Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary			
Company name	Tate & Lyle Ingredients Americas LLC	BRC Site Code	1818906
Site name	Tate & Lyle Ingredients Americas LLC -Duluth Plant		
Scope of audit	The hydrolysis and isomerization of maleic anhydride to make malic acid and fumaric acid, drying the material and packing into bags, drums and super sacks.		
Exclusions from scope	None		
Justification for exclusion			
Audit Finish Date	2017-04-19		
Re-audit due date	2018-05-06		

Voluntary modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	AA	Previous audit date	2016-04-27		

Number of non-conformities		
	Fundamental	0
	Critical	0
	Major	0
	Minor	1

3.Company Details

Address	Tate & Lyle Ingredients Americas LLC 110 Spring Street Duluth, MN 55808		
Country	United States	Site Telephone Number	2186280126
Commercial representative Name	Richard Benner	Email	Richard.benner@tateandlyle.com
Technical representative Name	Katherine Stephenson	Email	Katherine.stephenson@tateandlyle.com

4.Company Profile

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

Subcontracted processes	No
Other certificates held	Kosher, Halal, ISO 9001:2008
Regions exported to	North America South America Asia Europe Africa
Company registration number	FDA Facility Registration
Major changes since last BRC audit	Process controller upgrades on dryers.

The Duluth plant is one of the Tate and Lyle food grade acidulant plants. The building was built in 1977 and contains 2230 square meters of area. The plant employs 23 people on a 24- hours a day/7 days a week schedule. The plant is located on the shore of St. Louis River on the south side of Duluth. Maleic anhydride is received in rail cars and converted into dry malic acid and fumaric acid. Products are shipped in Kraft paper/poly bags, poly lined fiber barrels and poly super sacks. Finished goods are loaded onto a trailer and held on-site until the product is tested and released. The product is then shipped to an off-site warehouse for subsequent shipment to customers.

5.Product Characteristics					
Product categories	15 - Dried food and ingredients				
Finished product safety rationale	Processing temperatures greater than 180° F and moisture of less than 0.5%.				
High care	No	High risk	No	Ambient high care	No
Justification for area	The process and packaging areas are enclosed. All products are shelf stable at ambient temperatures; there is no “kill step”.				
Allergens handled on site	None				
Product claims made e.g. IP, organic	Kosher, Halal				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Fumaric acid and malic acid in poly totes and paper/poly bags.				

6.Audit Duration Details

On-site duration	13 man hours	Duration of production facility inspection	5 man hours
Reasons for deviation from typical or expected audit duration	The plant is very small, the process is completely enclosed and automated.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2017-04-18	09:00	16:00
2	2017-04-19	08:00	14:00

	Auditor (s) number(s)	Names and roles of others
Auditor Number	123259	Michael Waytowich
Second Auditor Number	N/A	

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 1.1.9) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Rich Benner/Plant Manager	X	X	X	X
Katy Stephenson/Quality Assurance Manager	X	X	X	X
Ken Borowicz/ Production Supervisor	X			X
Patrick Buyck/Engineer	X			X
Manley Olson/Maintenance Manager	X		X	X
Abhighew Shah/Engineer	X			X
Steve Abramson/Production Superintendent	X			X

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	**Clause**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Clause**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	4.4.5	There is a ceiling water leak in the process area. It was raining during this observation. Water was not contacting equipment or product.	Initial investigation of the water leak (with no contact to equipment or product) was conducted by our maintenance department. Their inspection did not reveal the source of the leak. No holes, cracks, or roof deterioration were found. The location of the water observed on the wall during the audit leads us to believe it was coming through the highest part of the plant roof, above the baghouse room. We have scheduled for a qualified roofing company to inspect the roof in June 2017.	A preventive maintenance work order has been entered in SAP for annual routine inspection of the roof for holes, cracks or deterioration.	Screenshot of preventive maintenance work order in SAP. Updated GMP audit form with addition to observe for any moisture on walls for possible roof leak.	2017-05-11	Michael Waytowich

Comments on non-conformities

Voluntary Modules Non-Conformity Summary Sheet

Critical			
No.	**Clause**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The facility has a quality policy. The Tate & Lyle Global Mission Statement states: Tate & Lyle is committed to providing Quality products and services for our customers. A culture of continuous improvement is supported by strong management and by the measurement of results. We believe that: Quality creates value for our customers and shareholders. Quality is a key part of every job and business process at Tate & Lyle. Quality is the key to customer preference. Quality is the key to competitiveness. Teamwork and clear focus coupled with measurement of results provides a culture for continuous improvement at Tate & Lyle. It is our mission to be: "Consistently First in Customer Satisfaction". The policy is signed by the President of Tate & Lyle. In addition, the Company has a 10 point Global Quality Policy concerning, for example, regulatory compliance, food safety, customer needs, corrective actions, etc.

Objectives and monitoring

1) Achieve 99.6% (actual 99.37%) or better first pass quality of finished product. 2) Reduce the quantity of tramp metal picked up by in-process magnet samples by 5% versus the previous year. 3) Achieve 0.71 or better complaint ratio (per 100 shipment). FY 2017 =1.72. 4) Deliver packaging improvements focused on the perfect pallet. Results are monitored/reviewed by the staff at various daily, weekly, monthly and annual meetings.

Management review and meeting program

The plant has quarterly Quality System Management Reviews (QSMR) to make sure that activities to meet these objectives are being completed. Results of the last meeting in January 12, 2017 indicated the results were being met. The minutes discussed the action items for the last QMSR, internal audit results, customer complaints, and a review of the HACCP Plan. The last management review was held October 2016. The plant passed their ISO 9002 recertification audit in 2016. Monthly management meetings are held to review the progress on meeting the plants quality objectives. The Duluth Plant is currently fully staffed for management positions. The Company is a member of the Corn Refiners Association (CRA) ,which communicates changes in regulatory requirements and technical changes in the industry. The plant has a hard copy of BRC Version 7. The last BRC Audit was completed on April 26-27, 2016. The plant's initial audit was completed in 2012. The audit window is April 8, 2017 through May 6, 2017; thus, the audit was conducted in the proper time frame. The Plant Manager attended both the opening and closing meetings and participated in the plant tours and records review. The Duluth Plant received two Non-conformances (3.5.1.2, and 4.9.1.1) during their last audit and they were confirmed as being corrected.

1.2 Organisational structure, responsibilities and management authority

The plant has an organization chart that was updated April 5 2017. The Quality Assurance Manager reports to the Corporate Quality Director, who reports to the Vice President of Global Quality, with a dotted line reporting relationship to the Plant Manager. The Decatur Corporate Office has a Global Quality Director who provides technical support to the plant. The managers who are responsible for key manager's absences are described as being filled "by the position one level up or their designee". For example, in the absence of the Quality Assurance Manager, the Laboratory Technician assumes the routine quality functions. Each person in the plant has a job description. The plant employees have the details of their quality responsibilities documented in the Skill Block Program used in Tate & Lyle Plants. Each Skill Block attainment is approved by the Production Superintendent. Managers have job descriptions and objectives are developed to support the plant's objectives. Examined the job descriptions for the Quality Assurance Manager and a Packaging Operator and they were very complete. Managers receive quarterly updates and annual reviews. Plant employees receive an annual appraisal.

Details of non-applicable clauses with justification

Clause reference	Justification
	NIL

2 The Food Safety Plan – HACCP

HACCP team: The HACCP Team is made up of the Quality Assurance Manager, the Plant Manager, the Production Superintendent, the Production Supervisor, the Maintenance Supervisor, the Process Engineer, the MRP Controller and a QA Technician. The Quality Assurance Manager is the Team Leader. She has quality control experience from previous jobs and has been trained by the Director of Quality Control. The Plant Manager has HACCP training from Zurich. Internal resources have trained the remainder of the team. The plant QA Manager also had FSMA training.

Products: There are two product descriptions. The Product Descriptions for malic acid and fumaric acid state: White crystalline powder/granule with strong acidic taste. Raw materials used are maleic anhydride (defined as a process aid in the HACCP Plan). The Physical/Chemical Properties that impact the product are processing temperatures greater than 140° F and moisture of less than 0.5%. The intended users are defined as: the food industry and industrial users. Packaging is into bags, drums and bulk containers. Distribution states: inspected, secure, cool, dry trucks. The shelf-life is listed as 5 years. Corporate Quality Control provides the HACCP Team with scientific, legal and historical information. Customer requirements are developed based on feedback from the customers. References are made to CFR and FDA regulations. The intended users for all products are defined as: "the food industry and industrial users".

Process flow steps: There are two process flow diagrams. The flow diagrams for both malic acid and fumaric acid are the same at the start of the process (from batch make-up, to reaction, to precipitation and to separation). After separation, the fumaric acid goes to drying and classification, and then into bins that supply the bagging and bulk stations. The malic acid product after separation goes through purification, to evaporation, to crystallization, to centrifuges, to a dryer, to classification and into holding bins that supply

the same bagger and tote filling stations used for fumaric acid. From the holding bins, the bagged and bulk product go through another classification sifter and the bulk containers are filled. The bagged products are filled and then go through a metal detector. The bulk metal detector (M814) is used to detect metal on the super sacks and barrels and it is a CCP. The sifter (Sweco M811) is also a CCP on the bulk line and the sifter (Vibrafeed M823) and the metal detector (M846) are CCPs on the bagged line. The flow diagrams were last reviewed and verified on 7/13/16 and were confirmed as current.
Hazards: Each step of the process was evaluated in the hazard analysis. There are two hazard analyses completed (one for each flow diagram). Ingredients, processing aids (including water) and packaging were evaluated as to their risk. All steps were evaluated for chemical, physical and biological risks. Allergens are addressed in the HACCP Plans. A scale of 0-3 was used for both the likelihood of occurrence and the severity axes of the matrix. All items ranked as 6 and above were considered CCPs. A scale of 0-3 was used to evaluate both the likelihood of occurrence and the severity (0 is no risk or no severity and 3 is high likelihood or high severity). Chemical risks are reduced through prerequisite programs for incoming raw and packaging materials. Biological risks are controlled through prerequisite programs and the products stability. Foreign material is the only risk that the plant controls through their CCP checks. The control measures used to eliminate or reduce the hazard were based on industry standards and legal requirements. The justification for acceptable levels is documented on the HACCP Master Plan.
CCPs and critical limits: There are 4 CCPs: 2 for bags and 2 for bulk. One metal detector and one screen for each of the two products. If metal detector or screens fail then product is held from the last good check. Screens are checked twice per shift and metal detector once per shift. For the sifters, critical limits state: "Screen not in place, any tears or signs of screen breakage, or screen with openings greater than 3 mm." For the metal detector, the critical limit states: "Metal Detector does not trip or reject the bag."
Validation methods of CCPs: The validation of the CCPs is done with a review of Deviation Reports, customer complaints and non-conforming product as a result of foreign material.
Monitoring and corrective actions: CCP monitoring is done by the "Dry-side Operator". The Screens are inspected by visual inspection once a shift (every 8 or 12 hours depending on the day of the week). The Dry-side Operator checks the metal detectors once a shift. The corrective action for the metal detectors states: "If metal detector fails to detect the test piece, stop packing, contact the Supervisor, place product on hold from the last good check. If the detector fails to detect the test pieces, contact Maintenance to investigate and correct by adjusting the sensitivity or repair." The auditor observed the Operator while he was performing his checks and they were completed properly. The PRP and HACCP plan were last reviewed on 9/14/2017 and 9/15/2017.

Details of non-applicable clauses with justification

Clause reference	Justification
	NIL

3. Food safety and quality management system

3.1 Food safety and quality manual

The plant has a Quality Manual that is signed off by the Global Quality Director and the Global Vice President of Quality. The manual contains corporate policies, plant policies and procedures. The Manual also contains quality related work instructions (SOPs). The manual is maintained in a SharePoint Database and is available to employees on the Intranet. All of the policies and procedures reviewed for this audit were clear and unambiguous. The Quality Assurance Manager is responsible for the generation, review and changes in the plant's quality procedures and policies. Documents are available to all employees on a "read only" shared drive.

3.2 Documentation control

The SharePoint database contains a list of all or the corporate policies and procedures, plant policies and procedures and SOPs for the Duluth Plant (both quality and production SOPs). Each file contains the history of changes made to the documents and the dates of all the revisions. Documents have a name and a revision number assigned to them when they are printed. The record contains the date the documented was generated, the last review date and the current review date.

3.3 Record completion and maintenance

All forms are available to employees in SharePoint. Paper records reviewed for this audit included inbound and outbound trailer inspections, reprocess checklists and sanitation checklists. All of the records were in good condition and changes made adhered to plant document change requirements. Electronic records are backed up daily. There is a corporate policy titled "Records Retention Schedule" that lists the retention requirements for all documents including quality related documents. Due to the five-year shelf life of the products, quality documents are retained for six years.

3.4 Internal audit

Completed by: All of the auditors who participate in the internal audit program are trained by Corporate auditors. The auditors do not audit in their area of work.

Program: There is a Global Compliance Audit (that covers all the items in the BRC audit, through the corporate Quality Assurance program). This is performed in sections throughout the year; records for November 2016, sections 1-4 were reviewed. Auditors from other Tate and Lyle plants (or Corporate Quality Assurance) audit the plant.

Inspections: Each monthly GMP inspection covers all of the plant and Good Manufacturing Practices. The GMP inspections from 1/15/17 and 1/22/17 were reviewed. The QA Manager enters the results of the audits into a database in SharePoint and the deviations, by location can be tracked. This allows the management team to identify recurring observations and develop corrective actions. A bi-annual glass and brittle plastic audit was also reviewed. No broken plastic items were recorded.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

The procedure titled “Supplier Approval and Monitoring”, updated 4/1/17, defines the requirements for raw material, packaging material and processing aid suppliers. The procedure includes a checklist that is to be used by the Tate & Lyle employee who visits the supplier’s site. The checklist addresses allergens, GMPs, legal and regulatory compliance, quality systems, traceability system and foreign material risks. Based on the definition of processing aids in the policy, there are not any raw materials used at the site, only processing aids. The policy identifies packaging material as high risk and requires them to have either a third party audit or be audited by a Tate & Lyle representative every two years. Any changes of suppliers for processing aids are managed through the Management of Change Process. Tate & Lyle currently only approves suppliers who have been audited by a Tate & Lyle employee using the checklist. The auditor examined documents (letter of continuing guarantee, specification) for the raw material, maleic anhydride. Also examined audit scores for a packaging supplier (There are records of the two plants that provide poly-lined bags to the plant being audited by a Tate & Lyle employee on 8/16/2016 with a passing score.

3.5.2 Raw material and packaging acceptance and monitoring procedures

The plant procedure titled “Inbound Chemical Ingredient Inspection Form” is used to describe the acceptance procedures for inbound materials. All loads are required to have a certificate of analysis (COA). Currently the plant does not test any processing aids or packaging receipts from their approved suppliers. A Raw Material Deviation Report is filled out if processing aids are not within specification. There have not been any Raw Material Deviation Reports completed in the last year. The Plant Operator who unloads chemicals confirmed he knows and adheres to the documented unloading requirements.

3.5.3 Management of suppliers of services

The plant has a document titled “Risk Assessment Reviews of Miscellaneous Contractor Services” that defines the risk level for waste haulers, contracted maintenance, laboratory service providers and the laundry provider. The level of risk determines whether the contractor should be audited quarterly or annually. Contracted laboratories (PACE Laboratories in Duluth) are required to be ISO 17025 compliant. Waste haulers (Hartel Waste) are required to have a current business license and a landfill permit. The contract with the PCO (Plunkett’s) is retained in the Pest Control Manual.

3.5.4 Management of outsourced processing and packing

The Duluth Plant does not outsource any of their production processes.

3.6 Specifications

All packaging material, processing aids and finished goods specifications are available on SharePoint. Packaging material specifications for the super sacks used for malic acid were reviewed. Finished goods specifications for malic acid granular (1/22/2015), and maleic anhydride (7/28/15) were reviewed. The finished goods list moisture, pH, particle size distribution and assay on all products. Some finished goods specifications have specifications for color and taste.
All packaging material, processing aids and finished goods specifications are available on SharePoint. Packaging material specifications for the malic acid super sacks were reviewed. The finished goods made in the plant are made to Tate & Lyle specifications, not customer specifications. Contracts with customers list the Tate & Lyle specifications. The raw material specifications and the finished goods specification

have all been reviewed within the last 2 years. Specifications are required to be reviewed every three years.

3.7 Corrective and preventive actions

The Duluth Plant documents corrective actions for internal audits, customer complaints, customer audits, and for non-conforming products. The customer complaint procedure requires the plant to do a root cause analysis and develop a corrective action. The requirements for handling non-conforming product are documented in the "OOS Incident Investigation Form". The procedure is used to document the root cause of the production of non-conforming product and the corrective action taken to keep it from recurring. Two customer complaints (one for ice inside the stretch-wrap and one for insects inside the stretch-wrap) were reviewed and the corrective actions were implemented and verified as effective.

3.8 Control of non-conforming product

In-process checks are taken to control the processes. Finished goods lots are sampled and tested by the Laboratory. Pallets of bags and totes are loaded directly onto a spotted trailer and the trailer is secured when loaded and left setting on the lot until the Laboratory conducts the analytical testing on the product. If it is within specification, the trailers are shipped to the contracted warehouse in Minneapolis, MN. This keeps non-conforming product from being shipped. Product can only be shipped from the Murphy Warehouse or the on-site warehouse (rarely done) if the Laboratory has released the product in SAP. Non-conforming products are not destroyed because of chemical and physical test results. Non-conforming product is reprocessed. No hold product was observed during the walkthrough.

3.9 Traceability

Site trace system: Lot numbers are reported on all COAs for processing aids and packaging materials. The lot numbers are reported in MDE and SAP to allow tracing of the materials.

Last trace exercises by the plant: Two traces are done per year in 2016 and three per year will be competed in 2017 per a customer request.

Product: Malic Fine Granular, 50 lb bags
Date: 10/24/16
Amount: 1200 bags
Results: 100%
Time: 40 min.

Packaging: Poly-lined Kraft Bags
Date: 10/25/16
Amount: 1200 bags
Results: 100%
Time: 60 min.

Completed during the audit:
Product: Malic Fine Granular 50 lb bags
Date: January 15, 2017
Amount: 1200 bags
Results: 100%
Time: 30 min.

Packaging: 50 lb Kraft poly lined bags
Date: September 6, 2016
Amount: 73702 units received

Results: 100%
Time: 30 min.

Examined various records gathered during the traceability exercise and they were all found to be completed as required.

3.10 Complaint handling

Customer complaints are received at the corporate level or by the Quality Assurance Manager. Complaints are entered into the SAP database (titled the Quality Notification System) that is maintained by Customer Services. The Customer Complaint Procedure requires that a corrective action be completed for each complaint. The Quality Assurance Manager is responsible for closing out customer complaints. The plant has had an increase in customer complaints this fiscal year due to insects inside the stretch-wrap (not in the product). LED lights were installed in the warehouse area which resulted in more insects being attracted the plant (based on the PCOs assessment of the problem). The corrective action was to install an air curtain at the warehouse door where pallets are brought into the plant from a remote pallet storage building and turning off the lights in the warehouse when picking up pallets at night. The complaints for May 1, 2016 to April 18, 2017 are primarily for damaged/ leaking bags and product clumping/caking. Some of these complaints are not plant controllable. Customer Service provides the plant and senior management with a summary of the plant complaints. The plant has determined that there is not a category of complaints to focus on. The plant is continuing to monitor the effectiveness of the corrective actions to address the insects. The complaints came on product that was several months old and the bugs were not present when the corrective actions were implemented.

3.11 Management of incidents, product withdrawal and product recall

The plant has a “Crisis/Emergency Management Team and Action Plan” dated 7/24/15 and a “Crisis Manual-Global Crisis Management Organization” manual that addresses what to do in the event of tornados, earthquakes, chemical spills, fire, bomb threats, etc. Elements of the program are tested. All shifts were tested on fire drill in August, 2016. The company has a policy titled “Global Recall Policy for Food and Feed” that is used to identify responsibilities and activities of the recall team. The recall team is made up of managers at the Decatur, IL corporate office. The recall team is listed in the procedure and their contact information is documented. Communication with customers and external agencies is a corporate responsibility. The plant provides the recall team with product information related to traceability. Tate & Lyle conducts a Recall Simulation using RQA Insurance Services. The 2016 simulation was conducted on 10/25/16. The plant has the phone number and address for SAI Global in Cleveland, Ohio documented in their recall procedure. The Crisis Manual also contains the foodrecall@saiglobal.com email address and the requirement to notify the CB within 3 days of the recall initiation.

3.12 Customer focus and communication

There are not any requirements for the plant to use customer specified products.

Details of non-applicable clauses with justification

Clause reference	Justification
3.5.1.3	The Duluth Plant does not currently purchase any processing aids (raw materials) from

	brokers or agents.
3.5.4	The Duluth Plant does not outsource any of their production processes.
3.12	There are not any requirements for the plant to use customer specified products.

4. Site standards

4.1 External standards

The Duluth Plant is located on a site on the St. Louis River (a tributary to Lake Superior). A boat storage company is located to the south side of the plant. A rail track is located along the east side of the plant and the river is one the north and west side. The entire site is fenced. To get to the plant, you must drive through a residential area. The environment of the areas around the plant does not pose a risk to the product. The grounds are well-maintained. There is concrete, gravel and asphalt adjacent to the walls and the areas are tended regularly. Inspections are conducted to verify that the grounds do not present a risk. The walls are masonry and corrugated metal panels and there were not any openings in the panels that provided pest entry.

4.2 Security

The company has a Food Defense Procedure that provides the plant with food defense requirements. The company uses an Operation Risk Management (ORM) process to determine the risks in predefined categories. The site is completely fenced and a guard service manages the entrances to the plant during business hours. After business hours, employees enter through the guard house using an electronic badge. Cameras are located around the site for surveillance. Employees park outside the secured area in a fenced-in parking lot. The most recent defense assessment was completed on 4/17/17 by the Quality Assurance Manager. All visitors, drivers and contractors sign in at the guard house. Long term contractors are provided electronic access and enter the site through the guard house. Once on-site, there are not any restrictions for employees and contractors. The offices are secured after business hours. Caustic, maleic anhydride, sulfuric acid and nitrogen are stored outside within the secure fenced area. All of the ports were also capped and locked to prevent access by unauthorized access. The Duluth Plant is registered with the FDA and the Minnesota Department of Agriculture.

4.3 Layout, product flow and segregation

The plant has a documented risk assessment that has identified the risks associated with all areas of the plant. The Duluth Plant has been determined to be a combination of enclosed processes and low-risk areas. The BRC Version 7 criteria were used to determine the risk. The entire wet-side and dry-side processes are enclosed. The bagging and tote filling areas are only open when changeovers (cleaning and screen changes) are being implemented and when the super sacks are opened up after filling. There are Food Security Plans that are used to identify the traffic flow around the site. The plans also include the flow of trash through the building and the water flow in the building. The Duluth Plant is contained in one buildings and only personnel for the plant need to enter the building. All reprocessing of finished goods is managed at the Duluth Plant. Contractors, visitors and drivers sign in at the guard house located at the plant entrance. Visitors are not allowed to enter the site unless the host approves their entrance and meets them at the guard house. Drivers are allowed to exit their trucks except to enter the shipping area. The sulphuric acid driver is allowed to exit his truck for unloading. Visitors must be accompanied at all times. All processing aids are received in bulk containers or in secured trailers. Bulk materials are unloaded into secure tanks. The raw materials are transferred into a closed process. Finished goods are

stored in secured bins and the trailers for finished goods are secured before they leave the plant. The entire process is closed. Work can be done in the Duluth Plant without affecting the process. Maintenance and contractors use external buildings to repair equipment or make modifications to minimize the risk to the process. There were not any temporary structures observes during the audit.

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

Walls are made of insulated corrugated metal panels and concrete. Structural I-beams observed during this audit were free of dust and accumulation. No mold growth was observed on the walls. Floors in the plant are in good condition. There are new floor coverings applied in many areas of the both the wet-side and the dry-side of the plant. There is a mix of circular drains and grate covered trough drains on the first floor. All or the floors are properly sloped to bring water to the drains. There are not any water sources directly piped to the drains. Most of the ceiling insulation in the entire plant is in very good condition. The insulation does not pose a risk since the Reactors are always closed. There are not any glass windows in the Duluth Plant. There are windows located in remote Control Rooms and the glass is shielded. They were in good condition and the areas adjacent to the windows are completely enclosed. All of the doors observed on this audit were in good condition and were adequately sealed to prevent pest egress. There are 7 ILTs in warehouse and the dry areas of the plant. The lights are shielded to reduce the risk of breakage. All other lights in the buildings are covered with plastic covers. All of the upper level doors were covered with screens to allow for ventilation of the building. All doors were open to allow cool air to enter the building.

NC 4.4.5: There is a ceiling water leak in the process area. It was raining during this observation. Water was not contacting equipment or product.

4.5 Utilities – water, ice, air and other gases

Water is provided to the plant by the City of Duluth. The plant has a Water Quality Report from the City of Duluth. The plant submits annual water samples to PACE Laboratories in Duluth which are tested for Fecal Coliforms, Heterotrophic Plate Count and for Total Coliforms. The test results from 10/12/16 were all less than the Federal limits. A detailed water flow diagram was examined, 4/27/15. The diagram shows how water is sourced to the Duluth Plant. Compressed air or steam are not used in contact with the product. Nitrogen is used to blanket the unloading of Maleic anhydride from rail care and the outside Storage Tank. The blanketing is done for safety, not for a quality function. Nitrogen is purchased to meet a Tate & Lyle specification of 99.95% purity.

4.6 Equipment

Plant and corporate Engineers are responsible for the design and installation of equipment in the plant. Based on observations during this audit, the equipment is designed to be maintained and cleaned. All the material in contact with the product is stainless steel or Titanium.

4.7 Maintenance

The plant's preventive maintenance program is based in SAP. All equipment (including electrical equipment) in the plant is on a PM program. The Duluth Plant never shuts down so PMs are scheduled with the input of production. The Maintenance Manager signs off on new equipment installations. A one-page list of all open work orders (preventive and corrective) was reviewed and there were not any open work orders that would pose a risk to the quality of the product. As part of the PM program, equipment is

inspected to prevent contamination from equipment failures. Tate & Lyle has a corporate "Temporary Repairs Policy" that identifies where temporary repairs can be installed. Temporary repairs are not allowed if there is a potential for food contact. The plant has 90 days to fix the temporary repair. Temporary repairs are tagged and dated. There were not open temporary repair work orders observed while reviewing the SAP database. All maintenance work is supported by either a preventive maintenance or a corrective maintenance work order in SAP. Work Permits are filled out for all work that is conducted in the plant. On the back of the form, the person doing the work and the employee responsible for the area sign the form verifying that the area and equipment has been cleaned and safe for product. Only food grade lubricants are used where there is a potential for food contact. White food grade lubricant was observed in the locked storage cabinet in the Maintenance Shop. All vessels are sealed and lubricants do not present a product risk. Grease guns with food grade lubricants are white and non-food grade guns are red or blue. The Quality Manager had just conducted an audit of all lubricants to verify that there are not any allergens in the lubricants. The auditor verified that the lubricant FM 100 was approved and allergen free. A Maintenance Shop is located in the building. Repairs and fabrications are done in the workshop to minimize potential contamination of the Duluth Plant. The Maintenance Shop was observed during this audit and it was clean and orderly.

4.8 Staff facilities

All Duluth plant employees share a common locker Room. Employees can change in the locker room or take their clean clothing home and wear it to work. The plant has conducted a risk assessment and determined that clothing is not a risk to the product since the Duluth plant is a totally closed system. In addition to the lockers in the locker room, employees have personal lockers in the control room where they can store personal items. Outdoor clothing is available to employees in the chemical unloading area for use during cold weather. Clean uniforms are available to plant employees in lockers. Soiled uniforms are returned to the bins located outside the Locker Room. Sinks are available in all locker rooms and rest rooms. The restrooms are stocked with antibacterial soaps and paper towels. Trash cans are available for waste containment. The primary rest rooms are located on the first floor along a hallway from the employee entrance near the Bagging Area. All rest rooms have double doors to separate them from the production and packaging areas. Smoking is not allowed on Tate & Lyle Property. There are refrigerators and drink dispensing machines located in the Break Room located on the third floor. The refrigerators are on a monthly inspection program to assure that food is not being left in the refrigerators.

4.9 Chemical and physical product contamination control

Raw material handling, preparation, processing, packing and storage areas

The plant has programs in place to manage the risks associated with glass and brittle plastics, chemical contamination, metal contamination and wood contamination.

4.9.1 Chemical control

The plant uses their list of chemicals in the MSDS database as their list of approved chemicals. The MSDS database is stored on one of the plant's shared drives. During the audit, two chemicals (lubricants) were selected to verify the effectiveness of the Chemical Control Program. There were MSDSs for both chemicals selected. All chemical containers were properly labelled. Chemicals are stored in locked cabinets. Lubricants are brought into the Plant by Mechanics and removed when the lubrication is complete.

The entire process is closed and work can be done on equipment, floors repaired or insulation added without a risk to the product.

4.9.2 Metal control

The plant has a policy that specifically addresses the use of knives and needles in the plant. The requirements are documented in the procedure for (Sharps) utility knives and needles. Knives are issued to employees and the Supervisor is responsible for issuing blades. The Dry Side Operator is responsible for checking and documenting the condition of the needles used on the bag sewer. The only place knives are used is when the Operator dumps purge bags or rework bags back into the process. Metal is not used in the bagging area. Corrugated covers are used on top of pallets of bags during shipment. Slip sheets are used under the bags and totes to minimize the risk of nails in the pallets coming into contact with the product.

4.9.3 Glass, brittle plastic, ceramics and similar materials

The plant's Control of Glass, Ceramic and Brittle Plastics policy was updated 3/6/15. Glass is not allowed to be taken into the plant. The entire process is closed so the risk of glass is very low. The plant has a list of glass and brittle plastic located in the Duluth Plant and inventories of the glass and brittle plastics in open areas are inventoried annually (broken down to areas being audited quarterly) by the Quality Assurance Manager. The auditor examined audits from January and April 2017. There are 9 specific areas in the plant that are audited for glass condition. Only Maintenance is allowed to change lights. The procedure for cleaning a glass breakage is documented in the procedure. Only the QA Manager can approve restarting the equipment after a breakage incident. The plant documents glass breakage incidences in the Nonconforming Product section of SharePoint. There have not been any reported breakage incidences in the last 12 months. All glass and brittle plastic items were intact during this audit.

4.9.4 Products packed into glass or other brittle containers

Products are not packaged into glass or brittle containers.

4.9.5 Wood

The only wood used in the plant is in the bagging and tote filling area. New wood pallets are used for stacking product packaged into bags. Pallets are inspected on receipt and the results are documented an inspection form. Empty bags are received on pallets and the load is inspected on receipt. The inspection of the pallets is documented on the Inbound Packaging and Chemical/Ingredient, Suppliers Inspection Form.

4.10 Foreign-body detection and removal equipment

4.10.1 Foreign-body detection and removal equipment

Foreign body risk assessment conducted and controls include: The plant uses filters in the liquid loading process to verify that there are not any foreign materials in the finished liquid products. Sifters, magnets and metal detectors are used in the dry processes. Filters used in the unloading process and in the manufacturing process range from 1 to 10 microns based on the product viscosity. Scalping Screens are used on both the malic acid and the fumaric acid processes. The Scalping Screens (a Sweco Sifter and a Vibrafeed Sifter) are CCPs in the HACCP Plan. A scalping screens and magnets are installed on the bagging lines prior to filling. A metal detector is installed on the bagging machines after the bags have been filled. A new flow through metal detector has been installed on the tote filling/barrel filling line just above the hopper. Both metal detectors are defined as CCPs. The sifters are the primary source of foreign material removal in the dry product flows. The magnets and metal detectors are designed to detect any failures of the sifters. The frequency of checking the sifters and metal detectors are based on the amount of time they would be able to have the product on-site. The Production Supervisor will fill out a

Deviation Report is there is a failure of the sifters or the metal detectors. The metal detectors have not failed a check in the last 12 months. The Deviation Report requires a root cause investigation and a corrective action.

4.10.2 Filters and sieves

Filters are located on the unloading lines for processing aids and in the Wet Side. Filters are inspected and cleaned weekly. All checks and changes are documented in MDE and Log Book. The Scalping Screens are identified as CCPs and challenged according to the HACCP Plan. The sifter screens in dry processes are changed out when signs of wear appear. Changes are documented in the Maintenance Portion of SAP. Failures for other than wear are reported in the HACCP Plan.

4.10.3 Metal detectors and X-ray equipment

All bags/ totes/barrels of malic acid and fumaric acid pass through a sifter and a metal detector prior to release for shipment. The metal detector for the 50 pound/25 kg bags is located on the conveyor after the bags have been filled and prior to code dating and palletizing. The new bulk detector is located on a mezzanine over the fill hopper for bulk products. The bags that trip the metal detector are rejected onto a reject chute. An alarm light notifies the Operator of a metal reject. If the metal detector trips on the bulk line, the filling system shuts down and the sack or barrel must be removed before the logic on the system allows the line to restart. All metal detector monitoring is done by the Dry-side Operator. Wands with a 2.0 mm Ferrous sphere, a 2.0 mm non-Ferrous sphere and a 3.0 mm stainless steel sphere are passed through the metal detector every 8 or 12 hours (depending on the length of the shift. Each wand is passed through three times. Verification is done by the Supervisor verifying the check was completed at the end of the shift and by observing the check being performed once every week. Results are recorded in MDE. The 2.0 mm Ferrous, 2.0 non-Ferrous spheres and the 3.0 mm 316 stainless steel test spheres are provided by the equipment manufacturer. The bags are spaced out using belt speeds such that only one bag can go through the metal detector and get rejected. The corrective actions for metal detector failures are documented in the HACCP Plan.

4.10.4 Magnets

There are magnets located under the Scalping Screens over the bag filling hoppers and on the tote filling line. The magnets are checked every 12 hours. The results are recorded in MDE. A third-party company conduct pull-tests annually (last on 4/26/2016) and the report was reviewed by the auditor. Several magnets were reported as damaged and were subsequently replaced.

4.10.5 Optical sorting equipment

There are not any optical sorters in the Duluth Plant.

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

Products are not packaged into glass, rigid or metal containers.

4.11 Housekeeping and hygiene

There are cleaning procedures for equipment. The walls, floors and outside of the tanks and pipes are washed down with water or swept. Equipment cleaning training is part of the Skill Block Training Program. Equipment cleaning is done by washing, flushing and purging. Caustic is used to clean the inside of certain pieces of equipment. Checklists for daily and weekly cleaning activities are completed by Operators and each Checklist is verified by Supervisors indicating the completion of the work. There are not any microbiological tests conducted on the equipment cleaning process. All cleaning activities are documented on Daily, Weekly and Monthly Equipment Cleaning Checklists. Equipment is cleaned by

Operators. The plant schedules down time to purge the equipment with water or a mixture of water and caustic. The flushes start at the beginning of the process and follow the flow through the process. Equipment cleanings in the Dry Side are done by Operators using broom and vacuums. The equipment from the Finished Bins to the Bagger and Tote Filling process are cleaned daily during product changeovers. Cleaning is part of the Skill Block Training Program. The Duluth Plant verifies the effectiveness of the cleaning program with visual inspections and pH of rinse water. The Supervisor signs off on the sheet indicating the cleaning activities have been completed. The auditor examined cleaning checklists from 3/14/17 and they were completed with date, person responsible, equipment ID, date and operator who cleaned the equipment.

4.11.7 Cleaning in place (CIP)

The plant does not CIP equipment. Tanks, lines and pumps are flushed with water and purged with product after cleaning.

4.12 Waste / waste disposal

Hazardous wastes are picked up by Safety Kleen. The plant is a very Small Quantity Generator. The Duluth Plant uses Hartel Waste to remove waste and trash. Trash is taken to the Duluth Landfill. Close-topped dumpsters are used to contain trash until they are picked up. There is a dumpster located the east side of the plant. The dumpster observed during this audit was clean and not full. All bags and totes are labeled with the Tate & Lyle name and the product name. Bags of non-conforming product are opened up and the material is reprocessed.

4.13 Management of surplus food and products for animal feed

There is not any customer branded product in the plant. All product is packed into Tate & Lyle bags or super sacks with labels containing Tate & Lyle's name. There are not any products made in the Duluth Plant that are used for animal feed.

4.14 Pest Control

All information is accessible on the vendor's website and was accessed as such. Last annual review was April 17, 2017. No issues were identified. Contract is current. Trend analysis showed no activity for rodents or insects. SDS for insecticide chemicals were reviewed. Licenses current for technician.

The Duluth Plant uses Plunkett's Pest Control to manage their pest control program. The PCO is on-site every week. Interior devices are monitored weekly and exterior devices are monitored monthly. The seven ILTs are serviced twice a month in May, June and October and weekly in July through September. The schematics, contracts, licenses, service reports, pesticide applications and trend reports for the pest control devices are available electronically. All of the devices are documented on the schematics. The schematics were last updated 12/7/15. All pest control activities are conducted by Technicians for Plunkett's Pest Control. The PCO issues a Service Report for every week he is on-site. Missing, inaccessible and damaged devices are documented on the Service Report. Bait stations are only used outside the plant. The plant uses glue-pad type devices to kill the insects in the 7 ILTs located in plant Pesticides are not applied in open product areas. The Quality Assurance Manager is responsible for managing the Pest Control Operators programs. The Quality Assurance Manager maintains a file of the corrective actions the PCO has requested. The file contains the work order numbers that were issued to address the PCOs concerns. Management from Plunkett's Pest Control audits the effectiveness of the program at the Duluth Plant quarterly. The program is also audited during monthly sanitation inspections

and during the internal audit for pest control. The electronic recording system used by Plunkett's Pest Control allows the Quality Assurance Manager to review results and trend the results to see if corrective actions need to be taken.

4.15 Storage facilities

All tanks and bins are closed. The dry product is humidity sensitive (will clump up) and conditioned air is used to control the humidity during transfer. There are dedicated process and shared packaging assets. The plant purges bins and tanks between product changes. All finished packaged goods are stored on pallets. Finished goods are loaded directly from the palletizer onto shuttle trailers and shipped to the Murphy Warehouse in Minneapolis, MN. The QA Manager visits this facility on a periodic basis Processing aids are stored outside in secured tanks and the tank of maleic anhydride is jacketed and heated to reduce the product viscosity. All packaging materials, processing aids and finished goods are managed using the SAP business system. The contracted warehouse is responsible for using SAP to manage the shelf life of bagged and toted products.

4.16 Dispatch and transport

The plant uses shuttle trailers to ship finished products to Murphy Warehouse. The trailers are inspected prior to loading and an inspection form is filled out by the Dry-Side Operator. The Wet-Side Operator does a visual inspection prior to unloading a bulk trailer. Covered vans are loaded at the east side of the plant. Each shift of finished products is assigned lot codes. Bills of Lading list each pallet that is loaded on the trailer, the location of each pallet in the trailer. Seal numbers are documented on the BOLs. Inbound bulk rail ingredients (maleic anhydride and caustic) are unloaded with plant hoses. The hoses are capped and stored off the ground. Bulk trailers of sulphuric acid are unloaded using the trailers pump and hoses. Wash tickets are used to verify the inbound trailers and hoses were cleaned prior to entering the plant. All finished goods (bags and totes) are loaded into a shuttle trailer and left on the site until the analytical testing of the product has been completed. The shuttle carriers have contracts where they agree to notify Tate & Lyle in the event of a trailer problem. All finished goods are shipped out of the Murphy Warehouse in Minneapolis, MN. Tate & Lyle follows a procedure titled "Assessment and Approval of Suppliers" (updated 3/7/14) to approve third party warehouses. The Murphy Warehouse was inspected on 12/22/14 by a Corporate auditor. Third party warehouse are required to be inspected every three years.
The auditor examined a preloading checklist for a shipment of malic acid and it was properly completed.

Details of non-applicable clauses with justification

Clause reference	Justification
4.3.5, 4.4.13, 4.8.4	There are not any high-risk areas in the plant.
4.3.6, 4.8.5	There are not any high-care areas in the plant.
4.3.7	There are not any ambient high-care areas in the plant.

4.3.9	There were not any temporary structures observes during the audit.
4.4.4, 4.7.5	There are not any high-care or high-risk areas in the plant.
4.4.6	There are not any suspended ceilings.
4.4.7	There are not any roof glazings.
4.5.3	All of the water used in the plant is potable.
4.8.10	There is not a catering facility on-site.
4.9.4	Products are not packaged into glass or brittle containers.
4.10.5	There are not any optical sorters.
4.10.6	Products are not packaged into glass, rigid or metal containers.
4.11.7	The plant does not CIP equipment. Tanks, lines and pumps are flushed with water and purged with product after cleaning.
4.12.3	The plant does not make trademarked materials.
4.13.1	There is not any customer branded product in the plant. All product is packed into Tate & Lyle bags or super sacks with labels containing Tate & Lyle's name.
4.13.2	There is not any customer branded product in the plant.
4.13.3	There are not any products made in the Duluth Plant that are used for animal feed.
4.14.3	The Duluth Plant uses Plunkett's Pest Control to manage their pest control program.
4.15.3	There is not a temperature requirement for storage of the products.
4.15.4	There is not a requirement for controlled atmospheric storage.
4.16.3	There are not any temperature requirements for transporting the products.

5. Product control

5.1 Product design/development

The company has a process titled the Step Gate Process that documents the steps that are required for the introduction of new products. The process includes a review by the plant which includes a HACCP review. Once a product is approved, the changes needed to make the product are managed through the Authorization of Funds for Expenditure (AFE) process. Tate & Lyle has a "Management of Change" procedure that is use when changes are made to the process. The AFE is the financial part of the MOC process. The Quality Assurance Manager (acting as the HACCP Coordinator) must approve the MOC forms. The validation of a process for the installation of new equipment is handled as part of the AFE process. The shelf life studies for the products were conducted when the products were developed. The shelf-lives are based on USP and FCC requirements. The products have remained the same since their introduction. Organoleptic tests are not conducted on product before it is released. There have been no new products in the past year.

5.2 Product labelling

Bagged product is shipped domestically and exported. Finished products are packed into the same bags regardless of the final country's destination. Murphy Warehouse in Minneapolis would handle any additional labelling of the bags for a specific country. The plant does not know the locations/countries of customer shipments. Bags are pre-printed with company name, product name. Codes are ink jet applied.

5.3 Management of allergens

Allergens in raw materials and processing aids are addressed in the questionnaire that all suppliers must complete. Only non-allergen suppliers are approved. Suppliers are approved at the corporate level. The plant has conducted a risk assessment (titled Risk Assessment Allergens and updated 4/30/14) to determine the allergen risk. Allergen awareness training was conducted in the annual refresher training in June 2016 and is also covered in monthly training as well.

5.4 Product authenticity, claims and chain of custody

The Duluth plant uses maleic anhydride and makes malic and fumaric acid. None of the products are on foodfraud.org as being a risk. The plant has resources in the corporate office in Decatur, IL as a resource to technical and legal changes. The current risk assessment is located in the HACCP Plan and is reviewed annually. The company has a supplier approval database that is used to determine risks of items or product groups. The company has determined the maleic anhydride is not a risk from adulteration and substitution. The plant is currently Kosher (circle U) and Halal (IFANCA) and their certificates were verified to be current (Kosher 12/31/17 and Halal 1/31/18).

5.5 Product packaging

The auditor examined letters of continuing guarantee for the paper bags and tote bags. The guarantee states the product meets federal guidelines for food contact packaging material. The Duluth Plant uses clear plastic liners for the fiber drums which are shipped to certain customers who require this. The plant has an MOC document that states the four customers that purchase the fiber drums are aware of the clear liners. There are blue liners which are used for the finished product, product storage and work in progress and a poly liner is used between the Kraft layers on the paper bags.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Finished goods testing requirements are documented in Test Procedures. Examined a test procedure for Moisture Content of Malic Acid, revised 8/6/2013. Process checks are done to control the process. Bagged, barrelled and toted product is sampled at defined frequencies. Samples are composited and tested by the Laboratory Technicians. The specification limits are listed in SAP. When the Laboratory Technician completes the testing and all of the test results are in specification, Technicians can release the product in SAP. All products are on hold until SAP confirms the product meets specifications (% 1A). Product that is not 1A cannot be shipped. Product that is not 1A may require a Non-Conforming Report to be filled out. A root cause investigation is part of the Non-conforming Report process. Examined an SAP product status record, which showed the hold status of products with a green or red light graphic.

5.6.2 Laboratory testing

No pathogen testing is performed on site. No micro testing is required on these products. The Laboratory is in a separate room adjacent to the Bagging and Tote Filling Areas. All of the processing equipment outside the lab is fully enclosed. The Laboratory is on a separate ventilation system from the rest of the building. Hoods are located in the Laboratory to vent fumes. Covance Laboratories in Madison, WI is used for quarterly heavy metal testing. The laboratory is certified to ISO 17025 and their certificate is current (expires 12/31/17). The certificate for PACE Laboratories (water quality testing) is current (2/8/18), as well.
In order to ensure the reliability of laboratory results, the Quality Assurance Manager selects finished goods and has each laboratory technician conduct the analytical tests which are required to release the product. The results are compared and deviations are addressed through retraining. The last test results (January 2017) were within accepted test limits.

5.7 Product release

The results of analytical and physical tests are entered into SAP and the results are compared to a specification. The product is released for shipment when all of the required tests have met specifications.

Details of non-applicable clauses with justification

Clause reference	Justification
5.2.2	Products made in the Duluth Plant do not contain any labels. The bags contain the name of the product (pre-printed) and Tate & Lyle's name and address in Decatur, IL.
5.2.3	There are not any nutritional or food related claims made on the product made in the plant.
5.3.2-5.3.8	The plant does not use or store allergens on-site. Allergens for new materials would be managed through the supplier approval process.

5.4.3	Products are not at risk of adulteration from allergens.
5.4.4	There are not any product claims based on the origin of raw materials.
5.6.2.1	Pathogen testing is not conducted on-site. There are no pathogen testing requirements for the malic and fumaric acids.

6. Process control

6.1 Control of operations

All of the temperatures, pHs, pressures, pump speeds and residence times are monitored electronically. The Controllers (Control Room Operators) monitor the readings in the Control Room and make adjustments to the processes. Samples of the product are taken by the Wet Side Operator at specified intervals to confirm that the process settings are making in-specification product. Process deviations result in efficiency loses and rarely can cause a quality, safety or legality issue. All of the electronic readings are capable of being reviewed from a historical standpoint using a program call OSI PI. Trends can be reviewed. Levels, speeds, pressures and temperatures can be reviewed to trouble shoot a process. Any of the monitored equipment can be alarmed to notify the Controller if a process is not in control or if a valve or pumps have failed. The PM program is used to verify that temperature controllers and sensors, pressure indicators and level indicators are providing accurate feedback. Analytical tests are used to verify the equipment is running properly to make an in-specification product. Changes can be made to the process settings to return the product to conformance.

6.2 Labelling and pack control

Pre-printed bags with Malic Acid or Fumaric Acid printed on them are used to pack 50 pound and 25 kg bags. The print is colored (red for malic acid and purple for fumaric acid) to minimize the risk of using wrong bags. Lot numbers of bags being used is recorded on the Production Report. Labels are printed by the Supervisor for super sacks and barrels. Pallet tags are printed on-site for each packaging run. Wet-side Operators conduct analytical testing while the products are being made to verify the equipment set points are providing in-specification product. Purges of products are made on changeovers to minimize any cross-contamination. Purged product is packaged into white unlabelled bags and is reworked back into the process. The first pallets are tested to verify the purges and composite samples are tested by the Laboratory Technicians to verify the lots meet specifications. Dry-side Operators document the lot of bags and the code date that is printed on the bags in MDE.
The auditor did not observe a changeover due to the nature of the extended product runs, but the plant manager described the changeover process for the bag line which involves purging product from the line and completing a changeover checklist to help prevent any cross contamination or mislabelling.

6.3 Quantity, weight, volume and number control

Malic and fumaric acid bags are filled on an electronic scale and the finished bags go across a check-weigher to verify that all bags meet the desired weight. Dry-side Operators verify the check-weigher by placing a test weight on the bagger scales and on the check-weigher once a shift. The results are reported in MDE. Totes are filled on calibrated electronic scales. The plant uses Kennedy Scales from Coon Rapids, MN to calibrate the plant scales. Scales are calibrated monthly. The scales were last calibrated in April, 2016.

6.4 Calibration and control of measuring and monitoring devices

The plant has identified the critical equipment in the plant that needs to be calibrated and it includes, for example, pH meters/probes, flow rate meters, and scales. Kennedy Scales calibrates the plant packaging scales on a monthly basis and lab scales on an annual basis. Metal detectors are calibrated by Safeline, annually and the last calibration was completed on 4/6/2017. Lot code printers and magnets are on a PM to be maintained. All equipment is tracked using the serial numbers or the plant location. All laboratory and lant testing equipment is verified to be accurate between calibrations. The instruments in the plant are calibrated and verified by the Wet-side Operators and a Laboratory Technician verifies the results. Results are recorded in MDE. In-house and contractor's standards are traceable to NIST. Testing is done for quality conformance, not safety and legality. If equipment is found to be out of calibration, the equipment is replaced with calibrated test equipment. Product made would be reprocessed if it were found to be non-conforming. The auditor examined a printout of calibration activities for April 2017 and a calibration schedule for calibration requirements as well.

Details of non-applicable clauses with justification

Clause reference	Justification
6.2.4	There are not any on-line vision devices.

7. Personnel

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

The plant uses Skill Block Training to determine that Operators are qualified to do their jobs. Refresher training is conducted annually for food safety and quality training. The Quality Assurance Manager is responsible for maintaining the quality and food safety training program. The Production Manager is responsible for all training record keeping. CCP checks are conducted by the Dry-side Operators and verified by the Supervisors. Training was verified for Operators who have entered CCP checks in MDE. Employees must gain the knowledge to perform the tasks listed in the Skill Block Program. Their performance is reviewed against the tasks in the Skill Block. Each block has quality and food safety tasks associated with it. The Maintenance Manager is responsible for providing training to contractors and engineers. Visitors, including this auditor, receive a 30-minute orientation presentation provided by their host. The Quality Assurance Manager is responsible for the food safety training program. The Duluth Plant holds monthly training sessions. Both plant and corporate managers provide training to employees. Attendance sheets list the trainer, the date, the material covers and the attendees. Testing is conducted to verify the employees understood the training. Each Supervisor is responsible for assuring the Operators on his shift stay current in their Skill Blocks and that they attend the refresher training. Examined various training records for several employees for GMPs, and other subjects. Examined training records for the Operator who demonstrated the metal detector checks on the bag line.

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

Tate & Lyle's GMP policy defines the Tote Filling and Bagging areas as Low-Risk areas. Jewelry is not allowed to be worn in the plant. False fingernails and polish are not to be worn in the open areas.

Colognes are not to be worn. Compliance is verified with monthly sanitation inspections. Hands are required to be cleaned after using the rest room, after eating and when they become heavily soiled. The plant provides blue bandages for employees to cover cuts and grazes. Samples of each lot of blue metal detectable plasters are checked and the information is maintained by the Quality Assurance Manager. The auditor examined the log for such results. Medicines are not allowed in the plant. Medicines can be stored in the Control Room Lockers.

7.3 Medical screening

Employees are to notify the Shift Coordinator is they have symptoms of infections of a contagious disease. The plant does not require visitors to complete a health questionnaire. The plant has determined that the systems are closed and the visitors do not present a risk to the products. Employees receive training on communicable diseases during refresher training. Contractors receive training during their orientation training.

7.4 Protective clothing: employees or visitors to production areas

The plant has conducted a risk assessment to determine that clothing does not present a risk to the product due to the enclosed system. Employees are provided uniforms without pockets and snaps are used for closure. The Locker Rooms for employees to change into uniforms is located in a hallway near the Bagging Area. Employees are required to wear hair coverings and beard covering when they are in the Bagging Room and the Tote Filling Room. Tate & Lyle uses Aramark as a corporate uniform provider. Employees are allowed to take their uniforms home and wear them to work. Uniforms have been determined not to present a risk to the product. There are not any high-risk or high-care areas in the plant but employees are required to change uninforms daily at a minimum. Gloves are provided for PPE.

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.4	There are not any high-risk or high care areas in the plant.
7.4.7	All clothing can be cleaned and clothing does not present a risk to the product.