lot # 40130594 which was used in the finished product Brown Sugar, 50 lbs. produced various days. with 105% of the packaging traced in 1 hr. 24 min. A CA was instituted due to the overage in the traced amount, the data sheet used was incorrect in when the bags were used.

A forward and backward traceability/mock recall exercise was conducted during the audit was completed in 45 min. with 100% of the ingredient, Coating Syrup, 50,200 lbs., received 23/05/04 and 23/04/10, Lot #s AX23094LT and ...97LT. The finished product, Light Brown Sugar, 50 lbs. Lot #s AN23097-AN23103, processed various days with 100% recovered. Scenario was raw material with unknown foreign material.

There were no items identified that require a corrective action.

3.10 Complaint-handling

A clearly documented complaint handling system is in place undertaken by appropriately trained staff; Customer Complaint Management, 1.6, 21/09/02. Complaints are managed by the Corp. QA Dept. which handles all aspects of complaints.

Corrective actions are implemented when complaints are received, including an investigation of the root cause. A computer program, Smart Sheet, is used to track and detail complaints.

In all cases, complaints must be entered and investigated within an ascribed time frame.

There have no complaints to date this year. All complaints are all are tracked, trended and analyzed for significant trends and presented to Managers during Monthly Management Meetings. Complaints are generally regarding weight and bag seals.

3.11 Management of incidents, product withdrawal and product recall

Contingency plans for the disruption of utilities, natural disasters and sabotage have been formulated and are documented. The facility has plans and systems in place to effectively manage incidents including product withdrawal and recall procedures.

A site-specific Crisis Management Plan, 3.8-SOP-01, 23/05/31 describes procedures along with intentional adulteration and contingency plans for the management of issues such as natural disasters, utility loss or threats; Crisis Management and Contingency Planning, 1.7, 22/01/27.

The facility has a plan and system in place to effectively manage incidents including product withdrawal and recall procedures. The product recall and withdrawal procedure tested annually using different scenarios; Recall Program and Testing, 3.2.1, 22/06/14; Recall Plan, 3.2-01, 22/01/31.

The facility has a plan and system in place to effectively manage product withdrawal and recalls. The product recall and withdrawal procedures are tested using different scenarios. The responsibilities of the recall team, recall classification, information gathering, timelines, product on-hold, retrieval of affected product, communications, and investigation of root cause is included.

The incident plans call for the notification of the BRCGS certifying body in the event of an incident or withdrawal within 24 hours. contact with SGS within 21 days with a root cause, preventative action and result of recall is not present in the procedures. The contact list was verified to ensure contacts are included and information is updated along with Emergency Contact Numbers.

The facility conducts Mock Recall exercises annually with the last forward exercise performed 22/08/17 on the ingredient Canola Oil, 22/08/07, 2.5 gal., Lot# 104440 and was used as lubricant for light brown sugar produced on various dates with various lot #s with 100% of the products produced recalled in 54 min. Scenario was a change in supplier of canola oil from previous producer.

A forward and backward traceability/mock recall exercise was conducted during the audit was completed in 45 min. with 100% of the ingredient, Coating Syrup, 50,200 lbs., received 23/05/04 and 23/04/10, Lot #s AX23094LT and ...97LT. The finished product, Light Brown Sugar, 50 lbs. Lot #s AN23097-AN23103, processed various days with 100% recovered. Scenario was raw material with unknown foreign material.

As part of the vertical audit, records were reviewed for raw material approval, packaging material, weights, BOL for shipped products, truck inspections, product labels, testing records and sanitation information.

There have been no actual recalls.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.1.5	No agent or brokers used.
3.5.2.3	No live animals.
3.5.4.1	No outsourced processing and packing.
3.5.4.2	No outsourced processing and packing.
3.5.4.3	No outsourced processing and packing.
3.5.4.4	No outsourced processing and packing.
3.5.4.1	No outsourced processing and packing.

4. Site standards

4.1 External standards

The facility is located within an industrial area of Nyssa OR. In general, the external areas of the facility are kept in acceptable condition. Access roads along with service roads around the facility are paved. No local activities that would risk product contamination were noted.

The building fabric is maintained to a good standard. Walls are made of appropriate materials, brick for the most part. There is one dry sugar silo and 6 liquid sugar tanks; all were locked and maintained.

All trash containers are covered and are removed from the premises at appropriate intervals. The dumpster is on a regular cleaning schedule and is located on a rigid, cleanable surface.

No active live-stock or farming industries are in the area which make the potential for sewage contamination from live animal waste low.

Ornamental landscaping is trimmed away from building and plant grounds appear to have adequate drainage.

Loading/unloading dock areas are clean and free of debris and spills.

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4.2 Site security and food defence

A corporate plan, Food Defense, 9.1, 20/01/24 and a site-specific plan, written using the FDA Food Defense Builder software; Food Defense Plan 2022, 8.0-SOP-06, 21/03/19 and was reviewed 22/05/18. The facility is registered with the FDA under the Bioterrorism Act (see first page).

A Corporate Annual Food Defense Audit Summary was conducted 23/05/17 by a trained, qualified auditor.

Measures observed in place include electronic locks for all entrances with key cards used to allow access. The facility being partially fenced with controlled access maintained. A CCTV system is installed in the facility including internal and external areas.

Access for employees is allowed through only one door.

Bulk receiving was not observed during the audit, however, all pipes and connectors secured when not in use.

Food Defense training is covered annually for all continuing employees. Employees are trained in food defense procedures with training is conducted annually for all shifts. Generally, employees enter to the facilities through an employee door.

Contractors and visitors must sign the visitor log. General policies must be reviewed at entry including GMP practices required in processing and storage areas. All visitors must be escorted, and contractors are supervised during their stay in the facility.

4.3 Layout, product flow and segregation

Based on the appendix 2 of the BRCGS Standard the facility is considered as a low-risk site. An enclosed system is used for the process such as mixers, filling equipment, raw materials and finished product storage.

The segregation of the different areas in the facility is appropriate to prevent a potential contamination; segregated areas were observed for raw materials storage and processing areas, warehouse, lunchroom, toilets and locker room. Waste handling and storage is managed accordingly with no issues noted. Adequate space was observed between the equipment to allow for cleaning, inspection, maintenance and product cross contamination.

Site maps are available including the low risk and enclosed product areas: Personnel/Raw Material/Waste/Remelt/Production/Staff Amenities, 08.1-MAP-001, 22/03/02; Floor Map-Personnel and Waste, 08.1-MAP-005, 22/03/02. Production process flow is also indicated (HACCP Plan Flow Chart-closed system).

Temporary structures were not observed in the facility at the time of the inspection.

Contractors and visitors must sign the visitor log. General policies must be reviewed at entry including GMP practices required in processing and storage areas along with allergen awareness. All visitors must be escorted, and contractors are supervised during their stay in the facility.

Appropriate procedures have been implemented by the facility based on the low risk and enclosed products such as hand washing and gloves for personnel working in direct contact with the product to minimize the risk of contamination.

Color coding is used for product handling equipment.

There are no temporary structures.

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

Most sections of the plant feature fabrication with suitable wall and ceiling materials, proper ventilation was observed in the facility. Drainage is available in the equipment washroom and process rooms and is suitable for the facility and the operation, drains are trapped and covered. Windows were observed in the process area in doors are in good condition. Floors are in adequate condition.

The doors observed include personnel man doors, roll up doors and metal shipping doors – all were effectively maintained as required and seal effectively when closed.

Lighting observed in the facility was appropriate for the operation. Shatter proof lights were observed in place where exposed products are handled. Adequate ventilation is in place throughout the facility. In general, exhaust fans were observed in place and in good condition.

Elevated walkways are only provided over packaged product. Suspended ceilings are open for inspection.

Strip curtains were noted to be clean and undamaged.

Filtered air is not required.

4.5 Utilities – water, ice, air and other gases

Water is supplied by the City of Nyssa and and is tested annually for pathogenic bacteria with the last test dated 23/06/05. The testing laboratory is Analytical Labs–accredited by Ore Dept. Lab. Accred., expiration 24/01/09 along with Idaho Lab Accred.

Water is used as an ingredient in the facility and is used to wash/clean processing tools and equipment and is filtered and softened. A site plan is available indicating the water distribution system, Production Line Water System, 08.1-MAP-003, 21/09/20.

Backflow preventers are checked annually with the last 22/08/24.

Non-potable water is not used in the facility; ice is not used in the facility.

Compressed air or steam is not used for food contact areas; no other gasses are used. Food appropriate boiler chemicals are used in the boiler.

4.6 Equipment

Equipment observed in the facility such as mixers, pipes, augers, tanks and tables, among other items, were noted made of stainless steel or plastic in appropriate condition for the manufacture of food products. Maintenance and cleaning conditions of equipment and areas were appropriate.

Equipment was appropriately sited for cleaning and inspection. The main equipment in the facility are tables, mixers, conveyors, pipes, tanks and metal detectors.

4.6.3-MI-An equipment commissioning procedure is not place to control new equipment installation along with the movement of static equipment.

4.7 Maintenance

Preventive Maintenance Program is planned and accomplished using the computerized system following manufacturer recommendations, or on a risk-based system for older equipment; Facility and Equipment Maintenance, 5.6, 19/04/08; Preventative Maintenance Schedule, 10.1.9-REC-04, 18/12/05.

Each maintenance work order provided includes a documented hand back, checking for the removal of tools and that hygiene standards are inspected.

Reviewed maintenance work order as part of the vertical audit. The information was complete and included reconciliation of tools and cleaning after maintenance activities. Food grade lubricants were observed in use in the facility with a known allergen status.

Temporary repairs are generally not permitted and their suitability in a food environment is determined ona case-by-case basis with labelling and logging of the repair required; temporary repairs were not observed during the audit.

The Warehouse Manager is required to sign-off the pre-operational check/hygiene inspections after service and before the equipment can be used in production; Maintenance Log for Final Product Equipment, 10.5-01.0, 22/03/16 was examined.

The workshop is segregated and tidy.

An inspection is completed after maintenance activities to ensure the area is cleaned and free of foreign material. Maintenance is performed during off production times and cleaning is performed as part of the normal daily activities and pre-production inspections.

4.8 Staff facilities

Catering is not applicable to this facility.

The facility has designated locker rooms that are of sufficient size to accommodate personal items with one locker assigned to each worker. Suitable hand washing stations are provided at strategic areas throughout the facility. They are of a “hands-free” design, have sufficient water pressure, are supplied with liquid soap and single use towels and/or air dryers and have appropriate signage.

Toilets are adequately segregated with a hand-wash sink located in each toilet room. Auditor observed all workers wash their hands when returning to work from break using the wash station at the entrance to the packing area.

Food brought into the facility is appropriately stored in a clean and hygienic manner. Food and beverages are not allowed in the manufacturing areas. The facility provides a suitable designated area, outside of the processing and storage areas, where the employees can take a break. Smoking is only allowed outside in a designated area.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Chemical and physical contamination risks have been assessed as part of the HACCP study.
A Chemical Control Program in place for products used for cleaning and maintenance following Chemical Control, 5.17, 21/04/22 and is applicable for all possible chemicals that could be used in the facility. All chemicals are stored in a locked cabinet with access restricted.

An Approved Chemical List along with SDS sheets are on file and available on BasicSafe.

Strongly scented products were not observed in use at the time of the audit.

4.9.1.1-MI-Food grade items on shelf in chemical storage building was not labelled as such. Non-food grade items were segregated on separate storage rack.

Training is provided annually on chemical handling and control.

As a requirement, chemicals must be maintained inside of locked cabinet, properly labelled with access permitted to only those who have been trained in chemical usage.

All secondary chemical containers were observed to be properly identified during the inspection. No issues noted due to strongly scented products. SDS sheets are on file for cleaning chemicals.

4.9.2 Metal control

Staples or other foreign materials were not observed for ingredients and packaging materials used in the facility. Box cutters are used the only blades used and rarely; Physical Contamination Control, 5.9, 19/09/12.

Snap-off blades are not used.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Physical Contaminant Control, 5.9, 19/09/12, is used to control glass and other breakable materials including breakage procedures; Broken Glass & Brittle Plastic Clean-up Procedures, 10.8.2-SOP-0-01, 20/02/21. There are no windows in the process room, other windows are protected against breakage.

Glass audits are conducted monthly in the facility with documentation present; an audit from 23/04/17 was examined and found to be complete; Glass & Brittle Plastics Inspection (Truck Loading Dock, Flaker Landing & Mixer Floor, Industrial Line, Retail Line).

In case of breakage, an Incident Investigation Report must be completed; Food Safety Quality Incident Report, 7.4-01.0.1. Cleaning procedures are described in the procedure mentioned above and included all required information.

There has been no incidents since the previous audit.

Nothing is packed into glass containers.

4.9.4 Products packed into glass or other brittle containers

N/A

4.9.5 Wood

Wood is used only in pallets used for finished products. A risk assessment is on file supporting the risk of contamination is minimal because products, raw materials or finished goods are never exposed in places where wood could represent a risk, slip sheets are used.

Generally, plastic pallets are in use.

4.9.6 Other physical contaminants

Metal detectible pens are being used with no small parts. Portable, hand-held devices are also addressed in the GMP policy.

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

Foreign material detection has been considered within the HACCP study with filters and metal detectors used for foreign material control.

Liquid coatings for sugar products are run through filters prior to coating the sugar. Granulated sugar is metal detected post storage prior to coating or bulk loading. All coated products are metal detected.

4.10.2 Filters and sieves

Screens are used in various places in the process to control foreign material (1/4") and for granulation
control with 28-56 mesh roto screens used; screens are examined before each load and after each load for raw material and in-process screens are examined every 2-3 weeks based on risk.

100 mesh filters are used for coatings and are examined at the beginning of each shift; Brown Sugar Data Sheet, 08.1-REC-006, 20/02/13.

Validation of filter/screen use is conducted during the customer complaint review, historical data review and product non-conformance review (during HACCP review).

There have been no issues to date.

4.10.3 Metal detectors and X-ray equipment

X-Ray is not used.

CCP #1-Metal Detection: Critical Limits (Retail & Industrial): 1.5 Fe, 1.8 NF, 2.0 SS and 2.0 AL.; Bulk Bags (50 & 25 lb.): 1.8 Fe, 2.0 Non-Fe, 2.5 SS and 2.0 Al. All shipped granulated and brown sugar product passes through an operating metal detector; functionality of metal detector was checked during audit. Corrective actions include putting the product on hold and evaluating.

A metal detector is used on all packaging lines and were challenged during the audit and found to be working correctly.

If metal is detected, the line stops with a visual and audible alarm.

Records were reviewed as part of the mock recall; CCP: Packaged Product Metal Detector, 6.3-01.0.

4.10.3.4-MI-It was noted that the rejection mechanism of product suspected of containing metal on the retail line is not being tested along with the detector itself. The line uses a compressed air blast to reject bags into a secured container.

An outside service calibrates metal detectors on annual basis.

4.10.4 Magnets

Rare earth magnets are located before the metal detector and at various points in the process, mostly to protect equipment. Magnets are checked before and after each load with pull tests carried out annually for each magnet.

4.10.5 Optical sorting equipment
N/A

4.10.6 Container cleanliness – glass jars, cans and other rigid containers
N/A

4.10.7 Other foreign-body detection and removal equipment
N/A

4.11 Housekeeping and hygiene
Cleaning, Sanitation, and Waste Management, 5.7, 19/04/08, is on file with SSOPs available for each piece of equipment in the facility. Sanitation schedules are on file and available for the coating lines and the granulated load-out area; Master Cleaning Schedule (1-7), 08.1-REC-032-38, 21/05/27; Warehouse Rack Cleaning Certificate, 08.1-REC-064, 20/02/21; Daily Hygiene Inspection Record, 08.1-REC-010, 22/03/03. Their sanitation program addresses responsibilities and covers all area of the facility, frequencies, methods, and records with limits of acceptability and unacceptable cleaning performance defined. SSOPs are present with Cleaning Contaminated Screw Conveyors, 10.6.1-SOP-009, 21/07/07, examined and found to be complete. **4.11.1-MI-Appropriate cleaning conditions observed in the different areas in the facility such as processing areas, however cobwebs and were observed on a wall of the B warehouse along with general dust and dirt on the shipping receiving dock.** Cleaning of equipment is generally performed on weekends during non-production hours. Cleaning is validated visually through post cleaning inspections (post sanitation checklist) every time cleaning occurs. No trends were observed, and no issues noted. Appropriate cleaning conditions observed in the different areas in the facility such as processing areas and warehouse areas. No product changeover as only brown sugar is processed. A review of records showed that cleaning activities were completed according to the schedule. Training is provided on SSOPs annually.

4.11.7 Cleaning in place (CIP)
A hot water flush is performed on all equipment that cannot be taken apart (tanks, pipes). No chemicals or sanitizers are used per a risk assessment and validation study.

4.11.8 Environmental monitoring
A risk assessment has determined that due to the type of products stored and processed, no monitoring is needed due to the low Aw, shelf stability and historical data. Validation studies based on published literature are included in the risk assessment including all possible pathogens that could thrive on non-food contact areas and surfaces. Granulated and brown sugar are the

only finished products handled and assessed. The molasses used as an ingredient for the brown sugar is included in the risk assessment and has also been risk assessed as part of the raw material assessment.

4.12 Waste and waste disposal

Waste containers observed inside of processing areas and the dumpster was observed clean and in good conditions. Cleaning, Sanitation and Waste Management, 5.7, 19/04/08.

No product is destroyed unless there is contamination.

Ontario Sanitation the waste hauler.

4.13 Management of surplus food and products for animal feed

N/A

4.14 Pest management

Pest control service is provided by Sprague; Integrated Pest Management, 5.4, 21/04/22.

Twice monthly service is conducted for the 113 internal rodent monitoring devices and the 24 ILTs with the 85 external bait stations and 7 external traps inspected monthly. Birds are excluded from buildings by closing doors and by using outdoor avicides as needed. Pest Operator licenses are on file, expiring 23/12/31.

A Device Schematic dated 22/12/30 is present and accurate.

Appropriate records were observed on file for chemicals applied on site; reviewed SDS for First Strike Soft Bait.

4.14.3 No in-house pest control
4.1.4.6 No insect killer or pheromone is used.
4.14.7 There was no evidence of bird roosting on-site at dock area.

Service records were reviewed for the last three months with the information complete and current according to the service schedule. Trending is on file and is updated quarterly with no relevant pest activity has been reported.

A Pest Program Review by a certified pest control operator is conducted annually for the facility with the last being 23/01/01.

Employees are trained in pest control annually.

4.15 Storage facilities

An adjacent warehouse stores finished products and packaging materials with bulk sugar stored in silos or railcars with all stock is identified and rotated. All materials were observed off the floor and properly sealed to prevent cross contamination, FIFO is used; Product Storage and Warehousing, 5.10, 19/04/08.

Controlled atmosphere storage was not applicable to this operation.

All storage and load-out facilities and equipment are well designed and maintained and suitable for their purpose**.**

Nothing is stored outside.

4.16 Dispatch and transport

Several written procedures are implemented in the facility describing the activities conducted; Dry Van Trailer and Container Shipments, 5.13, 19/04/08. Loads can be shipped a company managed warehouse or to the customer directly using contracted haulers.

Bulk Sugar Railcars, 5.11, 21/04/22, describes work instructions for unloading granulated sugar rail cars for transfer into storage silo.

Inbound tankers of liquid products (syrup) are inspected upon receipt for seals and condition; Syrup Receiving Checklist, 08.1-REC-054, 20/04/16.

All trucks are inspected prior to loading and information documented on the Work Order; Inspecting Empty Trailers, 5.11.1_S_08_IET, 12/07/31.

Reviewed trailer load-out forms for vertical audit with all found correct with no issues. All trucks are sealed or locked prior leaving the facility; temperature control is not required.

Traceability information is documented on Bills of Lading.

Receiving and shipping documents were examined as part of the mock recall for the products involved.

Vehicles on site (forklifts) are inspected daily.

No deliveries or shipments were witnessed.

No contractors used.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.3.9	No temporary structures constructed
4.5.3	No legislation that specifically permits the use of water which may not be potable for processing.
4.5.4	No gasses are used.
4.8.8	No catering facilities.
4.9.4	No products packed into glass or other brittle containers.

4.10.5	No optical sorting equipment.
4.11.7	No CIP.
4.11.8	No enviro. monitoring.
4.12.1	Licensing for the removal of waste isn't required by law.
4.13	No surplus food and products for animal feed.
4.14.3	The site doesn't undertake its own pest control.
4.15.4	No controlled atmosphere.
4.15.5	No outside storage.
4.16.6	No contractors used.

5. Product control

5.1 Product design/development

There is no product development at this site, product development is a corporate procedure. The HACCP team shall review all new products for compliance, shelf-life studies and risk.

5.2 Product labelling

No labels are required for pre-printed retail and industrial bags, only coding is applied, but totes are labelled; Policy: 8.2.1 Product Coding & Identification, 8.2.1; Product Nutritional & Safe Handling Labelling, 8.2.2; Food Regulation Compliance & Letters of Guarantee, 6.1. All lot and production information is on the BOL and labels for totes.

No claims are made. No changeover was observed.

5.3 Management of allergens

An allergen risk assessment, completed as part of the HACCP study and the and is included as part of the chemical hazards, detailed in section 2 of this report.

There are no allergens stored or processed on site.

There are no claims; no warning labels are required. Allergen awareness training is conducted annually. Visitors are also made aware of the allergen policy as was the auditor.

5.4 Product authenticity, claims and chain of custody

Vulnerability assessments are conducted annually on all raw materials and are included in the risk assessment for each raw material reviewed; Granulated Sugar, 23/02/22, Cane Molasses, 23/02/22, Coating Syrup, 23/02/22, Bags Polyethylene, 23/02/22, Flexible Intermediate Bulk Container (FIBC) Totes, 22/02/22.

Sugar and coatings are the only raw materials, with the sugar and coating syrup supplied from sister facilities in Idaho; there is no risk of substitution. Molasses coating is supplied by approved suppliers; Food Fraud, 9.2, 19/04/08.

Risks are classified as low, medium or high; all ingredients are low risk. Low risk suppliers are reviewed every 3 years using a questioner/GFSI audit and reviewing historical data. Due diligence in the vendor approval program and testing of products are mitigating factors. All bulk items are sampled and tested for purity, conformance to COAs and to global standards.

All products are Kosher certified by OU with the certificate expiring 23/12/31.

No claims are made on products manufactured in the facility.

5.5 Product packaging

Dedicated storage areas for totes are in place with letters of guarantee obtained indicating compliance with legislation and food grade applications. Product packaging is appropriate for the intended use and is stored under conditions to minimize contamination and deterioration. Totes and plastic bags make up all packaging.

Obsolete packaging and excess labels are segregated and destroyed to prevent use.

5.6 Product inspection, on-site product testing and laboratory analysis

The facility has an on-site lab and tests finished products for quality parameters. The laboratory is completely segregated outside of processing areas with access restricted.

All batches of finished product are analyzed for physical and chemical attributes including ash, color, pH, turbidity, coating %, moisture, sediment and brix. SOPs are present for all tests performed. COAs are produced based on the testing results. Product with unacceptable test results are placed on hold and examined.

Product Sampling: Brix Testing, 5.1.2-05; Procedure: Sediment Test, 5.1.2-02; Color and Turbidity, 5.1.2-03; pH, 5.1.2-04.

For raw materials, a physical inspection is conducted upon receipt and documented along with a sample taken.

The Amalgamated Sugar Central Lab performs shelf-life testing. Product quality parameters are re-confirmed by the Central Lab for each lot produced. Random pathogen monitoring is performed on finished product by the Central Lab.

Only qualified, trained individuals can adjust equipment or perform tests.

If testing does not confirm specifications, product is placed on hold an is handled using Non-Conforming Product procedures with the QA Manager and ultimately QA Director responsible for product disposition. Only qualified, trained individuals can adjust equipment or perform tests on all lines.

All parameter testing occurs on-site with yeast and mold testing of all finished products performed at the Amalgamated Sugar Central Lab in Twin Falls, ID.

Water testing is performed by Analytical Labs which is certified and uses approved test methods.

The Central Lab is ISO 17025 certified valid until 24/12/31; the testing they perform is only quality checks on finished product to verify the site labs' performance. All test methods are certified AOAC, BAM, FDA.

During the packaging stage, coding, packaging and labels are checked at the beginning of a run for and the information is documented.

Lab technicians have adequate training and use official testing procedures (AOAC and BAM). The facility performs proficiency testing at least annually on-site; Laboratory Proficiency Testing, 6.7, 19/04/08.

Lab results are tracked and trended quarterly per the program and are presented to Management at quarterly meetings. If positive results are indicated, product is traced and/or placed on hold and investigated. Equipment used will be thoroughly cleaned and swab testing.

5.7 Product release

The facility has a documented positive release product program which requires the review of lab results prior to the release of the finished product; Product Hold & Release, 7.3, 19/04/08.

Only product in compliance with the specs. and requirements can be loaded. Products on hold are not eligible for shipment and are blocked by the computerized inventory control system. Product destined for remelt was observed to be labelled and segregated.

Documents were reviewed for the product included in the vertical audit.

5.8 Pet food and animal feed

N/A

5.9 Animal primary conversion

N/A

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.1	No product development.

5.2.3	No claims made to satisfy a consumer group (no nutritional claims).
5.3.5	No rework used or reworking operations carried out.
5.8	No pet food produced.
5.9	No animal conversion.

6. Process control

6.1 Control of operations

The company operates using procedures and SOPs to verify that the processes and equipment employed can produce a consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan.

Operations are controlled using various procedures for product. SOPs are contained on the shared hard drive along with processing parameters which are monitored for each batch including water temperature, color, brix and pH.

Shelf life of granulated sugar is 5 years and 18 months for brown sugar.

Interviews indicate employees are familiar with corrective action procedures and in general operations. Only qualified, trained and authorized individuals can adjust equipment.

Auditor was not able to view changeover; only one product was being packed during audit.
With any breakdown of equipment, corrective actions are instituted.

No in-line monitoring is used.

In the case of equipment failure, product is placed on hold and evaluated.

6.2 Labelling and pack control

Labels are not required for bagged product, only verification and coding. Labels for totes are examined while being applied to the tote and confirmed by the operator.

6.2.4-N/A-Optical in-line systems are not used.

A product changeover was not observed due to the processing schedule.

Optical in-line systems are not used.

6.3 Quantity, weight, volume and number control

Each bag is weighed to assure correct weight with Retail and Industrial bags using an automatic weigher/bagger with check weights taken every hour on 6 bags. Totes are individually weighed.

Each packaging line has automatic check-weighing systems to ensure the required weight filled with a rejection feature.

During the audit, weight information was reviewed for lines in operation with the information recorded as being correct.

Records were reviewed for the vertical audit and were found to be complete and accurate.

6.4 Calibration and control of measuring and monitoring devices

Equipment in need of calibrating is clearly identified with an ID number and risk assessed due date, Package Weights and Scale Licensing, 6.6, 22/06/14; Equipment Calibration: Food Safety, 5.5, 22/06/14. Calibrations are performed and scheduled using a calibration matrix, Calibration Equipment List, WHS-REC-074, 23/06/20.

Scales are calibrated quarterly by Total Scales with the last dated 23/05/03; Rail Scale-22/11/11; Truck Scale, 23/05/03, Tote Scale-23/05/03. Lab equipment is calibrated annually by Quality Control Services including Lab Balance and equipment with the last calibrations dated 23/05/03. Metal Detectors were calibrated 23/03/01 by RL Scott. Magnets are pull tested annually, 23/05/21.

Only Qualified Operators verify and check metal detectors.

If a device is out of calibration, affected product is subject to the Non-Conforming Product Procedures.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.1.3	No in-line monitoring.
6.1.4	There is no variation in processing conditions.
6.2.4	No on-line label vision devices are used.

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

The facility has a comprehensive training program for all staff and employees including the subjects GMPs, food defense, sanitation, pest control, HACCP, allergens, document control and hygiene policy on induction with an annual refresher program for continuing employees described in Employee Food Safety and Quality Training, 5.2, 22/06/14.

A Training Register is present for all employees which indicates training required and received; Annual Training, Review & New Hire, 10.2.2-REC-01, 13/05/14.

7.1.6-MI-Training records for various employees were examined and were found to be accurate and timely, however, several training sign-up sheets did not have the subject, trainer or duration of training.

BasicSafe is used for Employee Training Management is used to record trainings with training materials and records available for review, i.e. Allergen Training, GMPs. Personnel involved with monitoring and QC receive specialized training.

Individuals are required to undergo adequate training in core subjects and must pass quizzes relating to operating procedures, testing parameters, GMPs and corrective actions, etc.

Individuals performing CCP monitoring are trained for each task with refresher training performed annually with trainings for all CCP monitors.

Interviews confirmed the competency and knowledge of monitors during the audit with the effectiveness of training evaluated by on the job observations and interviews. Employees are evaluated annually.

Training records for various workers were reviewed and found to be complete and accurate.

Visitors are trained in GMPs and Allergen Awareness using printed materials.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

GMP requirements are in place for all employees, visitors and contractors. Good Manufacturing Practices and Prerequisite Programs, 5.1, 22/06/14; Personnel Practices, 5.3, 21/04/22. The procedures describe the restrictions for jewellery and prohibits wearing of rings, fingernail polish, false fingernails and body jewellery. The policy restricts the use of strong perfume or cologne with instructions regarding the storage and use of personal medications is also present.

Hand cleaning is conducted at the entry to the production areas and after being in contact with dirty surfaces.

A visitor and contractor GMP policy is present, Visitors, 5.19, 19/04/08, which is to be reviewed and signed prior to entry to the facility. The policy contains information regarding allergens and general allergen requirements. Contractors on-site for construction have been trained in core subjects with documentation present.

Any cuts and grazes on exposed skin shall be covered by blue band aid that is issued by the company. Records of each lot tested of metal detectable band aids are in place; Metal Detector Validation Log for Band Aids, WHS-REC-122, 16/10/17.

Hand washing stations are installed at the entrance point and the processing areas.

7.3 Medical screening

All new employees are required to be medically screened prior to employment and is addressed in the screening program as part of their overall GMP program; workers are to contact office from home if ill. All new employees and visitors are required to be medically screened prior to employment or entrance to the facility; Medical Screening is managed following Personnel Practices, 5.3.2.1, 21/04/22.

Permission to return to work from health care provider is required if the illness is of an infectious nature. Management can request that employees and non-employees leave the site and refer them to competent medical experts.

Visitors are required to review and agree the visitor policy requiring reporting of any health issue.

No sick employees were observed in processing areas during the audit.

7.4 Protective clothing: employees or visitors to production areas

The rules regarding uniforms are communicated to all employees during GMP & PPE training and the information is clearly described in the procedure, Good Manufacturing Practices and Prerequisite Programs, 5.1, 22/06/14; Personnel Practices, 5.3, 21/04/22.

Coveralls and uniforms are provided to employees and are laundered by Cintas. Employees change into their coveralls on-site and they must be removed if they need to go outside of the facility or to the restroom.

The facility requires that disposable gloves be used with blue coloring. Gloves are changed when soiled, after touching dirty items or after leaving the process area and are used as a safety requirement only.

The plant verifies the cleanliness of protective clothing via visual inspection.

No un-washable PPE observed in the facility.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
7.4.7	All clothing can be laundered.

8. Production risk zones – high risk, high care and ambient high care production risk zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Equipment and maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

9. Requirements for traded products
9.1 The food safety plan - HACCP
Not applicable
9.2 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.3 Specifications
Not applicable
9.4 Product inspection and laboratory testing
Not applicable
9.5 Product legality
Not applicable
9.6 Traceability
Not applicable

Module 11: Meat Supply Chain Assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	

11.3 Raw material receipt and inspection
Click or tap here to enter text.
11.4 Management of cross-contamination between species
Click or tap here to enter text.
11.5 Product testing
Click or tap here to enter text.
11.6 Training
Click or tap here to enter text.

Module 13: Meeting FSMA Requirements for Food – July 2022
Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33)
Click or tap here to enter text.
Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)
Click or tap here to enter text.
Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)
Click or tap here to enter text.
Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)
Click or tap here to enter text.
Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)
Click or tap here to enter text.

14.1 Additional Specifier Requirements
14.1 Traceability
Click or tap here to enter text.
14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.