



SQF Food Safety Audit Edition 8.1

Beston Pure Dairies - Beston Pure Dairies Pty Ltd - Jervois

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
FSM44430 | 111026

AUDIT RATING

DECISION DATE
09/08/2020

AUDIT TYPE
RECERTIFICATION

91

RECERTIFICATION DATE
07/12/2021

AUDIT DATES
08/03/2020 - 08/07/2020

Good

EXPIRATION DATE
09/25/2021

ISSUE DATE
09/11/2020

Facility & Scope

Beston Pure Dairies (44347)
Beston Pure Dairies Pty Ltd - Jervois
2571 Jervois Road
Jervois, SU 5259
Australia

Food Sector Categories:
10. Dairy Food Processing

Products:
10. Dairy Food Processing: Mozzarella cheese, Creams, Whey Powder, Butter, Dairy Proteins

Scope of Certification:
10. Dairy Food Processing: Mozzarella cheese, Creams, Whey Powder, Butter, Dairy Proteins

Certification Body & Audit Team

SAI Global
680 George Street
Sydney, NSW
Australia

CB#: CB-1-SAI
Accreditation Body: JAS-ANZ
Accreditation Number: Z1440295AS

Lead Auditor: Juergens, Thomas (9141)
Technical Reviewer: Grabczak, Anna (204862)

Hours Auditing: 40
Hours Writing Report: 12

Non-Conforming

2.4.3 Food Safety Plan (Mandatory)

The HACCP plan covers food safety & quality and regulatory requirements are appropriate to the facility and there is no need for a risk assessment for any exclusion. PRPs are documented and implemented into the site food safety management system. The HACCP Team is multidisciplinary with L. Haebich being the team leader and suitably trained, as well as Quality and Operations personnel with considerable dairy industry experience. HACCP/food safety plans are based on CODEX HACCP principles. Each product has its own Food safety plan. Each HACCP/food safety plan covers food safety and regulatory requirements, product descriptions and intended use, Flow charts with all steps and process inputs/outputs, floor plans, identification of micro, physical, chemical, quality, traceability hazards and risk assessment using likelihood and severity matrix, as well as decision tree to determine CCP's and CQP's. PRPs are documented and well established. They are implemented into the site food safety management system. HACCP plan reviews and updates were as follows: HACCP plans reviewed: Mozzarella Processing – FSP 2.4 19/06/20 V9 (SS test piece size changed to 5.5mm, to prevent false rejects due to salt on cheese). Whey Powder– FSP 2.15.1, 16/06/20 V6 (amended step 11c fluid bed) Fresh Cream – FSP 2.14.1 16/06/20 V7 (amended to pasteuriser divert at 74.8C, minimum 15 seconds, validation via ANZDAC Pasteuriser validation and verification guideline June 2007 Ch 4 pg7, appendix b pg 11 Heat treatment equivalent to pasteurisation of dairy produce <10% fat, <200 micron, AS 3993-2003 (Appendix A) A2.1 (a) pg 16). Butter FSP 2.14.1 16/06/20 V5 (amended to pasteuriser divert at 74.8C, minimum 15 seconds , validation as above). Lactoferrin & Lactoperoxidase (Protein Powders) FSP 2.17.1 V3 14/01/2019 (currently under review) PRPs are documented and well established. They are implemented into the site food safety management system. CCP's relate to: CCP 1 - Raw Milk Receiveal – Antibiotics – Antibiotics <0.0025mg/kg (Limit of Detection), <0.25IU, Approved Supplier Program CCP 2 - Pasteurisation > Diverts at 72.2°C, min 15 seconds, current 35000 L /H (18.8 seconds) max 39000L/H pressure differential diversion <0.1 bar CCP 3 – Evaporator, Preheat 78 - 83°C, max 35,000 L/hr CCP 4 – X Ray Detector - No Metal – product identified Test pieces SS 5.5mm CCP5 -Cream Pasteurisation > 74.8 C Diversion temperature, min 15 seconds, 5700Lh flow CCP 6 - Butter Cream Pasteurisation >74.8 C Diversion temperature, min 15 seconds, 5700Lh flow Lactoferrin & Lactoperoxidase: CCP 7 – Refrigeration Stored 0-4°C, daily record. Minor NCR Lactoferrin Cold Storage CCP <5C monitoring frequency is daily, however this frequency would not demonstrate cold storage temperatures are being maintained with in safe time frames designated for the safe storage of chilled products being stored at <5C. CCP 8 – Thaw frozen bulk wet product 0-4°C up to 7 days QCP/RCP's Cheese whey PH during cheese make and mill, salting, weight checks Validation and Effectiveness include monitoring and measuring, validation of control measures, food safety plan updates, and food quality plan updates. The responsibilities of this process are managed by Quality Manager. The frequency of HACCP review is documented as annually with the last review dated June 2020 X-Ray machine detector test piece sizes have been validated via supplier calibration records, calibration by Mettler Toledo dated 14/05/20, Holding Tubes 5 yearly validation – dated 23-3-2018, other CCP's are validated by reference to the Food Standard 1.4.2 Schedule 1 pg. 50, ANZDAC Pasteuriser Validation and Verification Guideline June 2007, Ch 4 pg. 7 & AS 3993-2003 (Appendix A) A2.1(a) pg 16) Heat treatment equivalent to pasteurisation of dairy produce <10% fat, <200 micron, AS 3993-2003 (Appendix A) A2.1 (a) pg 16). Sighted monitoring records CCP1 Tanker antibiotic testing records 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 <0.0025mg/kg CCP 2 Milk Pasteurisation records 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 compliant to temperature and pressure differentials. CCP3 Evaporator Preheat temperature records verified 5/08/20, 28/07/20, 17/12/10 compliant to temperature CCP 4 X Ray Detector records verified 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 compliant to testing of metal detector with 5.5 mm stainless steel ball start/middle and end of shift as well as independent verification by team leader CCP 5 Cream Pasteuriser temperature records verified 4/08/20, 10/06/20, 9/06/20, 25/02/20 compliant to temperature limits. CCP 6 - Butter Cream Pasteurization temperature records verified 4/08/20, 10/06/20, 9/06/20, 25/02/20 compliant to temperature limits. CCP 7 – Refrigeration Stored 0-4°C, Sighted monitoring records between 4/08/20 to 2/01/20 <4C Compliant. CCP 8 – Continuous Thawing - 0-4°C up to 7 days, no thawing has occurred in last 12 months QCP/RCP's Cheese whey PH during cheese make and mill, salting, weight checks, sighted records 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 compliant

2.4.3.13 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.

RESPONSE: MINOR

EVIDENCE: Lactoferrin Cold Storage CCP <5C monitoring frequency is daily, however this frequency would not demonstrate cold storage temperatures are being maintained with in safe time frames designated for the safe storage of chilled products being stored at <5C.

ROOT CAUSE: Continuous temperature monitoring not in place. Continuous temperature recording required, add data logger to the cold room to undertake monitoring until temperature recording is automated on Scada. Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: Data logger has been placed in the cold room for continuous monitoring and down loaded once per week until the temperature recording is automated on Scada. Chiller Temp-recorder data and graph, keep in mind the red spikes are the hot gas defrost scheduled in the system

VERIFICATION OF CLOSEOUT: Data logger installed Lactoferrin Cold Storage as sighted download for continuous monitoring and ongoing recording of C/R temperature control, will be downloaded weekly. Is also intended to include temperature monitoring on Scada, for temperature trending and alarming of out of specification temperature.

COMPLETION DATE: 09/04/2020 **CLOSEOUT DATE:** 09/04/2020

2.4.5 Non-conforming Product or Equipment

Non-Conformance Program FSP 4.2.7 details requirements and management of non-conforming raw materials, work in progress, finished products and equipment. The procedure details quarantine requirements, labelling requirements, communication channels and release and/or disposal procedures. Actions are allocated to the most appropriate area manager and closed by the original issuer of the Corrective Action Register. Non conforming product and corrective action register maintained as sighted 15/07/20 to 8/01/20 eg 24/01/20 NCR 13 Lumpy Whey Powder internal failure, draining issue in bag house when CIP, bags became wet causing lumpy powder, bags were removed and CIP drain time extended to ensure adequate drainage.

2.4.5.1 The responsibility and methods outlining how non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment detected during receipt, storage, processing, handling or delivery is handled shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; ii. Non-conforming equipment is effectively repaired or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and iii. All relevant staff are aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status.

RESPONSE: MINOR

EVIDENCE: Non Conforming product (eg out of date, out of specification) being stored in the Lactoferrin cold store had not been isolated or identified with hold/reject stickers as required by the non conforming product procedure (has been included in non conforming product register).

ROOT CAUSE: Hold stock was not labelled with HOLD label, details of the stock were captured on the OOS Product form but not physically labelled with a HOLD label or segregated, spoke personally with the operator on the day of the audit who labelled and segregated the stock. Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: The non-conforming product was labelled "Hold" and segregated on the day of the audit 05/08/20. See below photographs

VERIFICATION OF CLOSEOUT: Sighted Lactoferrin non compliant product segregated and hold labels placed on the effected product. Operator retrained in quarantine and hold requirements for non conforming product as per non conforming product procedure. Review of effectiveness via weekly management review meetings and internal audits.

COMPLETION DATE: 08/05/2020 **CLOSEOUT DATE:** 09/04/2020

2.4.8 Environmental Monitoring

Environmental Listeria swabbing (monthly internally) Milk Processing and Butter plant, 9/07/20 to 9/01/20, (Butter plant drains 7,8,9 positive listeria, recheck drains 8,9 positive, Milk silo gallery drain 2 positive listeria 19/02/20 and 2 rechecks also positive), mozzarella plant (7 swabs per month) 23/07/20 to 6/01/20 (middle drain 7/07/20 positive, recheck negative, drain brine tank side positive 4/02/20, recheck negative, drain brine tank side positive 23/01/20, recheck negative). Protein plant 16/07/20 to 14/01/20 (positive listeria in column room Jan, Feb, April and July. Salmonella (Monthly externally), sighted monthly testing by ALS Nata lab 16/07/20, 18/06/20, 20/05/20, 22/04/20, 17/03/20, 26/02/20, 23/01/20 various swab points in powder plant, and internal Rapid ATP swabbing (Daily): Records sighted July 2019 to Jan 2020. Corrective action documented. Minor NCR: Whilst rechecks are being conducted, it has not been fully documented the corrective action taken in relation to +ve environmental listeria swabs (drains), ie clean and corrective action as per procedure SOP /LAB/GEN/009

2.4.8.4 Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.

RESPONSE: MINOR

EVIDENCE: Whilst rechecks are being conducted, it has not been fully documented the corrective action taken in relation to +ve environmental listeria swabs (drains), ie clean and corrective action as per procedure SOP /LAB/GEN/009

ROOT CAUSE: Corrective actions were not fully documented, now being raised as an NCR capturing corrective actions Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: Environmental positive pathogen detection to be raised as an NCR to document follow up corrective actions and retest results. Please see below example

VERIFICATION OF CLOSEOUT: NCR form is now utilised to capture environmental positive detections as sighted included in NCR report sighted 3/09/20 for detection in drains 3/08/20 included root cause and corrective action. Review of effectiveness via weekly management review meetings and internal audits.

COMPLETION DATE: 09/03/2020 **CLOSEOUT DATE:** 09/04/2020

2.5.3 Corrective and Preventative Action (Mandatory)

Non conforming product and corrective action register maintained as sighted 15/07/20 to 8/01/20 eg 19/06/20 NCR 77 Internal Audit HACCP, some documentation updates required and checks not completed as required. 6/05/20 NCR 63 Hygiene non compliance, unauthorised drink bottle in red production cupboard, cupboard has been removed, and there is continual monitoring of employee practices. 24/01/20 NCR 13 Lumpy Whey Powder internal failure, draining issue in bag house when CIP, bags became wet causing lumpy powder, bags were removed and CIP drain time extended to ensure adequate drainage. 27/03/20 NCR 55 Pest Control Mouse in cheese production room, root cause-gaps in roller doors in loading dock, WR 1267 raised, Issue escalated to pest control contractor, increased number of traps inside areas, including packing area and sticky pad traps in cheese room, thorough inspection undertaken for evidence of mice and pest proofing, also reinforced pest sighting and reporting requirements with employees, escalated again 18/06/20 with 2 mice captured in loading dock area, and escalated fixing of loading dock doors, and 2 further traps placed in the area, gaps on bottom of loading dock doors have not as yet been fixed however.

2.5.3.1 The responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented.

RESPONSE: MINOR

EVIDENCE: Mozzarella Product temperature on exit of brine cooler is consistently higher than target temperature of 30-35C, without corrective action referenced, eg 3/08/20 (42-48C) and records 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19, hence cooling profile may not be as originally validated.

ROOT CAUSE: The target temperature on the form was never able to be achieved. Remove target temperature and continue to monitor brine temperature Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: The target temperature on the form is not able to be achieved and has been removed from the form. The brine temperature 3-6deg will be continued to be monitored as per the the Cooker Stretcher and Prat Wheel Check List. Cooling profile is verified every batch (a days production) with finished goods microbiological testing records.

VERIFICATION OF CLOSEOUT: Sighted Cooker Stretcher & Prat Wheel Checklist FSP 5.14 F4-6 now monitoring of brine temperature only, and validation of finished product safety is via daily microbiological testing E Coli, Listeria, Salmonella, Coag +ve Staph, Y&M as sighted results during audit tested by ALS 20/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19, compliant. Product is not released until product test results received and are compliant to specification. Review of effectiveness via weekly management review meetings and internal audits.

COMPLETION DATE: 08/10/2020 **CLOSEOUT DATE:** 09/04/2020

11.2.10 Premises and Equipment Maintenance

Maintenance Program (FSP4.6-4), outlines the responsibilities for site QA Manager, Maintenance Staff and Manufacturing and Operations Personnel. The company manages the maintenance program through Mainpac Database, for both reactive and preventative maintenance, with historical data maintained for each asset and building / civil structure. The procedure indicates that maintenance is to be completed outside of processing times wherever possible to minimise potential contamination. Both internal and external maintenance staff are to comply with the GMP requirements. It was sighted PM maintenance conducted for the various assets associated with Mozzarella, Cream Processing, Butter, Whey Powder and Proteins processing facilities eg Spray Dryer Atomiser Full overhaul and rebuild conducted May to June 2020, scheduled for service per 18-24 months, Cheese room Multivac weekly sealing die inspection conducted 20/07/20 to 20/08/19, new service contract 19/06/20 for 3 monthly services, Cold Logic refrigeration service contract next service due September 2020, Separators annual service by FDPI conducted 8-14/05/20. Maintenance activities have not been completed to schedule or not as yet included on PM schedule for a number of priority items eg Mozzarella room Hepa Filter service scheduled 3/04/20 not as yet completed, hand wash station observed in butter room on entry from palletising room not functional since 7/01/20, Whey Powder dryer air intake hepa filters not included on PM schedule, Mozzarella cooker culinary steam filter not included on PM schedule. There is hygiene clearance required after maintenance as was sighted for maintenance work undertaken eg 30/05/20, 23/05/20, 2/05/20 for various intrusive maintenance conducted, tools and parts reconciled, cleaned, sanitised and inspected. Minor NCR Maintenance quality assessment forms have not always routinely completed for intrusive (sanitation clearance, or non intrusive (tools reconciliation), as only 3 forms were completed in May 2020 and nil completed June to July 2020 as demonstration of hygiene clearance. Food Grade lubricants are stored separately and used in all food grade applications eg CRC FG machine oil NSF H1 reg 017392, Moreys Crystal Clear MP2 FG Grease FDA reg 178.3620 compliant. The FG lubricants were stored in segregated FG lubricants cabinet appropriately labelled. The work shop was observed maintained in a clean and tidy state, no accumulation of swarf.

11.2.10.2 Routine maintenance of plant and equipment in any food processing, handling or storage area shall be performed according to a maintenance-control schedule and recorded. The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality.

RESPONSE: MINOR

EVIDENCE: Maintenance activities have not been completed to schedule or not as yet included on PM schedule for a number of priority items eg Mozzarella room Hepa Filter service scheduled 3/04/20 not as yet completed, hand wash station observed in butter room on entry from palletising room not functional since 7/01/20, Whey Powder dryer air intake hepa filters not included on PM schedule, Mozzarella cooker culinary steam filter not included on PM schedule.

ROOT CAUSE: PM Task were not put into system as there has been turnover of several Maintenance Managers in the last 12 months. John Dunbar Maintenance Manager at the time of the audit is being moved to another section, Nick Dimasi and Brett Wallace will be handling all maintenance activities going forward including scheduling of critical asset PM tasks.

CORRECTIVE ACTION: PM Task have been undertaken and now scheduled in Mainpac, please see attached documents

VERIFICATION OF CLOSEOUT: Sighted PM tasks now generated by Mainpac for culinary steam injector checks weekly with cleaning, repair, replacement as required. Mozzarella room annual primary filter replacements, cleaning and vacuum, as well as hepa filter inspection and replacement if necessary. Powder plant 3 monthly hepa filter inspection and replacement if required has also now been included on Mainpac. Have scheduled review of other potential critical assets to be included on Mainpac. Review of effectiveness via weekly management review meetings and internal audits

COMPLETION DATE: 09/02/2020 **CLOSEOUT DATE:** 09/04/2020

11.2.10.9 Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed and a pre-operational inspection conducted prior to the commencement of site operations.

RESPONSE: MINOR

EVIDENCE: Maintenance quality assessment forms have not always routinely completed for intrusive (sanitation clearance, or non intrusive (tools reconciliation), as only 3 forms were completed in May 2020 and nil completed June to July 2020 as demonstration of hygiene clearance

ROOT CAUSE: Maintenance training required. Training completed by the Maintenance Team July to September 2020. Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: Maintenance Training in Maintenance Program requirements and Maintenance Handover Form (was Quality Assessment) see attached

VERIFICATION OF CLOSEOUT: Sighted retraining records of maintenance personnel on requirements of maintenance program FSP 4.6 and Maintenance hand over to production form FSP 6.21 F1 all personnel completed training 13/07/20 to 1/09/20. Will review compliance via GMP and compliance audits. Review of effectiveness via weekly management review meetings and internal audits.

COMPLETION DATE: 09/01/2020 **CLOSEOUT DATE:** 09/04/2020

11.2.12 Pest Prevention

Pest Control (FSP4.8.4, 27/05/20), details the proactive approach to pest prevention and includes a number of initiatives in place to minimise pest activity and ensure any pest infestation does not present a risk of contamination to products, raw materials or packaging. Poisonous baits are not used in the factory, amenities, only rodent traps and glue boards. The Quality Manager is responsible for overseeing the Pest Control Procedure and ensuring that it is carried out in such a manner as to control vermin/pest on site. The company also undertakes periodic review of the pest control provider, performance of the service person and the efficacy of the program. Corrective action is undertaken, if rodent activity is found in an edible processing area, and if evidence of rodent activity is found in a storage or non-production area, the materials and containers are examined and rodent damage items are rejected and moveable equipment and debris is removed. The program includes the secured and clean storage of raw materials, packaging and finished product to minimise the risk of infestation performed as part of initial receivals process, all incoming goods are inspected for pest infestation. The buildings are pest proof and personnel trained in identification and reporting of pest/evidence of pest on site. Pest prevention program includes interior monitoring devices, such as indicator station and EFKs. Pest Incidence Register available, located at the staff lunchroom, with identified issues addressed at the next service and staff are to inform the Quality Manager of any pest activity, of which there has been no reported activity. Pest management at the site is conducted by approved service providers, Adams Pest Control Company. The site has available Adams Pest Control Company Profile and Proposal, signed 12-22-2017, and upgrade to Scope of Works, 8/02/2018 outlining the pest prevention program, included additional 25 Bait Stations, 24 traps and 8 fly stations and includes all internal and external areas, Tanker Bay Area, Cheese Plant, Pack Room, Plastic Store, Butter Plant and maintenance and surrounds. The pest control company attends to the site on a monthly basis, with seasonal highs on fortnightly basis to mitigate pest issues for Spring and Summer seasons. Site Plan Beston Pure Foods 3/04/20, includes external rodent stations, EFK, fly baits, mechanical traps, tin cats, non toxic mouse station and time mist units. Each bait station is numbered and identifiable to the reference bait map with rodent stations observed secured and no pest control chemicals are stored at the site. There is an escalation procedure for low activity 1% to 25%, medium activity 26 to 50% and high activity >51% bait consumed. Service reports were sighted as per Adams Pest Control Service Report (Jervois) ie fortnightly 30/07/20 to 8/01/20 with inclusion of rodent activity levels, % insect activity, baits used and batch numbers. Trending is also completed for all stations, sampled from Jan - Aug 2020, with defined levels of low to high fisc units and external stations, and additional corrective actions undertaken as required. The pest control company and technicians have the current licenses as per Pest Controller's License Number 2018-82315 Government of SA (SA Health), Adams Pest Control Pty Ltd 2020 82315 expire 30/07/21 and Technicians Licenses Full Pest Management Craig Thiele lic 85488 exp 9/05/21, Allan Ramsey lic 84381 exp 4/11/20. SDSs are available, sampled as per Temprid 10-06-2016, Contrac Blox Dec 2016, Storm 12-02-2016 and Ditrac Dec 2016 Minor NCR Corrective action NCR 55 raised 27/03/20 due to mouse sighting in the cheese room, identified gaps on bottom of loading dock door as potential entry area have not as yet been fixed, (other measures were taken including additional stations within and outside of the facility, and retraining of employees re pest sightings reporting and recording).

- 11.2.12.4** The pest prevention program shall: i. Describe the methods and responsibility for the development, implementation and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods; v. Outline the frequency with which pest status is to be checked; vi. Include on a site map the identification, location, number and type of bait stations set; vii. List the chemicals used (they are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available); viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests.

RESPONSE: MINOR

EVIDENCE: Corrective action NCR 55 raised 27/03/20 due to mouse sighting in the cheese room, identified gaps on bottom of loading dock door as potential entry area have not as yet been fixed, (other measures were taken including additional stations within and outside of the facility, and retraining of employees re pest sightings reporting and recording).

ROOT CAUSE: Despite escalating the NCR 55 the Maintenance Manager John Dunbar did not prioritise the requirement to fix the gaps in the roller doors as requested on several occasions and is subsequently being moved to another section of the business. Nick Dimasi and Brett Wallace will now be responsible for Maintenance job requests completion. Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: Fixed Roller doors 03/09/20

VERIFICATION OF CLOSEOUT: Sighted sealed loading dock door for prevention of pest ingress, continued monitoring via GMP audits, and weekly meetings held to prioritise any food safety, pest control concerns. Responsibility of tasks has now also been reassigned to other personnel managing the maintenance Mainpac system. Review of effectiveness via weekly management review meetings and internal audits

COMPLETION DATE: 09/03/2020 **CLOSEOUT DATE:** 09/04/2020

11.4.1 Staff Engaged in Food Handling and Processing Operations

Generally Good compliance to GMP policies and procedures observed during the audit for personnel observed in the processing and packing facility. No sensory evaluations are completed in production areas. Wash down hoses were observed stored on hooks provided.

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2; vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food; and vii. Hair restraints are used where product is exposed.

RESPONSE: MINOR

EVIDENCE: Sliding door accessing cheese room via salt and culture storage room provides no sanitary entry controls as per other entries into cheese room eg main entry via cross over bench and access passage way from pack room has hand wash and foot bath on entry.

ROOT CAUSE: Redline areas were being crossed with insufficient sanitation controls. Install floor foamers to control inwards movements and dedicate trolley jack to the mozzarella room to prevent crossover. Place footbath in testing room. Tool box requirement of forklift to stop at the rapid raise door to prevent crossover and once ingredients and packing for the day are supplied to the day room, the day room door is closed to prevent personnel entry and access is monitored by the area Team Leader. The day room door was unable to be locked due to emergency egress issues. Review that corrective actions are effective at weekly management meeting under external audit results

CORRECTIVE ACTION: Automated door way floor foamers (ordered and arrived at site) to be fitted in the coming days at the x-ray, day room and main redline room entry. A dedicated mozzarella room trolley jack has been designated to move plastic pallets in the mozz room to prevent crossover. A foot bath has been placed in the testing room and hand wash station in the testing room is being used on entry. The forklift is now stopping at the rapid raise door as to not cross over from cold rooms to crate packing and day room areas. Once ingredients and packaging for the day are supplied to the day room (store before mozzarella room) the door is closed to prevent to prevent any personnel entry and is monitored by the area Team Leader

VERIFICATION OF CLOSEOUT: Sanitation controls implemented as sighted -foamers purchased for floor entry from day room, main entry and X ray entry areas, trolley jack now dedicated to move plastic pallets into the mozzarella room, foot bath in test room entry and hand wash basin also used on entry, as well as locked entry to day store to prevent any entry to mozzarella room via this entry. Management Review meetings conducted weekly inclusive of review of effectiveness of sanitation processes implemented.

COMPLETION DATE: 09/03/2020 **CLOSEOUT DATE:** 09/04/2020

11.7.5 Control of Foreign Matter Contamination

Foreign object bag audits are undertaken monthly as sighted in Mozzarella areas 27/07/2020, 15/06/20, 20/05/20, 14/04/20, 19/03/20, 18/02/20, 29/01/20 with items found individually documented and reported back via management meetings as well as daily meetings as sighted meetings held 20/03/20, 21/01/20, 1-4 items found per audit in 2020. Documented as Foreign Matter Prevention (FSP4.3.1.5) details the metal control policies in place inclusive of knife integrity checks (monitoring record i.e. Cooker Stretcher and Prat Wheel Checklist), wood controls with limited use of wooden pallets only in the enclosed product areas, glass and brittle plastics, other plastics, cardboard, paper, thread, stationary and corrective actions as the need arise. Equipment Breakage or Loss Policy (FSP4.3.1), includes policies for loose metal or non-metal equipment or tools, forming part of the equipment and inspected as part of the GMP Housekeeping Audit to ensure that items remains intact. The procedure details the protocols to be followed for equipment breakages or loss, with the notification of the Production Manager and Quality Manager, whom will inspect the affected area and isolation of products and collection of fragments and corrective action undertaken. Permitted items registers are maintained in each area as was sighted Multivac area allowable items registered and confirmed via prestart checklist 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19. Minor NCR: Tools observed (3 Allen keys) observed adjacent to the mozzarella X ray machine not controlled via the permitted items register GMP audits undertaken bi monthly and includes all areas including cheese plant, protein plant, maintenance, butter and cream plant, whey powder plant, cool rooms, amenities areas and includes review of walls, floors, ceilings, drains, foot baths, lighting, work benches, pest activity, cleanliness and hygiene, foreign objects, glass, ceramics and hard plastics, PPE, external areas. Sighted undertaken in the various areas 3-29/06/20,15-28/04/20, 19-28/02/20 with detailed corrective action requirements noted and work orders raised.

11.7.5.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff.

RESPONSE: MINOR

EVIDENCE: Tools observed (3 Allen keys) observed adjacent to the mozzarella X ray machine not controlled via the permitted items register

ROOT CAUSE: Allen keys required were not captured on the form. Update form to include allen keys. Allen Keys were added to the form 10/08/20 Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: The allen keys are required for adjusting the labelling machine at the Multivac and have been added to the Multivac Area Form 10/08/20

VERIFICATION OF CLOSEOUT: Sighted Allen Keys added to the Brine Tank and Multivac checklist FSP 5.14 F5-6 includes operator double sign off. Review of compliance to checklist also via GMP and FO bag audits, as well as Management Review of effectiveness. .

COMPLETION DATE: 08/10/2020 **CLOSEOUT DATE:** 09/04/2020

Audit Statements

SQF Practitioner Name Name the designated SQF Practitioner
RESPONSE: Lorraine Haebich

SQF Practitioner Email Email of the designated SQF Practitioner
RESPONSE: lorraine.haebich@bestonpurefoods.com.au

Opening Meeting People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas)
RESPONSE: Lorraine Haebich: Quality Manager Jervois ; Wayne Austin: Quality and Environment Manager; Tom Juergens : Lead Auditor

Facility Description Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details)
RESPONSE: The facility is located in Jervois, South Australia and is approximately 50 years old with Beston Pure Foods operating the site since 2015. There were number of Food Safety Management Systems and Procedures are common between the Jervois facility and its sister site in Murray Bridge (cream cheese process) . The Jervois site manufactures mozzarella (facility had major upgrade and new mozzarella manufacturing equipment installed 2 years ago), butter, cream, whey powder and freeze dried dairy proteins(lactoferrin/Lactoperoxidase). The mozzarella manufacturing area is physically segregated from the other operational areas of the facility. Cream processing , butter, whey powder and freeze dried dairy proteins are also segregated operations. The facility operates with a morning and an afternoon shift 5 days a week with hygiene activities performed after production. Maintenance operations are covered during operational hours. There is approximately 28FTE staff employed on site over 2 shifts 5 days a week. The total size of the facility is 50,000 sq. meters. Strict Covid 19 controls have been introduced to mitigate potential impact on personal and operational activities, including the wearing of masks, distancing, temperature taking at beginning and end of shifts, numerous sanitation stations and continual cleaning and sanitation of touch points through out the facility

Closing Meeting People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas)
RESPONSE: Lorraine Haebich: Quality Manager Jervois ; Wayne Austin: Quality and Environment Manager; Paul Connolly: Operations Manager; Scott Laubsch: Plant Manager; Tom Juergens : Lead Auditor

Auditor Recommendation Auditor Recommendation
RESPONSE: Recertification recommended when NCR's are closed

Section Responses

2.1.1 Food Safety Policy (Mandatory)

The company Food Safety & Quality Policy is in place and is signed by the CEO – J Hicks, the policy is dated 22 March 2019. SQF requirements are covered by the policy. The policy commits the company to the supply safe, good quality foods compliant with customer, legal and regulatory requirements and is displayed in the reception area/lunch rooms.

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines as a minimum the: i. The site's commitment to supply safe food; ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; and iii. The site's commitment to establish and review food safety objectives.

RESPONSE: COMPLIANT

2.1.1.2 The policy statement shall be: i. Signed by senior site management; ii. Made available in language understood by all staff; iii. Displayed in a prominent position; and iv. Effectively communicated to all staff.

RESPONSE: COMPLIANT

2.1.2 Management Responsibility (Mandatory)

Organizational structure is documented and reflective of the site structure FSP 1.3.8 dated 26/06/20, from CEO to Operations Manager, Manufacturing Manager (vacant), Site Manager, Q&E Manager, QA Manager, Maintenance Manager, Operational Leaders, Lab QA Team. Management Authorities & Responsibilities are clearly documented in the Quality Management Systems (Alternate Delegates). Deputies for positions are documented for all positions although provisions to cover the absence of the key personnel have been documented in the QMS. i.e. Ops Manager deputy –Q & E Manager, Quality & Environmental manager deputy – Jervois QA manager, Team Leader Cheese Deputy – Manufacturing Manager. The Senior Management have put the resources in place to achieve food safety objectives and to support the development, implementation, maintenance, and ongoing improvement of the SQF system. The SQF Practitioner L. Haebich who is a full-time employee and completed a formal HACCP training on 27/03/2014 and again Principles and Application of HACCP SAI Global Cert C301033 issued 24/04/2019. The audit demonstrated that the SQF Practitioner has the competencies to implement and maintain the SQF Ed. 8 standard including SPC control. The responsibility for establishing and implementing the training needs has been documented in the FSP 4.4.-4. - Job Descriptions are detailed and clear with documented responsibilities, objectives and expected experience and qualifications to perform the role. Records sited for Team Leader Cheese FSP 1.4.10.2.1, 24/05/18 and Powder and Butter Plant Leader FSP 1.4.10.4.1, 24/05/18, Quality and Environment Manager FSP 1.4.5-3, 26/09/18, Quality Manager Jervois FSP 1.4.6.3, 26/09/18 including key accountabilities and responsibilities. SQF Practitioner responsibilities are stated into SQF Practitioner FSP 1.3.2.3. There is no use of the SQF Quality Shield.

2.1.2.1 The reporting structure describing those who have responsibility for food safety shall be identified and communicated within the site.

RESPONSE: COMPLIANT

2.1.2.2 The senior site management shall make provision to ensure food safety practices and all applicable requirements of the SQF System are adopted and maintained.

RESPONSE: COMPLIANT

2.1.2.3 The senior site management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System.

RESPONSE: COMPLIANT

2.1.2.4 Senior site management shall designate an SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF System, including good manufacturing practices outlined in 2.4.2, and the food safety plan outlined in 2.4.3. ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.1.2.5 The SQF practitioner shall: i. Be employed by the site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code for Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

2.1.2.6 Senior site management shall ensure the training needs of the site are resourced, implemented and meet the requirements outlined in system elements 2.9, and that site personnel have met the required competencies to carry out those functions affecting the legality and safety of food products.

RESPONSE: COMPLIANT

2.1.2.7	<p>Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements of the SQF Food Safety Code for Manufacturing, and are informed of their responsibility to report food safety problems to personnel with authority to initiate action.</p> <p>RESPONSE: COMPLIANT</p>
2.1.2.8	<p>Job descriptions for those responsible for food safety shall be documented and include a provision to cover for the absence of key personnel.</p> <p>RESPONSE: COMPLIANT</p>
2.1.2.9	<p>Senior site management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement.</p> <p>RESPONSE: COMPLIANT</p>
2.1.2.10	<p>Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities.</p> <p>RESPONSE: COMPLIANT</p>
2.1.2.11	<p>Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed upon unannounced audit.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: This was not unannounced audit</p>
2.1.3	<p>Management Review (Mandatory)</p> <p>Management Review Procedure FSP 1.5.1-7. The Quality Manager is responsible for reviewing the SQF system with the site management team, this has been performed on a 6 monthly basis for both Jervois and Murray Bridge Sites combined . It was sighted Management Review meeting conducted 14/05/20 involving senior Murray Bridge and Jervois site personnel and included review of logistics and purchasing, new raw materials and trials, production issues, new product trials, planning and results (Veg Oil Mozzarella), general issues and discussion, customer needs, customer complaints (no new Le Rice complaints, low level mozz and cheddar mould complaints, Whey Powder some issues with lumpiness, Mozzarella soft complaints), product non conformity, internal audit results, external audit results, summary of 2019 CARS in all areas (CI improvement process working, issues identified , for corrective action), housekeeping and GMP audits, non-conforming environmental pathogen monitoring results, pest control, training plans, trade waste, contract packing/suppliers, Quality KPI's -Cheese Moistures, Mozzarella cook score average, cheese grading points % per grade score, customer complaints, maintenance, general discussion and action items. Previous meeting was held 19/09/19 with review of the above agenda items. Further Review meetings held at Jervois involving the Management Team as sighted meeting held 20/07/07, included review of software, mozzarella -improved reporting and analysis of events, yield improvement, pasteuriser temperature reduction to 74C (divert remains 72.5), salt % focus, high acid whey recovery, Happy Valley fat recovery, Powder Plant PH control of LF, Butter Plant Moisture analysis. Weekly and daily meetings held to review quality and operational performance eg sighted daily meetings 20/03/20, 27/01/20 included review of GMP, bag and Bucket walk results, Quality holds, Production issues, purchasing, maintenance, logistics, weekly meeting 9/07/20 -next weeks production, product analysis results, production and quality issues, maintenance issues, quality/lab-internal and external audits, customer complaints, GMP/Housekeeping all areas, actions closeout, non conforming product, environment, NCR's (13 open), training (GMP, CCP training), regulatory and certification updates, maintenance -work requests, Mainpac, major projects/capitol works, HR-recruitment, Covid -19.</p>
2.1.3.1	<p>The senior site management shall be responsible for reviewing the SQF System and documenting the review procedure. Reviews shall include: i. The policy manual; ii. Internal and external audit findings; iii. Corrective actions and their investigations and resolution; iv. Customer complaints and their resolution and investigation; v. Hazard and risk management system; and vi. Follow-up action items from previous management review.</p> <p>RESPONSE: COMPLIANT</p>
2.1.3.2	<p>The SQF practitioner (s) shall update senior site management on a (minimum) monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented. The SQF System in its entirety shall be reviewed at least annually.</p> <p>RESPONSE: COMPLIANT</p>

2.1.3.3 Food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be reviewed and updated as needed when any potential changes implemented have an impact on the site's ability to deliver safe food.

RESPONSE: COMPLIANT

2.1.3.4 Records of all management reviews and updates shall be maintained.

RESPONSE: COMPLIANT

2.1.4 Complaint Management (Mandatory)

Customer complaint management is detailed in Non-Conformance Program FSP 4.2.10 dated 6/02/20; this details the requirements for trending, handling, timescales and root cause analysis investigation of complaints. Customer complaints are initially received by phone or/and emailed to the site for investigation. Root cause is identified where relevant and corrective action implemented where necessary. Trended analysis is monthly and managed via a spreadsheet system and Management review system includes trending 2020-Mozzarella Quality (20 NCR's), Butter Cream (3 NCR's), Lactoferrin (0 NCR's), Whey Powder (4 NCR's), Foreign Matter (5 NCR's), Supplier Failures (3 NCR's). It was sighted the complaints and corrective action register 15/07/20 to 8/01/20 as well as corrective action responses, eg 15/07/20 NCR 91 Pink Cleaning Glove found in Mozzarella, could not determine whether happened at shredding plant or at Jervois plant, the same pink gloves are used at Jervois for cleaning and gloves now issued and returned to Supervisor after use, and blue disposable gloves not to be left on equipment after use, to be disposed of as per tool box meeting and notice to employees 26/06/20. NCR 79 Mould complaints multiple customers, pierced by sharp edges on black plastic boxes used to transfer cheese through the cooling tunnel, all plastic boxes replaced in May 2020 and notice to employees re visual inspection. 16/06/20 NCR 74 Mozzarella cheese found with hairs, notice issued to employees 26/06/20 re wearing of hair nets and beard snoods, also covered in tool box meeting included photos of complaint.

2.1.4.1 The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities, arising from products manufactured or handled on site, shall be documented and implemented.

RESPONSE: COMPLIANT

2.1.4.2 Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents.

RESPONSE: COMPLIANT

2.1.4.3 Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.3.

RESPONSE: COMPLIANT

2.1.4.4 Records of customer complaints and their investigations shall be maintained.

RESPONSE: COMPLIANT

2.1.5 Crisis Management Planning

Business Continuity Plan FSP 4.21 Jervois 18/05/20, was updated to include pandemic risk (now rated as medium risk), details the business process and procedures around continuation of supply. The elements required by the SQF Edition 8 have been addressed in the procedure (responsibilities, BCP team, protocols, flowcharts, response plan for each scenario -man made and natural events including IT, Pandemic, Power Loss, Malicious contamination, loss of RM supply etc, and risk assessment undertaken, control measures identified for each risk). The procedure documents the requirement to test, review and verify the plan annually. The plan also includes a detailed key contact list. A Business Continuity Plan Mock Exercise was conducted on 13/03/20 relating to the Covid -19 pandemic, responses and control measures documented and implemented, contingencies reviewed and no impact on production or product. Mock Exercise also undertaken 30/07/20 using scenario power outage, reviewed BCP requirements and Hi Level Process flow diagram to determine actions required, responsibilities were designated to the relative crisis and site personnel, responses in 1 st hour, 1st day, 1st week documented, back up generator used for critical power requirements, and sourcing of SA Power Networks emergency pad mount transformers (with in 12 hours) and actions relating to each areas activities and contingencies documented, including restoration of normal operations, was an effective exercise, 5 opportunities for improvement identified.

2.1.5.1 A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis.

RESPONSE: COMPLIANT

2.1.5.2	<p>The crisis management plan shall include as a minimum: i. A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure a response does not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations and media.</p> <p>RESPONSE: COMPLIANT</p>
2.1.5.3	<p>The crisis management plan shall be reviewed, tested and verified at least annually.</p> <p>RESPONSE: COMPLIANT</p>
2.1.5.4	<p>Records of reviews of the crisis management plan shall be maintained.</p> <p>RESPONSE: COMPLIANT</p>
2.2.1	<p>Food Safety Management System (Mandatory)</p> <p>The HACCP plan covers food safety and regulatory requirements are appropriate to the facility and there is no need for a risk assessment for any exclusion. PRPs are documented and implemented into the site food safety management system. The HACCP/food safety plan covers food safety and regulatory requirements. The HACCP Plan scope, Hazard Analysis Table, HACCP Process Flow, the plan was last verified is dated for the following: Mozzarella Processing – FSP 2.4 19/06/20 V9 (SS test piece size changed to 5.5mm, to prevent false rejects due to salt on cheese). Whey Powder– FSP 2.15.1, 16/06/20 V6 (amended step 11c fluid bed) Fresh Cream – FSP 2.14.1 16/06/20 V7 (amended to pasteuriser divert at 74.8C, minimum 15 seconds, validation via ANZDAC Pasteuriser validation and verification guideline June 2007 Ch 4 pg7, appendix b pg 11 Heat treatment equivalent to pasteurisation of dairy produce <10% fat, <200 micron, AS 3993-2003 (Appendix A) A2.1 (a) pg 16). Butter FSP 2.14.1 16/06/20 V5 (amended to pasteuriser divert at 74.8C, minimum 15 seconds , validation as above). Lactoferrin & Lactoperoxidase (Protein Powders) FSP 2.17.1 V3 14/01/2019 (currently under review) PRPs are documented and well established. They are implemented into the site food safety management system. The site has identified CCP's relating antibiotic testing, milk pasteurisation temps, cream pasteurisation, whey evaporation pre heat, X Ray detection, Lactoferrin cold storage, the HACCP/food safety plan is based on CODEX HACCP principles. PRPs are documented and well established. They are implemented into the site food safety management system. The company subscribes to industry bodies which include dairy industry, training industry, certification industry and regulatory bodies which include notifications of changes to legislation and customer-based websites.</p>
2.2.1.1	<p>A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site will use to meet the requirements of the SQF Food Safety Code for Manufacturing, be made available to relevant staff and include: i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The scope of certification; iv. A list of the products covered under the scope of certification; v. Food safety procedures, pre-requisite programs, food safety plans; and vi. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.</p> <p>RESPONSE: COMPLIANT</p>
2.2.1.2	<p>All changes made to food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be validated or justified.</p> <p>RESPONSE: COMPLIANT</p>
2.2.2	<p>Document Control (Mandatory)</p> <p>Document Control is detailed in the Control of site Management Procedures FSP 1.7.1-2. Documents were observed to be managed electronically using the company shared server. Hard copies are kept, and the system details a document log and records of amendments and the reason for the change is in place. System register FSP 1.7-2 is kept electronically as well as on hard copy for reference if required. All the documents and records are securely and accessibly stored.</p>
2.2.2.1	<p>The methods and responsibility for maintaining document control and ensuring staff have access to current documents shall be documented and implemented.</p> <p>RESPONSE: COMPLIANT</p>
2.2.2.2	<p>A register of current SQF System documents and amendments to documents shall be maintained.</p> <p>RESPONSE: COMPLIANT</p>
2.2.2.3	<p>Documents shall be safely stored and readily accessible.</p> <p>RESPONSE: COMPLIANT</p>

2.2.3 Records (Mandatory)

The control of records is stated in the Records management Procedure FSP 1.7.1 which includes the methods and responsibility (QA & E Manager, Unit Managers and Receptionist) maintaining and retaining records. All records sighted during the audit were deemed legible and were suitably authorized by those undertaking monitoring activities. The hard copies and soft copies of records were readily accessible, retrievable, securely stored to prevent damage and deterioration during the audit, the retention time for records are 7 years. (Records are boxed, labelled and archived and deemed controlled. Electronic records are backed up on a regular basis by a 3rd Party IT company.

2.2.3.1 The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented.

RESPONSE: COMPLIANT

2.2.3.2 All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.

RESPONSE: COMPLIANT

2.2.3.3 Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations.

RESPONSE: COMPLIANT

2.3.1 Product Development and Realization

Product Development and Specification management is detailed in the Specification and Product Development Procedure BPF FSP 1.16.1 dated 21/03/19. The ultimate responsibility belongs to the Site Management Team (GM, QA manager, Ops Manager, Marketing Exe) the process covers product develop & design (hazard analysis study, site trials, specs checked, customer signoff, shelf life trials), label review & specification review, NIP, RM & Packaging spec. If there are any new products or processes which may influence the food safety and quality of the products manufactured, the facility's food safety plans are reviewed. New product development is managed by a corporate team in the head office in Adelaide and at the actual site. There has been no new product development in the last 12 months. The handover and validation process are documented in a Change Management Review Procedure FSP 1.5.2 (Changed planned, assess risk to change, plan & ID risk mitigation activities, undertake risk mitigation, implement changes, verify risk mitigation activities).

2.3.1.1 The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by site trials, shelf life trials and product testing.

RESPONSE: COMPLIANT

2.3.1.3 Shelf life trials where necessary shall be conducted to establish and validate a product's: i. Handling and storage requirements including the establishment of "use by" or "best before dates"; ii. Microbiological criteria; and iii. Consumer preparation, storage and handling requirements.

RESPONSE: COMPLIANT

2.3.1.4 A food safety plan shall be validated and verified for each new product and its associated process through conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food safety.

RESPONSE: COMPLIANT

2.3.1.5 Records of all product design, process development, shelf life trials and approvals shall be maintained.

RESPONSE: COMPLIANT

2.3.2 Raw and Packaging Materials

Approved Supplier Procedure FSP 4.9.5 dated 13/08/19 details suppliers' approval process, contingency arrangements, emergency approvals, contract service providers, how suppliers are risk assessed, approved and reviewed, provision of certifications, raw material and packaging specifications as well as raw material receipt inspection requirements and provision of C of A. An approved supplier list is a 'live' document which includes RM suppliers, service providers, packaging suppliers. The vendor assurance program is managed by a Quality Team. Approval of a supplier is based on a supplier being at least HACCP certified and the credential must be kept in file. Copies of a raw material specification for the material supplied must also be kept on file. Packaging suppliers must demonstrate that the material complies with the relevant legislation. Supplier issues are raised directly with the supplier via an external CAR system and the QA team reviews these on a regular basis. Raw materials are delivered with a COA where applicable. Records reviewed via vertical trace exercise demonstrated compliance with COA. Specifications raw material and packaging specs are available on the central shared drive & hard copies are kept on site. All specifications are controlled by the Site Quality Team. Finished product specifications form part of the factory documentation. Raw material and packaging specifications were observed during the audit and were readily accessible. Packaging conforms to local legislative requirements. A register of raw materials and packaging specifications is maintained live. A register of raw materials and packaging is maintained live on the system with specifications and certifications maintained eg Records sighted: DSM Rennet Maxiren 600 Spec 21/08/13, HACCP expiry dated 15/10/21 DSM Culture CP-122 PIF 16/01/15, HACCP expiry dated 15/10/21 Crown PDV Salt PIF 16/11/17, Cheetham Salt HACCP expiry dated 15/11/20 Mermaid Premium Salt PIF 12/04/16, Cheetham Salt HACCP expiry dated 15/11/20 Multivac Film 150 micron/300micron Product Data sheet 15/09/15, Food Grade Compliance Declaration 20/06/17 complaint to EC Reg 1935/2004, 2023/2006, 10/2011, 1895/2005, EC Dir 94/62/EC.

2.3.2.1 Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety shall be documented and kept current.

RESPONSE: COMPLIANT

2.3.2.2 All raw and packaging materials and ingredients shall comply with the relevant legislation in the country of manufacture and country of destination, if known.

RESPONSE: COMPLIANT

2.3.2.3 The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented.

RESPONSE: COMPLIANT

2.3.2.4 Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, certificate of analysis, or sampling and testing.

RESPONSE: COMPLIANT

2.3.2.5 Verification of packaging materials shall include: i. Certification that all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

RESPONSE: COMPLIANT

2.3.2.6 Finished product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel.

RESPONSE: COMPLIANT

2.3.2.7 A register of raw and packaging material specifications and labels shall be maintained and kept current.

RESPONSE: COMPLIANT

2.3.3 Contract Service Providers

Approved Supplier Procedure FSP 4.9.5 details suppliers' approval process, contingency arrangements, emergency approvals, supplier audit frequencies and how suppliers are risk assessed and how they become approved. A 'Live' approved supplier list includes contract Service Providers. Sighted service agreements: Veolia Waste 01/06/2018 Adams Pest Control 22/12/2017 Eades Transport - Finished product transport 25/07/18

2.3.3.1	<p>Specifications for contract services that have an impact on product safety shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of all contract personnel.</p> <p>RESPONSE: COMPLIANT</p>
2.3.3.2	<p>A register of all contract service specifications shall be maintained.</p> <p>RESPONSE: COMPLIANT</p>
<p>2.3.4 Contract Manufacturers</p> <p>No Contract Manufacturers</p>	
2.3.4.1	<p>The methods and responsibility for ensuring all agreements relating to food safety and customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No Contract Manufacturers</p>
2.3.4.2	<p>The site shall: i. Verify compliance with the SQF Food Safety Code for Manufacturing and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the site or other third-party agency to confirm compliance to the SQF Food Safety Code for Manufacturing and agreed arrangements; and ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No Contract Manufacturers</p>
2.3.4.3	<p>Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No Contract Manufacturers</p>
<p>2.3.5 Finished Product Specifications</p> <p>Food Safety and Quality attributes for finished products and finished product specification are in place which details labelling, packaging requirements & product quality attributes. Shelf life testing has been completed and this is clearly documented include in the finished product specifications. A register of finished product specifications is maintained and constantly being updated, sighted the following Finished Product Specifications: Edwards Crossing -Dairy Country Mozzarella Block Cheese 10kg (4x2.5 kg) issue 1, 4/08/20 Bulk Pasteurised Cream Issue 7, 11/09/19 Bulk Salted Fresh Cream Butter 25kg issue 7, 12/06/20 Whey Powder 25kg Bag, issue 9, 20/12/19. Lactoferrin Powder 90-95% RW, issue 4, 13/07/20</p>	
2.3.5.1	<p>Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include: i. Microbiological and chemical limits; and ii. Labeling and packaging requirements.</p> <p>RESPONSE: COMPLIANT</p>
2.3.5.2	<p>A register of finished product specifications shall be maintained.</p> <p>RESPONSE: COMPLIANT</p>
<p>2.4.1 Food Legislation (Mandatory)</p> <p>Food Legislation Requirements are clearly documented in the Food Legislation Procedure FSP 4.23.1. The Quality Manager has final responsibility for Food Safety and clearly demonstrated knowledge of the requirement to inform the Certification Body (SAIG) and SQFI within 24 hours of a food safety event. The business is kept up to date of any legislative changes via the local health department and regular contact with Dairy Authority South Australia. The site is registered with the Dairy Authority South Australia expiry dated 30/06/2022 cert # 1357. The site is also registered for export. License No.872 effective 15/04/20. The company subscribes to industry bodies which include dairy industry, training industry, certification industry and regulatory bodies which include notifications of changes to legislation and customer-based websites.</p>	

2.4.1.1 The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of use or sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice.

RESPONSE: COMPLIANT

2.4.1.2 The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.1.3 SQFI and the certification body shall be notified in writing within twenty-four (24) hours in the event of a regulatory warning. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

These requirements are managed through the Good Manufacturing Requirements FSP 4.3.1.1.9 dated 20/02/20. This covers all requirements of the SQF standard it was well demonstrated at the time of the audit.

2.4.2.1 The site shall ensure the Good Manufacturing Practices described in modules 3, 4, 9, 10 or 11 (as applicable) of this Food Safety Code are applied, or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

RESPONSE: COMPLIANT

2.4.2.2 The Good Manufacturing Practices applicable to the scope of certification that outline how food safety is controlled and assured shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

The HACCP plan covers food safety & quality and regulatory requirements are appropriate to the facility and there is no need for a risk assessment for any exclusion. PRPs are documented and implemented into the site food safety management system. The HACCP Team is multidisciplinary with L. Haebich being the team leader and suitably trained, as well as Quality and Operations personnel with considerable dairy industry experience. HACCP/food safety plans are based on CODEX HACCP principles. Each product has its own Food safety plan. Each HACCP/food safety plan covers food safety and regulatory requirements, product descriptions and intended use, Flow charts with all steps and process inputs/outputs, floor plans, identification of micro, physical, chemical, quality, traceability hazards and risk assessment using likelihood and severity matrix, as well as decision tree to determine CCP's and CQP's. PRPs are documented and well established. They are implemented into the site food safety management system. HACCP plan reviews and updates were as follows: HACCP plans reviewed: Mozzarella Processing – FSP 2.4 19/06/20 V9 (SS test piece size changed to 5.5mm, to prevent false rejects due to salt on cheese). Whey Powder– FSP 2.15.1, 16/06/20 V6 (amended step 11c fluid bed) Fresh Cream – FSP 2.14.1 16/06/20 V7 (amended to pasteuriser divert at 74.8C, minimum 15 seconds, validation via ANZDAC Pasteuriser validation and verification guideline June 2007 Ch 4 pg7, appendix b pg 11 Heat treatment equivalent to pasteurisation of dairy produce <10% fat, <200 micron, AS 3993-2003 (Appendix A) A2.1 (a) pg 16). Butter FSP 2.14.1 16/06/20 V5 (amended to pasteuriser divert at 74.8C, minimum 15 seconds, validation as above). Lactoferrin & Lactoperoxidase (Protein Powders) FSP 2.17.1 V3 14/01/2019 (currently under review) PRPs are documented and well established. They are implemented into the site food safety management system. CCP's relate to: CCP 1 - Raw Milk Receival – Antibiotics – Antibiotics <0.0025mg/kg (Limit of Detection), <0.25IU, Approved Supplier Program CCP 2 - Pasteurisation > Diverts at 72.2°C, min 15 seconds, current 35000 L /H (18.8 seconds) max 39000L/H pressure differential diversion <0.1 bar CCP 3 – Evaporator, Preheat 78 - 83°C, max 35,000 L/hr CCP 4 – X Ray Detector - No Metal – product identified Test pieces SS 5.5mm CCP5 -Cream Pasteurisation > 74.8 C Diversion temperature, min 15 seconds, 5700Lh flow CCP 6 - Butter Cream Pasteurisation >74.8 C Diversion temperature, min 15 seconds, 5700Lh flow Lactoferrin & Lactoperoxidase: CCP 7 – Refrigeration Stored 0-4°C, daily record. Minor NCR Lactoferrin Cold Storage CCP <5C monitoring frequency is daily, however this frequency would not demonstrate cold storage temperatures are being maintained with in safe time frames designated for the safe storage of chilled products being stored at <5C. CCP 8 – Thaw frozen bulk wet product 0-4°C up to 7 days QCP/RCP's Cheese whey PH during cheese make and mill, salting, weight checks Validation and Effectiveness include monitoring and measuring, validation of control measures, food safety plan updates, and food quality plan updates. The responsibilities of this process are managed by Quality Manager. The frequency of HACCP review is documented as annually with the last review dated June 2020 X-Ray machine detector test piece sizes have been validated via supplier calibration records, calibration by Mettler Toledo dated 14/05/20, Holding Tubes 5 yearly validation – dated 23-3-2018, other CCP's are validated by reference to the Food Standard 1.4.2 Schedule 1 pg. 50, ANZDAC Pasteuriser Validation and Verification Guideline June 2007, Ch 4 pg. 7 & AS 3993-2003 (Appendix A) A2.1(a) pg 16) Heat treatment equivalent to pasteurisation of dairy produce <10% fat, <200 micron, AS 3993-2003 (Appendix A) A2.1 (a) pg 16). Sighted monitoring records CCP1 Tanker antibiotic testing records 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 <0.0025mg/kg CCP 2 Milk Pasteurisation records 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 compliant to temperature and pressure differentials. CCP3 Evaporator Preheat temperature records verified 5/08/20, 28/07/20, 17/12/10 compliant to temperature CCP 4 X Ray Detector records verified 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 compliant to testing of metal detector with 5.5 mm stainless steel ball start/middle and end of shift as well as independent verification by team leader CCP 5 Cream Pasteuriser temperature records verified 4/08/20, 10/06/20, 9/06/20, 25/02/20 compliant to temperature limits. CCP 6 - Butter Cream Pasteurization temperature records verified 4/08/20, 10/06/20, 9/06/20, 25/02/20 compliant to temperature limits. CCP 7 – Refrigeration Stored 0-4°C, Sighted monitoring records between 4/08/20 to 2/01/20 <4C Compliant. CCP 8 – Continuous Thawing - 0-4°C up to 7 days, no thawing has occurred in last 12 months QCP/RCP's Cheese whey PH during cheese make and mill, salting, weight checks, sighted records 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 compliant

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. Feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

RESPONSE: COMPLIANT

2.4.3.2 The food safety plan shall be effectively implemented, maintained and outline the means by which the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

RESPONSE: COMPLIANT

2.4.3.3 The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant products and associated processes. Where the relevant expertise is not available on site, advice may be obtained from other sources to assist the food safety team.

RESPONSE: COMPLIANT

2.4.3.4 The scope of each food safety plan shall be developed and documented including the start and end-point of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

2.4.3.5	<p>Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.5.1) plus any additional information relevant to product safety, such as pH, water activity, and/or composition.</p> <p>RESPONSE: COMPLIANT</p>
2.4.3.6	<p>The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative use of the product.</p> <p>RESPONSE: COMPLIANT</p>
2.4.3.7	<p>The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw material, packaging material, service inputs (e.g. water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation.</p> <p>RESPONSE: COMPLIANT</p>
2.4.3.8	<p>The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.</p> <p>RESPONSE: COMPLIANT</p>
2.4.3.9	<p>The food safety team shall conduct a hazard analysis for every identified hazard to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.</p> <p>RESPONSE: COMPLIANT</p>
2.4.3.10	<p>The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.</p> <p>RESPONSE: COMPLIANT</p>
2.4.3.11	<p>Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e. a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.</p> <p>RESPONSE: COMPLIANT</p>
2.4.3.12	<p>For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard (s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).</p> <p>RESPONSE: COMPLIANT</p>

2.4.3.13 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.

RESPONSE: MINOR

EVIDENCE: Lactoferrin Cold Storage CCP <5C monitoring frequency is daily, however this frequency would not demonstrate cold storage temperatures are being maintained within safe time frames designated for the safe storage of chilled products being stored at <5C.

ROOT CAUSE: Continuous temperature monitoring not in place. Continuous temperature recording required, add data logger to the cold room to undertake monitoring until temperature recording is automated on Scada. Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: Data logger has been placed in the cold room for continuous monitoring and downloaded once per week until the temperature recording is automated on Scada. Chiller Temp-recorder data and graph, keep in mind the red spikes are the hot gas defrost scheduled in the system

VERIFICATION OF CLOSEOUT: Data logger installed Lactoferrin Cold Storage as sighted download for continuous monitoring and ongoing recording of C/R temperature control, will be downloaded weekly. Is also intended to include temperature monitoring on Scada, for temperature trending and alarming of out of specification temperature.

COMPLETION DATE: 09/04/2020 **CLOSEOUT DATE:** 09/04/2020

2.4.3.14 The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.

RESPONSE: COMPLIANT

2.4.3.15 The documented and approved food safety plan (s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs or other changes affecting product safety occur.

RESPONSE: COMPLIANT

2.4.3.16 Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).

RESPONSE: COMPLIANT

2.4.3.17 Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.

RESPONSE: COMPLIANT

2.4.4 Approved Supplier Program (Mandatory)

Approved Supplier Procedure FSP 4.9.5 dated 13/08/19 details suppliers' approval process, contingency arrangements, emergency approvals, contract service providers, how suppliers are risk assessed, approved and reviewed, provision of certifications, raw material and packaging specifications as well as raw material receipt inspection requirements and provision of C of A. An approved supplier list is a 'live' document which includes RM suppliers, service providers, packaging suppliers. The vendor assurance program is managed by a Quality Team. Approval of a supplier is based on a supplier being at least HACCP certified and the credential must be kept in file. Copies of a raw material specification for the material supplied must also be kept on file. Packaging suppliers must demonstrate that the material complies with the relevant legislation. Supplier issues are raised directly with the supplier via an external CAR system and the QA team reviews these on a regular basis. Raw materials are delivered with a COA where applicable. Records demonstrated compliance with COA. A register of raw materials and packaging is maintained live on the system with specifications and certifications maintained eg DSM (Cultures and Rennet) HACCP expiry dated 15/10/21 Cheetham Salt HACCP expiry dated 15/11/20 Multivac (Film) Sunrise packaging BRC Expiry 1/06/21

2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification (refer to 2.3.2) and be supplied by an approved supplier.

RESPONSE: COMPLIANT

2.4.4.2 The receipt of raw materials, ingredients, and packaging materials received from non-approved suppliers shall be acceptable only in an emergency situation, and provided they are inspected or analyzed before use.

RESPONSE: COMPLIANT

2.4.4.3	<p>The responsibility and procedure for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented.</p> <p>RESPONSE: COMPLIANT</p>
2.4.4.4	<p>The site's food defense plan (refer to 2.7.1.1) shall include measures to secure incoming materials and ingredients and protect them from deliberate act of sabotage or terrorist-like incidents.</p> <p>RESPONSE: COMPLIANT</p>
2.4.4.5	<p>The site's food fraud vulnerability assessment (refer to 2.7.2.1) shall include the site's susceptibility to raw material or ingredient substitution, mislabeling, dilution or counterfeiting which may adversely impact food safety.</p> <p>RESPONSE: COMPLIANT</p>
2.4.4.6	<p>The food fraud mitigation plan (refer to 2.7.2.2) shall include methods by which the identified food safety vulnerabilities from ingredients and materials shall be controlled.</p> <p>RESPONSE: COMPLIANT</p>
2.4.4.7	<p>Raw materials, ingredients, and packaging materials received from other sites under the same corporate ownership shall be subject to the same specification requirements (refer to 2.3.2) and approved supplier requirements as all other material providers.</p> <p>RESPONSE: COMPLIANT</p>
2.4.4.8	<p>The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw materials ingredients, packaging materials, and services supplied, and shall contain as a minimum: i. Agreed specifications (refer to 2.3.2); ii. Reference to the rating of the level of risk applied to a raw material, ingredients, packaging materials and services and the approved supplier; iii. A summary of the food safety controls implemented by the approved supplier; iv. Methods for granting approved supplier status; v. Methods and frequency of monitoring approved suppliers; vi. Details of the certificates of conformance if required; and vii. Methods and frequency of reviewing approved supplier performance and status.</p> <p>RESPONSE: COMPLIANT</p>
2.4.4.9	<p>Supplier audits shall be based on risk and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.</p> <p>RESPONSE: COMPLIANT</p>
2.4.4.10	<p>A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained.</p> <p>RESPONSE: COMPLIANT</p>
2.4.5	<p>Non-conforming Product or Equipment</p> <p>Non- Conformance Program FSP 4.2.7 details requirements and management of non-conforming raw materials, work in progress, finished products and equipment. The procedure details quarantine requirements, labelling requirements, communication channels and release and/or disposal procedures. Actions are allocated to the most appropriate area manager and closed by the original issuer of the Corrective Action Register. Non conforming product and corrective action register maintained as sighted 15/07/20 to 8/01/20 eg 24/01/20 NCR 13 Lumpy Whey Powder internal failure, draining issue in bag house when CIP, bags became wet causing lumpy powder, bags were removed and CIP drain time extended to ensure adequate drainage.</p>

2.4.5.1 The responsibility and methods outlining how non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment detected during receipt, storage, processing, handling or delivery is handled shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; ii. Non-conforming equipment is effectively repaired or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and iii. All relevant staff are aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status.

RESPONSE: MINOR

EVIDENCE: Non Conforming product (eg out of date, out of specification) being stored in the Lactoferrin cold store had not been isolated or identified with hold/reject stickers as required by the non conforming product procedure (has been included in non conforming product register).

ROOT CAUSE: Hold stock was not labelled with HOLD label, details of the stock were captured on the OOS Product form but not physically labelled with a HOLD label or segregated, spoke personally with the operator on the day of the audit who labelled and segregated the stock. Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: The non-conforming product was labelled "Hold" and segregated on the day of the audit 05/08/20. See below photographs

VERIFICATION OF CLOSEOUT: Sighted Lactoferrin non compliant product segregated and hold labels placed on the effected product. Operator retrained in quarantine and hold requirements for non conforming product as per non conforming product procedure. Review of effectiveness via weekly management review meetings and internal audits.

COMPLETION DATE: 08/05/2020 **CLOSEOUT DATE:** 09/04/2020

2.4.5.2 Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.

RESPONSE: COMPLIANT

2.4.6 Product Rework

Product Rework Procedure FSP 4.24.1 details the requirements of responsibilities (QA Manager and Manufacturing) rework guidelines, conditions of use, rework WIP, product returned for rework, assessment of product. The main rework complies to the left overs/end of run cheese that gets reworked with the same product the following day or days. Traceability is via production logs and signage.

2.4.6.1 The responsibility and methods outlining how ingredients, packaging materials, or products are reworked shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are supervised by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Each batch of reworked product is inspected or analyzed as required before release; iv. Inspections and analyses shall conform to the requirements outlined in element 2.5.4.1; and v. Release of reworked product shall conform to element 2.4.7.

RESPONSE: COMPLIANT

2.4.6.2 Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

2.4.7 Product Release (Mandatory)

Product Hold and Release Procedure FSP 4.15.1-2 detail requirements and management of releasing non-conforming raw materials, work in progress & finished products. The procedure details labelling requirements, inspections, communication channels and authorized personnel. Product release is based on finished product micro being within specification. Records are maintained via a spreadsheet. Product cannot be picked for dispatch until unlocked in the SAP system. Note: Quarantine stickers and designated areas are used, this system was demonstrated during the audit. Micro Testing includes pathogens Listeria and Salmonella.

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released: i. By authorized personnel; and ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release shall be maintained.

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

Environmental Listeria swabbing (monthly internally) Milk Processing and Butter plant, 9/07/20 to 9/01/20, (Butter plant drains 7,8,9 positive listeria, recheck drains 8,9 positive, Milk silo gallery drain 2 positive listeria 19/02/20 and 2 rechecks also positive), mozzarella plant (7 swabs per month) 23/07/20 to 6/01/20 (middle drain 7/07/20 positive, recheck negative, drain brine tank side positive 4/02/20, recheck negative, drain brine tank side positive 23/01/20, recheck negative). Protein plant 16/07/20 to 14/01/20 (positive listeria in column room Jan, Feb, April and July. Salmonella (Monthly externally), sighted monthly testing by ALS Nata lab 16/07/20, 18/06/20, 20/05/20, 22/04/20, 17/03/20, 26/02/20, 23/01/20 various swab points in powder plant, and internal Rapid ATP swabbing (Daily): Records sighted July 2019 to Jan 2020. Corrective action documented. Minor NCR: Whilst rechecks are being conducted, it has not been fully documented the corrective action taken in relation to +ve environmental listeria swabs (drains), ie clean and corrective action as per procedure SOP /LAB/GEN/009

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food and pet food manufacturing processes.

RESPONSE: COMPLIANT

2.4.8.2 The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.8.3 An environmental sampling and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.

RESPONSE: COMPLIANT

2.4.8.4 Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.

RESPONSE: MINOR

EVIDENCE: Whilst rechecks are being conducted, it has not been fully documented the corrective action taken in relation to +ve environmental listeria swabs (drains), ie clean and corrective action as per procedure SOP /LAB/GEN/009

ROOT CAUSE: Corrective actions were not fully documented, now being raised as an NCR capturing corrective actions Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: Environmental positive pathogen detection to be raised as an NCR to document follow up corrective actions and retest results. Please see below example

VERIFICATION OF CLOSEOUT: NCR form is now utilised to capture environmental positive detections as sighted included in NCR report sighted 3/09/20 for detection in drains 3/08/20 included root cause and corrective action. Review of effectiveness via weekly management review meetings and internal audits.

COMPLETION DATE: 09/03/2020 **CLOSEOUT DATE:** 09/04/2020

2.5.1 Validation and Effectiveness (Mandatory)

Validation and Effectiveness include monitoring and measuring, validation of control measures, food safety plan updates, and food quality plan updates. The responsibilities of this process are managed by Quality Manager. The frequency of HACCP review is documented as annually with the last review dated June 2020 X-Ray machine detector test piece sizes have been validated via supplier calibration records, calibrated by Mettler Toledo dated 2/06/20 , Holding Tubes 5 yearly validation – dated 23-3-2018, other CCP's are validated by reference to the Food Standard 1.4.2 Schedule 1 pg. 50, ANZDAC Pasteuriser Validation and Verification Guideline June 2007, Ch 4 pg. 7 & AS 3993-2003 (Appendix A) A2.1(a) pg 16)

2.5.1.1 The methods, responsibility and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall ensure that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required result; ii. Critical food safety limits are validated, and re-validated annually; iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and iv. All applicable elements of the SQF Program are implemented and effective.

RESPONSE: COMPLIANT

2.5.1.2 Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

Verification activities are documented in the individual Verification and Validation Table under each specific product and stated in the Internal Audit schedule FSP 6.26.3. Records sighted demonstrate CCP's have been monitored and compliance with critical limits observed or corrective action demonstrated to be undertaken. Monitoring records are verified by an internal auditing system and record cited demonstrated that these have been completed as per documented schedule. Verification activities have been performed as per documented schedule. Records sighted: HACCP Review June 2020, GMP bi monthly Audits 3-29/06/20,15-28/04/20, 19-28/02/20, Metal Detection Calibration 2/06/20, X Ray Calibration 2/06/20. Pre-Operational Checks: daily – completed as per records sighted 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19, Glass Audits – monthly - wc 27/07/20, 20/07/20, 13/07/20, through to 8/01/20 (weekly), 22/06/20, 5/05/20, 21/04/20, 17/03/20, 10/02/20, (Monthly). Internal audits undertaken as per schedule 2019/20. HACCP plans reviewed: Mozzarella Processing – FSP 2.4 19/06/20 V9 (SS test piece size changed to 5.5mm, to prevent false rejects due to salt on cheese). Whey Powder– FSP 2.15.1, 16/06/20 V6 (amended step 11c fluid bed) Fresh Cream – FSP 2.14.1 16/06/20 V7 (amended to pasteurizer divert at 74.8C, minimum 15 seconds, validation via ANZDAC Pasteurizer validation and verification guideline June 2007 Ch 4 pg7, appendix b pg 11 Heat treatment equivalent to pasteurisation of dairy produce <10% fat, <200 micron, AS 3993-2003 (Appendix A) A2.1 (a) pg 16). Butter FSP 2.14.1 16/06/20 V5 (amended to pasteurizer divert at 74.8C, minimum 15 seconds, validation as above). Lactoferrin & Lactoperoxidase (Protein Powders) FSP 2.17.1 V3 14/01/2019 (currently under review)

2.5.2.1 A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity shall be prepared and implemented.

RESPONSE: COMPLIANT

2.5.2.2 The methods, responsibility and criteria for verifying monitoring of Good Manufacturing Practices, critical control points and other food safety controls, and the legality of certified products, shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record.

RESPONSE: COMPLIANT

2.5.2.3 Records of the verification of monitoring activities shall be maintained.

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

Non conforming product and corrective action register maintained as sighted 15/07/20 to 8/01/20 eg 19/06/20 NCR 77 Internal Audit HACCP, some documentation updates required and checks not completed as required. 6/05/20 NCR 63 Hygiene non compliance, unauthorised drink bottle in red production cupboard, cupboard has been removed, and there is continual monitoring of employee practices. 24/01/20 NCR 13 Lumpy Whey Powder internal failure, draining issue in bag house when CIP, bags became wet causing lumpy powder, bags were removed and CIP drain time extended to ensure adequate drainage. 27/03/20 NCR 55 Pest Control Mouse in cheese production room, root cause-gaps in roller doors in loading dock, WR 1267 raised, Issue escalated to pest control contractor, increased number of traps inside areas, including packing area and sticky pad traps in cheese room, thorough inspection undertaken for evidence of mice and pest proofing, also reinforced pest sighting and reporting requirements with employees, escalated again 18/06/20 with 2 mice captured in loading dock area, and escalated fixing of loading dock doors, and 2 further traps placed in the area, gaps on bottom of loading dock doors have not as yet been fixed however.

2.5.3.1 The responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented.

RESPONSE: MINOR

EVIDENCE: Mozzarella Product temperature on exit of brine cooler is consistently higher than target temperature of 30-35C, without corrective action referenced, eg 3/08/20 (42-48C) and records 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19, hence cooling profile may not be as originally validated.

ROOT CAUSE: The target temperature on the form was never able to be achieved. Remove target temperature and continue to monitor brine temperature Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: The target temperature on the form is not able to be achieved and has been removed from the form. The brine temperature 3-6deg will be continued to be monitored as per the the Cooker Stretcher and Prat Wheel Check List. Cooling profile is verified every batch (a days production) with finished goods microbiological testing records.

VERIFICATION OF CLOSEOUT: Sighted Cooker Stretcher & Prat Wheel Checklist FSP 5.14 F4-6 now monitoring of brine temperature only, and validation of finished product safety is via daily microbiological testing E Coli, Listeria, Salmonella, Coag +ve Staph, Y&M as sighted results during audit tested by ALS 20/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19, compliant. Product is not released until product test results received and are compliant to specification. Review of effectiveness via weekly management review meetings and internal audits.

COMPLETION DATE: 08/10/2020 **CLOSEOUT DATE:** 09/04/2020

2.5.3.2 Records of all investigation and resolution of non-conformities including their corrections and corrective action shall be maintained.

RESPONSE: COMPLIANT

2.5.4 Product Sampling, Inspection and Analysis

Sampling and testing as per schedule. Jervois product testing by Murray Bridge Proficiency testing - Lab – sampling and testing requirements and ALS NATA Lab Acc 1247 utilised for chemical analysis and micro analysis. Mozzarella Cheese: Micro testing E.Coli <10, Listeria/25g – 0, Salmonella /25g – 0, Staph <10, Yeast <100, Mould <100, confirmed micro test results from ALS Nata Lab and in house results for dates 20/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19, compliant Chemical Testing guidelines are in Cheese Parameters SOP 5.2.1, Includes (Mill times, pH, acidity guidelines, recipes, calculations, cultures & whey off pH standards, salt settings, cut duration, pump out) sighted records 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19. Chemical analysis 31/07/20 Moisture (spec is 46-49% max): actual (Range 47.1 to 48.76%), Fat (spec is 20-24%): actual (Range 21.63 to 22.17%), Salt (spec is 1.0-1.5%): actual (Range 1.25 to 1.44%), pH (spec is 5.0-5.4): actual (Range 5.29 to 5.36), Results compliant Current SPC processes relate to Product Quality & Composition parameters Mozzarella Cheese moisture Averages Aim 48.0 LCL 46.0%, UCL 49.0% results 2020 July 47.0-48.3, June 46.2 – 48.2, Mar 47.6 –49.0% , Butterfat LCL 20.0%, UCL 24.0 % results July 20.9-20.4, June 20.8 - 23.8, Mar 19.8 – 23.7 % , PH Aim LCL 5.0 UCL 5.4 results July 5.2 – 5.4, June 5.2 – 5.4, Mar 5.2 – 5.4, Salt LCL 1.0 UCL 1.5 % results July 1.2-1.4, June 1.2-1.5, Mar 1.2-1.4% Also sighted standard deviations achieved eg June 2020 Moisture 0.788, Salt 0.160, Fat 0.747, PH 0.04. Mozzarella Cook Score, Aim monthly LCL 2.5, UCL 2.80, results June 2.6-2.8, Mar 2.3-2.8 Whey Powder: DOM 16/06/20, 23/04/20, 18/12/20 E. coli 95%, Ash 4.0%, PH 5.5 to 6.5, Iron <350mg/100g, Moisture <4.0% sighted results 1/01/20 to 19/06/20 generally good compliance to specification, full compliance with micro specification, occasional LF protein <95% (sold as lower grade) .

2.5.4.1 The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work-in-progress shall be documented and implemented. The methods applied shall ensure: i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements; ii. Inspections are conducted to ensure raw materials, work in process and finished products comply with the relevant specification, regulatory requirements and are true to label; and iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods.

RESPONSE: COMPLIANT

2.5.4.2 On-site personnel that conduct environmental or product testing shall participate in an applicable proficiency testing program at least annually to ensure accuracy of results.

RESPONSE: COMPLIANT

2.5.4.3 Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard and shall be included on the site's contract service specifications register (refer to 2.3.3.1).

RESPONSE: COMPLIANT

2.5.4.4 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.5.5 Internal Audits and Inspections (Mandatory)

These requirements are managed through an Internal Audits Procedure FSP 4.3.1 This includes how Internal audits are scheduled, non-conformance grading, corrective actions, communication routes and how records are maintained. The responsibilities of this process are managed by Quality Manager. There are 6 trained Internal auditors that conduct the audits throughout the year. Internal Audits cover all aspects of the SQF standard. All aspects of the food safety system are subject to an Internal audit on an annual basis by the Quality manager. Records demonstrated good level of detail and reporting of both compliance and non-compliance. Any issues found fall into the Corrective and Preventative Action procedure. Sighted completed audits: Pest Control 5/05/20, Cleaning and sanitation 5/05/20, Calibration 5/05/20, Rework 20/02/20, Mozzarella HACCP 18/06/20, Management Responsibility 28/01/20, Potable Water 8/01/20, BCP plan 18/05/20 (Added Pandemic response). GMP audits undertaken bi monthly and includes all areas including cheese plant, protein plant, maintenance, butter and cream plant, whey powder plant, cool rooms, amenities areas and includes review of walls, floors, ceilings, drains, foot baths, lighting, work benches, pest activity, cleanliness and hygiene, foreign objects, glass, ceramics and hard plastics, PPE, external areas. Sighted undertaken in the various areas 3-29/06/20,15-28/04/20, 19-28/02/20 with detailed corrective action requirements noted and work orders raised.

2.5.5.1 The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code for Manufacturing are audited as per the SQF audit checklist or similar tool; ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken; and iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions.

RESPONSE: COMPLIANT

2.5.5.2 Staff conducting internal audits shall be trained and competent in internal audit procedures.

RESPONSE: COMPLIANT

2.5.5.3 Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and building/equipment maintenance is compliant to the SQF Food Safety Code for Manufacturing. The site shall: i. Take corrections or corrective and preventative action; and ii. Maintain records of inspections and any corrective action taken.

RESPONSE: COMPLIANT

2.5.5.4 Where practical staff conducting internal audits shall be independent of the function being audited.

RESPONSE: COMPLIANT

2.5.5.5 Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained.

RESPONSE: COMPLIANT

2.6.1 Product Identification (Mandatory)

These requirements are managed through a Product & Identification Procedure FSP 4.12-8 . This includes how raw materials, work in progress and finished product are clearly identified during all stages of receipt, production, storage and dispatch, finished product is labelled to the customer specification and/or regulatory requirements. The responsibilities of this process are managed by Site Management Team. Product at all stages of the process was observed to be labelled appropriately. Records demonstrated that traceability is maintained i.e. Milk receival files and milk tanker dockets, cheese - batch #, packed date, pallet #.

2.6.1.1 The methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in -progress, process inputs and finished products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure: i. Raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are clearly identified during all stages of receipt, production, storage and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements.

RESPONSE: COMPLIANT

2.6.1.2 Product identification records shall be maintained.

RESPONSE: COMPLIANT

2.6.1.3 Product start up and changeover procedures during packing shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label, and that the changeover is inspected and approved by an authorized person.

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

These requirements are managed through a Product & Identification Procedure FSP 4.12-8 dated. This includes how raw materials, work in progress and finished product are clearly identified during all stages of receipt, production, storage and dispatch, finished product is labelled to the customer specification and/or regulatory requirements. The responsibilities of this process are managed by Site Management Team. Product at all stages of the process was observed to be labelled appropriately. Records demonstrated that traceability is maintained i.e. Milk receival files and milk tanker dockets, cheese - batch #, packed date, pallet #. Bestons Jervois Mock Recall and Trace excersize was undertaken 23/07/2020 traced from raw milk silo (scenario antibiotic in milk 17/06/20), stock placed on hold, through to all products processed and packed including mozzarella, cream, whey powders, whey protein, as well as production and quality logs, through to ingredients and batch numbers, as well as distribution, and mass balance completed, all completed in 2.5 hours. Opportunities identified including recording of packaging batch codes, protein plant batch code recording and traceability records, evaporator top up vat recording (have been summarised and communicated to employees via Mock Recall summary on notice board).

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable to the customer (one up) and provides traceability through the process to the manufacturing supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back); ii. Traceability is maintained where product is reworked; and iii. The effectiveness of the product trace system shall be reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.3).

RESPONSE: COMPLIANT

2.6.2.2 Records of raw and packaging material receipt and use, and finished product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

Product Recall and Withdrawal Procedure FSP 4.14 details the business process and procedures around the event of a product recall or withdrawal. The elements stated are comprehensive and meet the requirements of the SQF Ed 8 standard. SQF & CB details were observed to be current and correct. The procedure documents the requirement to test, review and verify the system annually. Bestons Jervois Mock Recall and Trace excersize was undertaken 23/07/2020 traced from raw milk silo (scenario antibiotic in milk 17/06/20), stock placed on hold, through to all products processed and packed including mozzarella, cream, whey powders, whey protein, as well as production and quality logs, through to ingredients and batch numbers, as well as distribution, and mass balance completed, all completed in 2.5 hours. Opportunities identified including recording of packaging batch codes, protein plant batch code recording and traceability records, evaporator top up vat recording (have been summarised and communicated to employees via Mock Recall summary on notice board).

2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall; ii. Describe the management procedures to be implemented including sources of legal, regulatory and expert advice and essential traceability information; and iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; iv. SQFI, the certification body, and the appropriate regulatory authority shall be listed as an essential body and notified in instances of a food safety incident of a public nature, or product recall for any reason.

RESPONSE: COMPLIANT

2.6.3.2 Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.

RESPONSE: COMPLIANT

2.6.3.3 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually. Testing shall include incoming materials (one back) and finished product (one up).

RESPONSE: COMPLIANT

2.6.3.4 SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

2.6.3.5 Records of all product withdrawals, recalls and mock recalls shall be maintained.

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

These requirements are managed through the Food Security Plan FSP 4.20-4. This includes how raw materials, finished product, operations of water, security strategy, data systems, are managed to prevent adulteration caused by a deliberate act of sabotage or terrorist-like incident during all stages of receipt, production, storage and dispatch. The responsibilities of this process are managed by Quality Manager. The site was observed to be secured by a perimeter fence and gates are locked outside of working hours with CCTV cameras in strategic external locations, and swipe card access. Site map includes product flows, CIP and site boundaries 1/12/17. A Food Security risk assessment and defence challenge conducted 29/07/20 including assessment of challenges and actions implemented ie outside challenges, shipping/receiving, mail handling, inside challenges, process areas, storage areas, utilities and services, chemical, hazardous materials security, information security, personnel security, non employee security, incident response security measures, several actions identified for completion 30/09/20. All employees have annual Security training as part of their GMP training. Food Defence testing

2.7.1.1 The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained.

RESPONSE: COMPLIANT

2.7.1.2 A food defense plan shall include: i. The name of the senior site management person responsible for food defense; ii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing and storage areas through designated access points; iii. The methods implemented to protect sensitive processing points from intentional adulteration; iv. The measures taken to ensure the secure receipt and storage of raw materials, packaging, equipment and hazardous chemicals; v. The measures implemented to ensure raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are held under secure storage and transportation conditions; and vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.

RESPONSE: COMPLIANT

2.7.1.3 The food defense plan shall be reviewed and challenged at least annually.

RESPONSE: COMPLIANT

2.7.1.4 Records of reviews of the food defense plan shall be maintained.

RESPONSE: COMPLIANT

2.7.2 Food Fraud

These requirements are managed through the Food Fraud Risk Procedure FSP 4.20.1 outlines requirements for VACCP methodology and steps, and Food Fraud reduction strategies. VACCP Food Fraud Risk Assessment was reviewed 16/07/20. This includes how raw materials, work in progress and finished product are managed to prevent concealment, counterfeiting, dilution, mislabelling, grey market diversion, substitution & emerging concerns. The responsibilities of this process are managed by Quality Manager and the VACCP team. As part of review have assessed Historical incidents eg melamine contamination of milk in China, economic/price fluctuations, geographical origin, length and complexity of supply chain, storage and distribution, ease of access to materials, material value and market size, physical form, emerging concerns-nil identified for dairy ingredients, existing controls, standards, availability. All raw materials associated with the finished product have been assessed including raw materials and packaging, assessed for likelihood of occurrence, likelihood of detection, likelihood of profitability from food fraud and controls including approved supplier program, purchased from reputable suppliers, good supplier relationships, C of A's, Food Safety/Food Quality/Operational controls, finished product testing and assessment. No immediate potential for food fraud risks have been identified including ingredients reviewed during the audit, salt, culture, rennet, milk, primary packaging all low probability.

2.7.2.1 The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.

RESPONSE: COMPLIANT

2.7.2.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.

RESPONSE: COMPLIANT

2.7.2.3 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.

RESPONSE: COMPLIANT

2.7.2.4 Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.

RESPONSE: COMPLIANT

2.8.1 Allergen Management for Food Manufacturing (Mandatory)

Allergen Management Procedure FSP 4.22.1 dated 24/09/19 covers all requirements of the standard which includes responsibilities, assessment and labelling training requirements, allergen listing and matrix. Flow chart of allergen assessment process includes assessment of ingredients/product for allergens, assessment for cross contamination, labelling requirements. Controls include a risk assessment, cleaning procedures and segregation procedures. Allergen risk assessment conducted 16/07/20, milk is the only allergen and so only step 1 of risk assessment undertaken with the identification of milk as the only allergen, is in all products and so no risk of cross contamination. The responsibilities of this process are managed by Site team. Allergen controls begin at product development process where raw material specifications (PIFs) are obtained and assessed and incorporated in to the control procedures as required. Allergen training is provided at induction. GMP Refresher training (Allergens, FO Matter control, tools, maintenance handover, housekeeping) in 2020.

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A register of allergens which is applicable in the country of manufacture and the country (ies) of destination if known; iv. A list of allergens which is accessible by relevant staff. v. The hazards associated with allergens and their control incorporated into the food safety plan. vi. A management plan for control of identified allergens. The allergen management program shall include the identification, management, and labelling of products containing gluten, where applicable.

RESPONSE: COMPLIANT

2.8.1.2 Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in progress, rework or finished product on how to identify, handle, store and segregate raw materials containing allergens.

RESPONSE: COMPLIANT

2.8.1.3 Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

RESPONSE: COMPLIANT

2.8.1.4 Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided where satisfactory line hygiene and clean-up or segregation is not possible.

RESPONSE: COMPLIANT

2.8.1.5 Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented.

RESPONSE: COMPLIANT

2.8.1.6 Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

RESPONSE: COMPLIANT

2.8.1.7 The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured.

RESPONSE: COMPLIANT

2.8.1.8 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in-progress and finished product is true to label with regard to allergens. Such measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures.

RESPONSE: COMPLIANT

2.8.1.9	<p>The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used.</p> <p>RESPONSE: COMPLIANT</p>
2.8.1.10	<p>Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable.</p> <p>RESPONSE: COMPLIANT</p>
2.8.1.11	<p>Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introducing unintended allergens through supplier, contract manufacturer, employee and visitor activities.</p> <p>RESPONSE: COMPLIANT</p> <p>EVIDENCE: Allergen is handled on site-milk</p>
<p>2.8.2 Allergen Management for Pet Food Manufacturing</p> <p>No Pet Food Manufacturing</p>	
2.8.2.1	<p>The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those inputs and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A list of allergens which is accessible by relevant staff; and iv. The hazards associated with allergens and their control incorporated into the food safety plan.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No Pet Food Manufacturing</p>
2.8.2.2	<p>Product labeling, in accordance with regulatory requirements, shall include allergens where risks from cross-contact have been identified.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No Pet Food Manufacturing</p>
<p>2.8.3 Allergen Management for Manufacturers of Animal Feed</p> <p>No Animal Food Manufacturing</p>	
2.8.3.1	<p>Sites that exclusively manufacture animal feed and do not manufacture, handle or store food or pet food products are not required to implement an allergen management plan unless required by regulation or customer requirement.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No Animal Food Manufacturing</p>
2.8.3.2	<p>Where an allergen management plan is required by regulation or customer specification, the requirements of 2.8.2 shall apply.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No Animal Food Manufacturing</p>
<p>2.9.1 Training Requirements</p> <p>Requirements addressed as per FSP 4.4 Training Procedure. This covers all requirements of the SQF standard. The procedure includes highlighting of critical tasks, specific training requirements, effective implementation of the food management system, the provision for refresher training & records in the form of a current training matrix (for each personnel) and training records. The responsibilities of this process are managed by the Site Management Team. Training plan implemented and records sighted: The Quality and Food Safety training plan 2019/20 4.4 F1 includes training course, trainer/responsibility, duration, frequency, employees required to train, includes re induction (3 years), GMP/Food Safety and HACCP (yearly), Tanker Driver training Beta Star, Milk cooling and unloading (2 years), Maintenance handover procedure (2 years), Glass and Hard Plastics (yearly), Equipment Breakage and Loss policy (Yearly), AMRA training (once of by key personnel), HACCP and CCP training (yearly), HACCP Refresher training (yearly), Internal Auditor (3 years), GMP auditing (3 years).</p>	

2.9.1.1 The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented.

RESPONSE: COMPLIANT

2.9.1.2 Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

It was sighted training records for employees interviewed/observed during the audit: Milk Tanker Driver CY, Beta Star Antibiotic testing (CCP) Training completed 26/02/2020. Milk Pasteuriser operator DS SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, GMP and Food Safety Questionnaire completed 6/03/20. Trained in milk pasteuriser and CCP/QCP procedures 30/07/20. Cheese Maker VvE, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, GMP and Food Safety Questionnaire completed 6/01/20, 6/03/20, cheesemaker training FSP 5.14.1 to 5.14.6. 16/01/19. Cream Processing and Buttermaker CP SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, Food Fraud/VACCP, Food Defence GMP and Food Safety Questionnaire completed 9/07/20, trained in cream pasteurising QCP's/CCP's 23/06/20, Butter and Cream procedures 12/06/19. Lactoferrin Protein plant operator WH, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, GMP and Food Safety Questionnaire completed 3/12/19. Lactoferrin protein CCP/QCP procedures 18/12/19, Protein plant procedures training 13/01/20, 18/12/19. Mozzarella Packing and X ray operations, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, Food Fraud/VACCP, Food Defence GMP and Food Safety Questionnaire completed 8/07/20, Multi vac procedures training 15/07/20, X ray operations/CCP requirements, corrective action 19/07/19, refresher training 7/08/20. Whey Powder Operator JH, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, Food Fraud/VACCP, Food Defence GMP and Food Safety Questionnaire completed 27/07/20. Evaporator Operations and CCP training 23/06/20. Maintenance personnel ND, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, GMP and Food Safety Questionnaire completed 20/05/20 GMP and Food Safety Questionnaire is very detailed, includes quality policy, company quality philosophy (Right 1st time every time), records, CCP's, allergens, illness, GMP specific requirements, hand washing, gloves, hair covering, boots, clothing, lockers, personal hygiene, pest control reporting, pest proofing, foreign objects, breakages, cleaning and sanitation, colour coding, chemical labelling, traceability, rework, maintenance handover, tools and metal items, raw materials acceptance, food defence. SQF Practitioner Lorraine Haebich who is a full time employee and formal HACCP training (SAI global) Principles and Application of HACCP 24/04/19, certificate C301033. Also has experience in SPC control - moisture, fat, salt and pH.

2.9.2.1 An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Developing and applying Good Manufacturing Practices; ii. Applying food regulatory requirements; iii. Steps identified by the hazard analysis and/or other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety; and iv. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.9.3 Instructions

SOP and training instructions were observed to be in English and understood by all staff interviewed.

2.9.3.1 Instructions shall be available in the languages relevant to the staff, explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety, and process efficiency are to be performed.

RESPONSE: COMPLIANT

2.9.4 HACCP Training Requirements

SQF Practitioner Lorraine Haebich who is a full time employee and formal HACCP training (SAI global) Principles and Application of HACCP 24/04/19, certificate C301033.

2.9.4.1 HACCP training shall be provided for staff involved in developing and maintaining food safety plans.

RESPONSE: COMPLIANT

2.9.5 Language

Instructions were observed to be in English and understood by all staff interviewed.

2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.

RESPONSE: COMPLIANT

2.9.6 Refresher Training

It was sighted training records for employees interviewed/observed during the audit: Milk Tanker Driver CY, Beta Star Antibiotic testing (CCP) Training completed 26/02/2020. Milk Pasteuriser operator DS SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, GMP and Food Safety Questionnaire completed 6/03/20. Trained in milk pasteuriser and CCP/QCP procedures 30/07/20. Cheese Maker VvE, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, GMP and Food Safety Questionnaire completed 6/01/20, 6/03/20, cheesemaker training FSP 5.14.1 to 5.14.6. 16/01/19. Cream Processing and Buttermaker CP SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, Food Fraud/VACCP, Food Defence GMP and Food Safety Questionnaire completed 9/07/20, trained in cream pasteurising QCP's/CCP's 23/06/20, Butter and Cream procedures 12/06/19. Lactoferrin Protein plant operator WH, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, GMP and Food Safety Questionnaire completed 3/12/19. Lactoferrin protein CCP/QCP procedures 18/12/19, Protein plant procedures training 13/01/20, 18/12/19. Mozzarella Packing and X ray operations, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, Food Fraud/VACCP, Food Defence GMP and Food Safety Questionnaire completed 8/07/20, Multi vac procedures training 15/07/20, X ray operations/CCP requirements, corrective action 19/07/19, refresher training 7/08/20. Whey Powder Operator JH, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, Food Fraud/VACCP, Food Defence GMP and Food Safety Questionnaire completed 27/07/20. Evaporator Operations and CCP training 23/06/20. Maintenance personnel ND, SQF Code, GMP and personal hygiene, tools, rework, designated eating areas, floor contact, protective clothing, HACCP Refresher, Foreign Matter prevention, equipment breakage policy, maintenance hand over to production, allergens, corrective action, GMP and Food Safety Questionnaire completed 20/05/20 GMP and Food Safety Questionnaire is very detailed, includes quality policy, company quality philosophy (Right 1st time every time), records, CCP's, allergens, illness, GMP specific requirements, hand washing, gloves, hair covering, boots, clothing, lockers, personal hygiene, pest control reporting, pest proofing, foreign objects, breakages, cleaning and sanitation, colour coding, chemical labelling, traceability, rework, maintenance handover, tools and metal items, raw materials acceptance, food defence. SQF Practitioner Lorraine Haebich who is a full time employee and formal HACCP training (SAI global) Principles and Application of HACCP 24/04/19, certificate C301033. Also has experience in SPC control - moisture, fat, salt and pH. All personnel have received Refresher GMP/Hygiene training ie GMP/Hygiene Procedures FSP4.3.1.1-4, Protective clothing 8.5, Designated eating areas 8.9, Floor Contact 8.3, Hoses 8.0, tools 11.0, rework 11.0, Foreign Matter Prevention FSP 4.1.15, Maintenance handover FSP 6.21.3, Allergen Management FSP 4,2,2,1, Lunch box control FSP 4.2.2.3, undertaken 27/03/19 to 24/06/19

2.9.6.1 The training program shall include provision for identifying and implementing the refresher training needs of the organization.

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

Training skills register maintained by site Quality manager - updated accordingly for each staff with training dates and competency status

2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Supervisor's verification that the training was completed, and that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

The manufacturing facility is located in regional Jervois, South Australia. A rural landscape surrounds the manufacturing facility with two dairies on either side and irrigated lands behind. The neighbouring operations do not impact the site's activities, with the manufacturing facility enclosed. The facility has the approvals from relevant authorities to undertake manufacturing operations at the current site's location. Sighted Dairy Authority of SA Accreditation 1357, 1/07/19, exp 30/06/2022. Also Dept of Agriculture Export certificate of registration 872, 15/04/2020.

11.1.1.1 The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations.

RESPONSE: COMPLIANT

11.1.1.2 The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

11.2.1 Materials and Surfaces

Product contact surfaces in all facilities are stainless steel or food grade rubber and observed well maintained and in good repair, with the Mozzarella facility and equipment newly designed and operating since Feb 2018.

11.2.1.1 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage, and cold storage areas shall be constructed of materials that will not contribute a food safety risk.

RESPONSE: COMPLIANT

11.2.2 Floors, Drains, and Waste Traps

Floors in the processing areas were observed to be impact resistant and impervious to liquid. Drains were located to not pose a risk to the product and waste traps are located away from food handling areas. The new mozzarella processing room was fully refurbished 2 years ago, including new epoxy floors, grated drains.

11.2.2.1 Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

RESPONSE: COMPLIANT

11.2.2.2 Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions.

RESPONSE: COMPLIANT

11.2.2.3 Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

RESPONSE: COMPLIANT

11.2.2.4 Waste trap system shall be located away from any food handling area or entrance to the premises.

RESPONSE: COMPLIANT

11.2.3 Walls, Partitions, Doors and Ceilings

Walls, ceilings and doors were observed of appropriate construction and well maintained with service pipes, roller door and personnel access doors observed in sound condition and observed well maintained and clean.

11.2.3.1 Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light-colored finish and shall be kept clean (refer to 11.2.13.1).

RESPONSE: COMPLIANT

11.2.3.2 Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: COMPLIANT

11.2.3.3 Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed to prevent the contamination of food, ingredients and food contact surfaces and allow ease of cleaning.

RESPONSE: COMPLIANT

11.2.3.4	<p>Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients and food contact surfaces, and shall allow ease of cleaning.</p> <p>RESPONSE: COMPLIANT</p>
11.2.3.5	<p>Doors, hatches and windows and their frames in food processing, handling or storage areas shall be of a material and construction which meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction and windows shall be made of shatterproof glass or similar material.</p> <p>RESPONSE: COMPLIANT</p>
11.2.3.6	<p>Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products.</p> <p>RESPONSE: COMPLIANT</p>
11.2.3.7	<p>Drop ceilings shall be constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.</p> <p>RESPONSE: COMPLIANT</p>
11.2.4	<p>Stairs, Catwalks and Platforms</p> <p>Stairs and walkways leading Whey Powder Dryer platforms and the Mozzarella Vat Area and platforms at the Stretcher, were observed constructed of suitable materials and not directly overhead exposed food product surfaces.</p>
11.2.4.1	<p>Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1).</p> <p>RESPONSE: COMPLIANT</p>
11.2.5	<p>Lightings and Light Fittings</p> <p>Light fittings observed covered with diffusers and appropriate intensity to facilitate inspections of products</p>
11.2.5.1	<p>Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.</p> <p>RESPONSE: COMPLIANT</p>
11.2.5.2	<p>Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program.</p> <p>RESPONSE: COMPLIANT</p>
11.2.5.3	<p>Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination.</p> <p>RESPONSE: COMPLIANT</p>
11.2.6	<p>Inspection / Quality Control Area</p> <p>Product is inspected at designated areas and with sufficient lighting intensity, also includes a dedicated facility located in the Mozzarella Processing Facility, for product testing for weights, and includes a hand wash basin.</p>
11.2.6.1	<p>A suitable area shall be provided for the inspection of the product if required.</p> <p>RESPONSE: COMPLIANT</p>
11.2.6.2	<p>The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to hand washing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.</p> <p>RESPONSE: COMPLIANT</p>

11.2.7 Dust, Insect, and Pest Proofing

Doors and viewing windows in all facilities were observed in good condition. The loading dock area and doors were observed to be adequate and with air curtains.

11.2.7.1 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin and other pests.

RESPONSE: COMPLIANT

11.2.7.2 External personnel access doors shall be provided. They shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against ingress of dust, vermin and other pests.

RESPONSE: COMPLIANT

11.2.7.3 External doors, including overhead dock doors in food handling areas used for product, pedestrian or truck access shall be insect-proofed by at least one or a combination of the following methods: i. A self-closing device; ii. An effective air curtain; iii. An insect-proof screen; iv. An insect-proof annex; v. Adequate sealing around trucks in docking areas.

RESPONSE: COMPLIANT

11.2.7.4 Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison rodenticide bait shall not be used inside ingredient or product storage areas or processing areas.

RESPONSE: COMPLIANT

11.2.8 Ventilation

Positive air pressure in the Mozzarella Processing Facility. Adequate ventilation has been provided in all processing and packing areas.

11.2.8.1 Adequate ventilation shall be provided in enclosed processing and food handling areas.

RESPONSE: COMPLIANT

11.2.8.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.12, to prevent unsanitary conditions.

RESPONSE: COMPLIANT

11.2.8.3 Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features: i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over the cooker(s); ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk; and iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.

RESPONSE: COMPLIANT

11.2.9 Equipment, Utensils, and Protective Clothing

Equipment and utensils are specified prior to purchase to ensure that it is of suitable construction and used in a processing environment. Mechanical equipment are designed stainless steel and food grade rubber for conveyors and designed to facilitate cleaning operations. Equipment were observed well maintained and in good repair. Protective clothing limited to hair nets/beard snoods, aprons and gloves/sleeves.

11.2.9.1 Specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented.

RESPONSE: COMPLIANT

11.2.9.2 Equipment and utensils shall be designed, constructed, installed, operated and maintained to meet any applicable regulatory requirements and not to pose a contamination threat to products.

RESPONSE: COMPLIANT

11.2.9.3 Benches, tables, conveyors, mixers, mincers, graders and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious and free from cracks or crevices.

RESPONSE: COMPLIANT

11.2.9.4 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned as per 11.2.13. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

11.2.9.5 Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system, and to meet local regulatory requirements.

RESPONSE: COMPLIANT

11.2.9.6 Protective clothing shall be manufactured from material that will not contaminate food and is easily cleaned.

RESPONSE: COMPLIANT

11.2.9.7 Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.

RESPONSE: COMPLIANT

11.2.9.8 All equipment, utensils and protective clothing shall be cleaned after use or at a frequency to control contamination and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

11.2.10 Premises and Equipment Maintenance

Maintenance Program (FSP4.6-4), outlines the responsibilities for site QA Manager, Maintenance Staff and Manufacturing and Operations Personnel. The company manages the maintenance program through Mainpac Database, for both reactive and preventative maintenance, with historical data maintained for each asset and building / civil structure. The procedure indicates that maintenance is to be completed outside of processing times wherever possible to minimise potential contamination. Both internal and external maintenance staff are to comply with the GMP requirements. It was sighted PM maintenance conducted for the various assets associated with Mozzarella, Cream Processing, Butter, Whey Powder and Proteins processing facilities eg Spray Dryer Atomiser Full overhaul and rebuild conducted May to June 2020, scheduled for service per 18-24 months, Cheese room Multivac weekly sealing die inspection conducted 20/07/20 to 20/08/19, new service contract 19/06/20 for 3 monthly services, Cold Logic refrigeration service contract next service due September 2020, Separators annual service by FDPI conducted 8-14/05/20. Maintenance activities have not been completed to schedule or not as yet included on PM schedule for a number of priority items eg Mozzarella room Hepa Filter service scheduled 3/04/20 not as yet completed, hand wash station observed in butter room on entry from palletising room not functional since 7/01/20, Whey Powder dryer air intake hepa filters not included on PM schedule, Mozzarella cooker culinary steam filter not included on PM schedule. There is hygiene clearance required after maintenance as was sighted for maintenance work undertaken eg 30/05/20, 23/05/20, 2/05/20 for various intrusive maintenance conducted, tools and parts reconciled, cleaned, sanitised and inspected. Minor NCR Maintenance quality assessment forms have not always routinely completed for intrusive (sanitation clearance, or non intrusive (tools reconciliation), as only 3 forms were completed in May 2020 and nil completed June to July 2020 as demonstration of hygiene clearance. Food Grade lubricants are stored separately and used in all food grade applications eg CRC FG machine oil NSF H1 reg 017392, Moreys Crystal Clear MP2 FG Grease FDA reg 178.3620 compliant. The FG lubricants were stored in segregated FG lubricants cabinet appropriately labelled. The work shop was observed maintained in a clean and tidy state, no accumulation of swarf.

11.2.10.1 The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and implemented in a manner that minimizes the risk of product, packaging or equipment contamination.

RESPONSE: COMPLIANT

11.2.10.2 Routine maintenance of plant and equipment in any food processing, handling or storage area shall be performed according to a maintenance-control schedule and recorded. The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality.

RESPONSE: MINOR

EVIDENCE: Maintenance activities have not been completed to schedule or not as yet included on PM schedule for a number of priority items eg Mozzarella room Hepa Filter service scheduled 3/04/20 not as yet completed, hand wash station observed in butter room on entry from palletising room not functional since 7/01/20, Whey Powder dryer air intake hepa filters not included on PM schedule, Mozzarella cooker culinary steam filter not included on PM schedule.

ROOT CAUSE: PM Task were not put into system as there has been turnover of several Maintenance Managers in the last 12 months. John Dunbar Maintenance Manager at the time of the audit is being moved to another section, Nick Dimasi and Brett Wallace will be handling all maintenance activities going forward including scheduling of critical asset PM tasks.

CORRECTIVE ACTION: PM Task have been undertaken and now scheduled in Mainpac, please see attached documents

VERIFICATION OF CLOSEOUT: Sighted PM tasks now generated by Mainpac for culinary steam injector checks weekly with cleaning, repair, replacement as required. Mozzarella room annual primary filter replacements, cleaning and vacuum, as well as hepa filter inspection and replacement if necessary. Powder plant 3 monthly hepa filter inspection and replacement if required has also now been included on Mainpac. Have scheduled review of other potential critical assets to be included on Mainpac. Review of effectiveness via weekly management review meetings and internal audits

COMPLETION DATE: 09/02/2020 **CLOSEOUT DATE:** 09/04/2020

11.2.10.3 Failures of plant and equipment in any food processing, handling or storage area shall be documented, reviewed and their repair incorporated into the maintenance control schedule.

RESPONSE: COMPLIANT

11.2.10.4 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3.1, 11.3.2, 11.3.3, 11.3.4).

RESPONSE: COMPLIANT

11.2.10.5 All maintenance and other engineering contractors required to work on site shall be trained in the site's food safety and hygiene procedures, or shall be escorted at all times, until their work is completed.

RESPONSE: COMPLIANT

11.2.10.6 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling or storage area.

RESPONSE: COMPLIANT

11.2.10.7 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times.

RESPONSE: COMPLIANT

11.2.10.8 Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: COMPLIANT

11.2.10.9 Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed and a pre-operational inspection conducted prior to the commencement of site operations.

RESPONSE: MINOR

EVIDENCE: Maintenance quality assessment forms have not always routinely completed for intrusive (sanitation clearance, or non intrusive (tools reconciliation), as only 3 forms were completed in May 2020 and nil completed June to July 2020 as demonstration of hygiene clearance

ROOT CAUSE: Maintenance training required. Training completed by the Maintenance Team July to September 2020. Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: Maintenance Training in Maintenance Program requirements and Maintenance Handover Form (was Quality Assessment) see attached

VERIFICATION OF CLOSEOUT: Sighted retraining records of maintenance personnel on requirements of maintenance program FSP 4.6 and Maintenance hand over to production form FSP 6.21 F1 all personnel completed training 13/07/20 to 1/09/20. Will review compliance via GMP and compliance audits. Review of effectiveness via weekly management review meetings and internal audits.

COMPLETION DATE: 09/01/2020 **CLOSEOUT DATE:** 09/04/2020

11.2.10.10 Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product.

RESPONSE: COMPLIANT

11.2.10.11 Paint used in a food handling or contact zone shall be suitable for use, in good condition and shall not be used on any product contact surface.

RESPONSE: NOT APPLICABLE

EVIDENCE: No paint used in food contact zones

11.2.11 Calibration

Calibration Program (FSP4.7-3), scope includes the equipment used to measure, monitor and manufacture product on site to meet regulatory requirements and product safety and quality. A calibration schedule is utilised for all monitoring and measuring equipment critical to product safety and quality, maintained in hard copies. Each equipment is labelled with unique identification code which flows to documentation and each equipment calibrated is also marked with calibration and due date, release when functionality is proven for use in production. All equipment is subject to regular servicing and preventative maintenance and records maintained. The calibration programme is managed by the Quality Manager and Maintenance Engineer whom organises the approved service providers to calibrate site equipment, within the due timeframe (eg Sudel contracted to conduct all critical temperature, pressure and flow instruments. All equipment is maintained based on manufacturers' handbooks / manuals with only authorised personnel permitted to adjust or use as provided by training. Equipment malfunctions are isolated and removed from use and marked the validity or previous inspection and test results is to be assessed, documented and where necessary appropriate recall action taken and records maintained of actions undertaken. Sampled and reviewed as follows: Mettler Toledo : Calibrations Cheese room X Ray ex multi vac (5.5 SS test piece as per CCP), Whey Powder bagging room Metal Detector, calibrated Mettler Toledo, All factory scales calibrated by 2/06/20 eg Mozzarella s/n B829148423. 5kg Test mass B929976258 used for daily verification 24/07/2019. Mettler Toledo Essential Care Agreement Beston Pure Foods Agreement Number 17ST027 02-09-2018 Matrix Process Solutions : Cream Pasteuriser Gas Integrity test 24/07/20 all passed at 300-600kpa, Holding time verification 27/11/18 32.4 seconds. Milk pasteuriser Gas integrity test 24/07/20, all passed at 300-600kpa. Whey Pasteuriser gas integrity Test 24/07/20, external leaks at 300kpa, quotes obtained for gaskets change. FDPI Spares and Maintenance Holding Time Test Main Pasteuriser Flow Rate 35000 -18.18 secs, 38000-17.28 seconds, 39000 16.99 Seconds, 40000L/H- 15.2 seconds, conducted 23-3-2018. Pasteuriser operates at max 39000L/H. Sudel Instruments: Calibration Certificates provided and sighted for all critical control instruments ie Evaporator, Milk and Cream pasteurizers temperature RTD's, Pressure transmitters and flow meters calibrated on 14/5/20 by Sudel. Lactoferrin Cold room temperature gauge (CCP) calibration also undertaken by Sudel 19/12/19

11.2.11.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite programs and food safety plans, or to demonstrate compliance with customer specifications shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

11.2.11.2 Procedures shall be documented and implemented to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state.

RESPONSE: COMPLIANT

- 11.2.11.3** Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment.
RESPONSE: COMPLIANT
- 11.2.11.4** Equipment shall be calibrated against national or international reference standards and methods or to accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.
RESPONSE: COMPLIANT
- 11.2.11.5** Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.
RESPONSE: COMPLIANT
- 11.2.11.6** Calibration records shall be maintained.
RESPONSE: COMPLIANT

11.2.12 Pest Prevention

Pest Control (FSP4.8.4, 27/05/20), details the proactive approach to pest prevention and includes a number of initiatives in place to minimise pest activity and ensure any pest infestation does not present a risk of contamination to products, raw materials or packaging. Poisonous baits are not used in the factory, amenities, only rodent traps and glue boards. The Quality Manager is responsible for overseeing the Pest Control Procedure and ensuring that it is carried out in such a manner as to control vermin/pest on site. The company also undertakes periodic review of the pest control provider, performance of the service person and the efficacy of the program. Corrective action is undertaken, if rodent activity is found in an edible processing area, and if evidence of rodent activity is found in a storage or non-production area, the materials and containers are examined and rodent damage items are rejected and moveable equipment and debris is removed. The program includes the secured and clean storage of raw materials, packaging and finished product to minimise the risk of infestation performed as part of initial receivals process, all incoming goods are inspected for pest infestation. The buildings are pest proof and personnel trained in identification and reporting of pest/evidence of pest on site. Pest prevention program includes interior monitoring devices, such as indicator station and EFks. Pest Incidence Register available, located at the staff lunchroom, with identified issues addressed at the next service and staff are to inform the Quality Manager of any pest activity, of which there has been no reported activity. Pest management at the site is conducted by approved service providers, Adams Pest Control Company . The site has available Adams Pest Control Company Profile and Proposal, signed 12-22-2017, and upgrade to Scope of Works, 8/02/2018 outlining the pest prevention program, included additional 25 Bait Stations, 24 traps and 8 fly stations and includes all internal and external areas, Tanker Bay Area, Cheese Plant, Pack Room, Plastic Store, Butter Plant and maintenance and surrounds. The pest control company attends to the site on a monthly basis, with seasonal highs on fortnightly basis to mitigate pest issues for Spring and Summer seasons. Site Plan Beston Pure Foods 3/04/20, includes external rodent stations, EFk, fly baits, mechanical traps, tin cats, non toxic mouse station and time mist units. Each bait station is numbered and identifiable to the reference bait map with rodent stations observed secured and no pest control chemicals are stored at the site. There is an escalation procedure for low activity 1% to 25%, medium activity 26 to 50% and high activity >51% bait consumed. Service reports were sighted as per Adams Pest Control Service Report (Jervois) ie fortnightly 30/07/20 to 8/01/20 with inclusion of rodent activity levels, % insect activity, baits used and batch numbers. Trending is also completed for all stations, sampled from Jan - Aug 2020, with defined levels of low to high fisc units and external stations, and additional corrective actions undertaken as required. The pest control company and technicians have the current licenses as per Pest Controller's License Number 2018-82315 Government of SA (SA Health), Adams Pest Control Pty Ltd 2020 82315 expire 30/07/21 and Technicians Licenses Full Pest Management Craig Thiele lic 85488 exp 9/05/21, Allan Ramsey lic 84381 exp 4/11/20 . SDSs are available, sampled as per Temprid 10-06-2016, Contrac Blox Dec 2016, Storm 12-02-2016 and Ditrac Dec 2016 Minor NCR Corrective action NCR 55 raised 27/03/20 due to mouse sighting in the cheese room, identified gaps on bottom of loading dock door as potential entry area have not as yet been fixed, (other measures were taken including additional stations within and outside of the facility, and retraining of employees re pest sightings reporting and recording).

- 11.2.12.1** The methods and responsibility for pest prevention shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.
RESPONSE: COMPLIANT
- 11.2.12.2** Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging.
RESPONSE: COMPLIANT
- 11.2.12.3** Food products, raw materials or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.
RESPONSE: COMPLIANT

11.2.12.4 The pest prevention program shall: i. Describe the methods and responsibility for the development, implementation and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods; v. Outline the frequency with which pest status is to be checked; vi. Include on a site map the identification, location, number and type of bait stations set; vii. List the chemicals used (they are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available); viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests.

RESPONSE: MINOR

EVIDENCE: Corrective action NCR 55 raised 27/03/20 due to mouse sighting in the cheese room, identified gaps on bottom of loading dock door as potential entry area have not as yet been fixed, (other measures were taken including additional stations within and outside of the facility, and retraining of employees re pest sightings reporting and recording).

ROOT CAUSE: Despite escalating the NCR 55 the Maintenance Manager John Dunbar did not prioritise the requirement to fix the gaps in the roller doors as requested on several occasions and is subsequently being moved to another section of the business. Nick Dimasi and Brett Wallace will now be responsible for Maintenance job requests completion. Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: Fixed Roller doors 03/09/20

VERIFICATION OF CLOSEOUT: Sighted sealed loading dock door for prevention of pest ingress, continued monitoring via GMP audits, and weekly meetings held to prioritise any food safety, pest control concerns. Responsibility of tasks has now also been reassigned to other personnel managing the maintenance Mainpac system. Review of effectiveness via weekly management review meetings and internal audits

COMPLETION DATE: 09/03/2020 **CLOSEOUT DATE:** 09/04/2020

11.2.12.5 Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present.

RESPONSE: COMPLIANT

11.2.12.6 Records of all pest control applications shall be maintained.

RESPONSE: COMPLIANT

11.2.12.7 Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.4 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces.

RESPONSE: COMPLIANT

11.2.12.8 Pest contractors shall be: i. Licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.3) which will include and maintain a site map indicating the location of bait stations traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and vi. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

11.2.12.9 The site shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that: i. Empty chemical containers are not reused; ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor.

RESPONSE: NOT APPLICABLE

EVIDENCE: NA - The approved pest control service provider handles and disposes of the pest control chemicals and empty containers.

11.2.13 Cleaning and Sanitation

Cleaning and Sanitation Manual (FSP4.5.2.3 issued 26/05/2020), details the responsibility of program is assigned to the site QA Manager and Site Manager. The cleaning is completed as per scheduled requirements and includes the internal facility structure, tools and equipment and processing equipment, frequency of cleaning, chemicals/detergents required and cleaning equipment as defined in work instructions for each equipment. Cleaning verification is completed based on inspections and environmental swabs of surfaces. Sampled SOP Cheese Making Process (FSP5.14.1), End of Cheese Making (FSP5.14.2), Cooker Stretcher Operation and Cleaning (FSP5.14.7) and Salter Operation and Cleaning (FSP5.14.9), Whey Powder Evap CIP SOP WH 003, Butter making cleaning SOP CRE/BUT/011, CIP of Cream Pasteuriser SOP CRE/022, Protein plant LF Eluate tank CIP SOP BPF/PP/004. CIP Validation for Cheese Room - Integra Cheese Room CIP Commissioning Validation 13/02/18 SOP-CLE-001-1 Cleaning Procedure by Area or Item (include post maintenance cleaning, chemical, frequency, contact times, temperature and concentrations). Also documented in Cleaning in Place Standard (FSP4.5.3.2 24/04/19), which includes requirements for design, CIP validation and verification, dismantling and dead spots, and reference to specific cleaning SOP's. Sampled and reviewed: Pasteurizer Room CIP and Inspection Sheet (FSP5.13.2 F5) / Cheese Manufacture CIP Control (FSP5.14.1 F4), Fresh Cream CIP Control (Form3/CRE/016), Mozzarella House Keeping Record (FSP5.14 F1) ATP Surface Testing, Milk Treatment House Keeping Record (FSP5.13.2 F6), Form 2 Housekeeping Butter Plant (Form2/CRE/QUA/002), Powder Plant CIP Log Sheet (Form2/WHP/004), sighted records of clean and ATP swabbing for dates 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19. GMP audits undertaken bi monthly and includes all areas including cheese plant, protein plant, maintenance, butter and cream plant, whey powder plant, cool rooms, amenities areas and includes review of walls, floors, ceilings, drains, foot baths, lighting, work benches, pest activity, cleanliness and hygiene, foreign objects, glass, ceramics and hard plastics, PPE, external areas. Sighted undertaken in the various areas 3-29/06/20,15-28/04/20, 19-28/02/20 with detailed corrective action requirements noted and work orders raised. Verification of effectiveness of the cleaning and sanitation program is managed through the Environmental Monitoring Procedure testing for Listeria and Environmental swabs SOP /LAB/GEN/009, includes swabbing program, corrective action process, recleaning, reswabbing and NCR reporting and investigation. Water testing is conducted monthly by a NATA lab - ALS (Coliforms & E. Coli) Records sighted 16/07/20, 19/06/20, 21/05/20, 21/04/20, 17/03/20, 26/02/20, 21/01/20 tested main water tank, and samples in powder plant, protein plant, butter plant, milk treatment, mozzarella plant (3) all ND/100ml. Air Testing (plates) testing for yeast and mould, per 2 weeks, as well as yeast, mould and Enterobacteriaceae swabs, with records sighted 23/07/20 to 7/01/20 results appear satisfactory. Integra Water Treatment Solutions Service Report 21/07/2020 includes checks for chemical storage and SDS's, chemical handling and equipment performance, plant and equipment condition, titration for CIP, tanker bay, milk pasteuriser, CIP A (Milk Silos), CIP B (Cheese), butter plant, powder plant, footbaths, foamers, recommendations and corrective action comments recorded. All cleaning equipment is colour coded, red equipment for floors, black for drains, yellow external contact surfaces and blue for contact surfaces.

11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Methods used to confirm the correct concentrations of detergents and sanitizers, and vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.2.13.2 Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing.

RESPONSE: COMPLIANT

11.2.13.3 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils shall be provided as required.

RESPONSE: COMPLIANT

11.2.13.4 Cleaning in place (CIP) systems where used shall not pose a chemical contamination risk to raw materials, ingredients or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored and recorded (e.g., chemical and concentration used, contact time and temperature). CIP equipment including spray balls shall be maintained and modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.

RESPONSE: COMPLIANT

11.2.13.5 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities and sanitary facilities and other essential areas are clean before the commencement of production. Pre-operational inspections shall be conducted by qualified personnel.

RESPONSE: COMPLIANT

11.2.13.6 Staff amenities, sanitary facilities and other essential areas shall be inspected by qualified personnel to ensure the areas are clean, at a defined frequency.

RESPONSE: COMPLIANT

<p>11.2.13.7</p>	<p>The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.</p> <p>RESPONSE: COMPLIANT</p>
<p>11.2.13.8</p>	<p>Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use; ii. An inventory of all chemicals purchased and used shall be maintained; iii. Detergents and sanitizers are stored as outlined in element 11.6.4; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v. Only trained staff handles sanitizers and detergents.</p> <p>RESPONSE: COMPLIANT</p>
<p>11.2.13.9</p>	<p>Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.</p> <p>RESPONSE: COMPLIANT</p>
<p>11.2.13.10</p>	<p>The site shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor.</p> <p>RESPONSE: COMPLIANT</p>
<p>11.2.13.11</p>	<p>A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.</p> <p>RESPONSE: COMPLIANT</p>
<p>11.3.1 Personnel</p> <p>Documented as part of the GMP Requirements (FSP4.3.1 -7 28/06/19), for red zone (High Hygiene), yellow zone (medium hygiene zone), green (low risk hygiene zone), details requirements for Employees, Staff and Visitors, pertaining to badges, jewellery, smoking, hair, personal hygiene, protective clothing and employee health. There are designated areas for smoking, eating and drinking, with change rooms and lockers available for staff. Staff were observed in compliance with the GMP requirements during the audit, with clean uniforms, red hair nets and beard snoods for high hygiene areas and white hair nets for low risk areas, white captive boots, coloured gloves and opaque arm sleeves. Comfort areas are provided for staff for lunch / tea breaks, smoking and toilets. Issues associated with illness or injury, staff are to inform their area supervisor.</p>	
<p>11.3.1.1</p>	<p>Personnel who are carriers or are known to have been carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed.</p> <p>RESPONSE: COMPLIANT</p>
<p>11.3.1.2</p>	<p>The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids from open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury which causes spillage of bodily fluid, a properly trained employee shall ensure that all affected areas including handling and processing areas have been adequately cleaned and that all materials and products have been quarantined and disposed of.</p> <p>RESPONSE: COMPLIANT</p>
<p>11.3.1.3</p>	<p>Personnel with exposed cuts, sores or lesions shall not engage in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing.</p> <p>RESPONSE: COMPLIANT</p>
<p>11.3.1.4</p>	<p>Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging or equipment.</p> <p>RESPONSE: COMPLIANT</p>

11.3.2 Hand Washing

Observed during the audit, hand wash basins were located in the red line room (changeover area), and designated areas in the manufacturing facility, with sensor operated taps, stainless steel basins and ample supplies of single use disposable towels, soap and sanitiser and hot water for hand washing. The GMP Requirements (FSP4.3.1 -9), outlines staff personal hygiene requirements for washing of hands and use of gloves, in line with best practice.

11.3.2.1 Hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

RESPONSE: COMPLIANT

11.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as a minimum supplied with: i. A potable water supply at an appropriate temperature; ii. Liquid soap contained within a fixed dispenser; iii. Paper towels in a hands-free cleanable dispenser; and iv. A means of containing used paper towels.

RESPONSE: COMPLIANT

11.3.2.3 The following additional facilities shall be provided in high risk areas: i. Hands free operated taps; and ii. Hand sanitizers.

RESPONSE: COMPLIANT

11.3.2.4 A sign instructing people to wash their hands, and in appropriate languages, shall be provided in a prominent position.

RESPONSE: COMPLIANT

11.3.2.5 Personnel shall have clean hands and hands shall be washed by all personnel, including staff, contractors and visitors: i. On entering food handling or processing areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating or drinking; and v. After handling wash down hoses, dropped product or contaminated material.

RESPONSE: COMPLIANT

11.3.2.6 When gloves are used, personnel shall maintain the hand washing practices outlined above.

RESPONSE: COMPLIANT

11.3.3 Clothing

Documented as part of the GMP Requirements (FSP4.3.1 -9), details for Employees, Staff and Visitors, requirements pertaining to badges, jewellery, smoking, hair, personal hygiene, protective clothing and employee health. There are designated areas for smoking, eating and drinking, with change rooms and lockers available for staff. Staff were observed in compliance with the GMP requirements during the audit. Non-disposable aprons were observed in good condition, with sanitisation processes in place at the end of day's production, and captive white boots observed stored in the red line room only. Clothing is laundered by an approved service provider, AlSCO Pty Ltd, whom visit the site twice weekly to remove soiled linen and replenish with clean laundered uniforms.

11.3.3.1 The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food and food contact surfaces from unintentional microbiological or physical contamination.

RESPONSE: COMPLIANT

11.3.3.2 Clothing worn by staff engaged in handling food shall be maintained, stored, laundered and worn so as not to present a contamination risk to products.

RESPONSE: COMPLIANT

11.3.3.3 Clothing, including shoes, shall be clean at the commencement of each shift and maintained in a serviceable condition.

RESPONSE: COMPLIANT

11.3.3.4 Excessively soiled uniforms shall be changed or replaced where they present a product contamination risk.

RESPONSE: COMPLIANT

11.3.3.5 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or designated sealed containers in personnel lockers and not on packaging, ingredients, product or equipment.

RESPONSE: COMPLIANT

11.3.4 Jewelry and Personal Effects

Documented as part of the GMP Requirements (FSP4.3.1 -9), for Employees, Staff and Visitors, there are requirements pertaining to badges, jewellery, smoking, hair, personal hygiene, protective clothing and employee health. There are designated areas for smoking, eating and drinking, with change rooms and lockers available for staff. Staff were observed in compliance with the GMP requirements during the audit, with exception noted for medic alert jewellery, with a copy of physician's authorisation held in medical files. There are currently no staff members with medic alert jewellery.

- 11.3.4.1** Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and prescribed medical alert bracelets can be permitted, however the site will need to consider their customer requirements and the applicable food legislation.

RESPONSE: COMPLIANT

11.3.5 Visitors

Documented as part of the GMP Requirements (FSP4.3.1-9), for Employees, Staff and Visitors, there are requirements pertaining to badges, jewellery, smoking, hair, personal hygiene, protective clothing and employee health. There are designated areas for smoking, eating and drinking, with change rooms and lockers available for staff. Visitors and contractors are to comply with the GMP requirements of the site, with detailed inductions in place, as per Category 3 Induction for Visitors and Contractor Procedure (MBMS028).

- 11.3.5.1** All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area.

RESPONSE: COMPLIANT

- 11.3.5.2** All visitors shall be required to remove jewelry and other loose objects.

RESPONSE: COMPLIANT

- 11.3.5.3** Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed.

RESPONSE: COMPLIANT

- 11.3.5.4** Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all hand washing and personnel practice requirements.

RESPONSE: COMPLIANT

- 11.3.5.5** All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing or handling areas or shall be escorted at all times in food processing, handling and storage areas.

RESPONSE: COMPLIANT

11.3.6 Staff Amenities

Staff amenities were observed in good condition, with lighting and ventilation available.

- 11.3.6.1** Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and processing of product.

RESPONSE: COMPLIANT

11.3.7 Change Rooms

Documented as part of the GMP Requirements (FSP4.3.1-9), for Employees, Staff and Visitors, there are requirements pertaining to badges, jewellery, smoking, hair, personal hygiene, protective clothing and employee health. There are designated areas for smoking, eating and drinking, with change rooms and lockers available for staff.

- 11.3.7.1** Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required.

RESPONSE: COMPLIANT

11.3.7.2	<p>Change rooms shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no high risk foods manufactured.</p>
11.3.7.3	<p>Provision shall be made for staff to store their street clothing and personal items separate from food contact zones and food and packaging storage areas.</p> <p>RESPONSE: COMPLIANT</p>
11.3.7.4	<p>Where required, a sufficient number of showers shall be provided for use by staff.</p> <p>RESPONSE: COMPLIANT</p>
11.3.8	<p>Laundry</p> <p>Staff are provided with smocks and pants, with high visibility strip, which when soiled as laundered by approved service provider, AlSCO Pty Ltd, HACCP Program and GMP Certificate of Registration 18022021 Expiry 7/10/2021. Bestons Food Safety Questionnaire completed 21/05/19 approved supplier 25/05/19 There is a laundry bag in each change room for soiled linen and clean uniforms are replaced twice weekly. Visitors are provided with single use disposable coats, Velcro fastenings, and disposed when used.</p>
11.3.8.1	<p>Provision shall be made for the laundering and storage of clothing worn by staff engaged in high risk processes and for staff engaged in processing operations in which clothing can be heavily soiled.</p> <p>RESPONSE: COMPLIANT</p>
11.3.9	<p>Sanitary Facilities</p> <p>Toilet facilities are provided at the site and away from manufacturing facility with hand wash basins with sensor operated taps provided inside the toilet facilities. Sanitary drainage are not connected to any other drains as per regulations. Staff are to comply with the documented GMP policies for hand washing.</p>
11.3.9.1	<p>Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and vi. Kept clean and tidy.</p> <p>RESPONSE: COMPLIANT</p>
11.3.9.2	<p>Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance in regulations.</p> <p>RESPONSE: COMPLIANT</p>
11.3.9.3	<p>Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.2.</p> <p>RESPONSE: COMPLIANT</p>
11.3.10	<p>Lunch Rooms</p> <p>Lunchrooms are made available and separate to the manufacturing facility. Lunchrooms observed to be well ventilated, with supplies of tables, chairs, cooking and heating and cooling facilities available.</p>
11.3.10.1	<p>Separate lunch-room facilities shall be provided away from a food contact/handling zone.</p> <p>RESPONSE: COMPLIANT</p>
11.3.10.2	<p>Lunch-room facilities shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities enabling them to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.</p> <p>RESPONSE: COMPLIANT</p>

11.3.10.3 Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for introduction of contamination including pests to the site.

RESPONSE: COMPLIANT

11.3.10.4 Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in lunch-rooms, at lunch-room exits and in outside eating areas if applicable.

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

Generally Good compliance to GMP policies and procedures observed during the audit for personnel observed in the processing and packing facility. No sensory evaluations are completed in production areas. Wash down hoses were observed stored on hooks provided.

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2; vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food; and vii. Hair restraints are used where product is exposed.

RESPONSE: MINOR

EVIDENCE: Sliding door accessing cheese room via salt and culture storage room provides no sanitary entry controls as per other entries into cheese room eg main entry via cross over bench and access passage way from pack room has hand wash and foot bath on entry.

ROOT CAUSE: Redline areas were being crossed with insufficient sanitation controls. Install floor foamers to control inwards movements and dedicate trolley jack to the mozzarella room to prevent crossover. Place footbath in testing room. Tool box requirement of forklift to stop at the rapid raise door to prevent crossover and once ingredients and packing for the day are supplied to the day room, the day room door is closed to prevent personnel entry and access is monitored by the area Team Leader. The day room door was unable to be locked due to emergency egress issues. Review that corrective actions are effective at weekly management meeting under external audit results

CORRECTIVE ACTION: Automated door way floor foamers (ordered and arrived at site) to be fitted in the coming days at the x-ray, day room and main redline room entry. A dedicated mozzarella room trolley jack has been designated to move plastic pallets in the mozz room to prevent crossover. A foot bath has been placed in the testing room and hand wash station in the testing room is being used on entry. The forklift is now stopping at the rapid raise door as to not cross over from cold rooms to crate packing and day room areas. Once ingredients and packaging for the day are supplied to the day room (store before mozzarella room) the door is closed to prevent to prevent any personnel entry and is monitored by the area Team Leader

VERIFICATION OF CLOSEOUT: Sanitation controls implemented as sighted -foamers purchased for floor entry from day room, main entry and X ray entry areas, trolley jack now dedicated to move plastic pallets into the mozzarella room, foot bath in test room entry and hand wash basin also used on entry, as well as locked entry to day store to prevent any entry to mozzarella room via this entry. Management Review meetings conducted weekly inclusive of review of effectiveness of sanitation processes implemented.

COMPLETION DATE: 09/03/2020 **CLOSEOUT DATE:** 09/04/2020

11.4.1.2 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the site shall implement proper controls and procedures to ensure: i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel only; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; and v. Equipment used for sensory evaluations is sanitized, maintained and stored separate from processing equipment.

RESPONSE: NOT APPLICABLE

EVIDENCE: No sensory evaluations undertaken in production zones

11.4.1.3 All wash down hoses shall be stored on hose racks after use and not left on the floor.

RESPONSE: COMPLIANT

11.5.1 Water Supply

Treated potable water used for whole of site as well as RO water for production purposes eg rennet addition. Documented as per SOP Water Testing Factory and External - Jervois (FSP4.16.2.1), outlines the water sampling points, the process to collect the samples, and testing parameters for E Coli and Coliforms. Sampled and reviewed Main Water Tank, Powder Plant Handwash Station, Butter Plant Handwash Station, Butter Plant CIP Rinse Tank, Mozzarella Redline Room Handwash Station, White Conveyor Tap Mozzarella, Mozzarella Vat Hose for Water testing is conducted monthly by a NATA lab - ALS (Coliforms & E. Coli) Records sighted 16/07/20, 19/06/20, 21/05/20, 21/04/20, 17/03/20, 26/02/20, 21/01/20 all ND/100ml.

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment.

RESPONSE: COMPLIANT

11.5.1.2 Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

11.5.1.3 The delivery of water within the premises shall ensure potable water is not contaminated.

RESPONSE: COMPLIANT

11.5.1.4 The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent back flow or back siphonage.

RESPONSE: COMPLIANT

11.5.1.5 Where water is stored on site, storage facilities shall be adequately designed, constructed and maintained to prevent contamination.

RESPONSE: COMPLIANT

11.5.2 Water Treatment

River water is drawn from the Murray River, 89000KL/yr licensed granted by the Department of Environment, Water and Natural Resources, approval number 175387. The river water drawn goes to the water treatment plant, tank and inoculant added and 4 celled settling tank, gravel filtration and automated chlorine dosing system, and passed through UV light prior to use in the facility. The water is then stored in the tank with mains water and prior to entry into the mozzarella plant, goes through pipe works with 5 micron filter. Sampled and reviewed Water Treatment Log Sheet (Form1/Man/Water/002), completed by trained maintenance staff and >1ppm of Free Chlorine, UV light operating for January to August 2020 compliant.

11.5.2.1 Water treatment methods, equipment and materials, if required, shall be designed, installed and operated to ensure water receives an effective treatment.

RESPONSE: COMPLIANT

11.5.2.2 Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

RESPONSE: COMPLIANT

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the indicators specified.

RESPONSE: COMPLIANT

11.5.2.4 Water used in as an ingredient in processing, or in cleaning and sanitizing equipment, shall be tested, and if required, treated to maintain potability (refer to 11.5.2.1).

RESPONSE: COMPLIANT

11.5.3 Ice Supply

NA - No ice used in the process.

11.5.3.1 Ice provided for use during processing operations or as a processing aid or an ingredient shall comply with 11.5.4.1.

RESPONSE: NOT APPLICABLE

EVIDENCE: NA - No ice used in the process.

11.5.3.2 Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution.

RESPONSE: NOT APPLICABLE

EVIDENCE: NA - No ice used in the process.

11.5.4 Water Quality

Documented as per SOP Water Testing Factory and External - Jervois (FSP4.16.2.1), outlines the water sampling points, the process to collect the samples, and testing parameters for E Coli and Coliforms. Sampled and reviewed Main Water Tank, Powder Plant Handwash Station, Butter Plant Handwash Station, Butter Plant CIP Rinse Tank, Mozzarella Redline Room Handwash Station, White Conveyor Tap Mozzarella, Mozzarella Vat Hose for Water testing is conducted monthly by a NATA lab - ALS (Coliforms & E. Coli) Records sighted 16/07/20, 19/06/20, 21/05/20, 21/04/20, 17/03/20, 26/02/20, 21/01/20 all ND/100ml.

11.5.4.1 Water shall comply with local, national or internationally recognized potable water microbiological and quality standards as required when used for: i. washing, thawing and treating food; ii. handwashing iii. to convey food; iv. as an ingredient or food processing aid; v. cleaning food contact surfaces and equipment; vi. the manufacture of ice; or vii. the manufacture of steam that will come into contact with food or used to heat water that will come in contact with food.

RESPONSE: COMPLIANT

11.5.4.2 Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning, or from within the site. The frequency of analysis shall be risk-based, and at a minimum annually.

RESPONSE: COMPLIANT

11.5.4.3 Water and ice shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

11.5.5 The Quality of Air and Other Gasses

Compressed air systems used are filtered air into the site. Air Testing (plates). Records sighted Jan to July 2020. No issues noted.

11.5.5.1 Compressed air or other gases (e.g. nitrogen, carbon dioxide) that contacts food or food contact surfaces shall be clean and present no risk to food safety.

RESPONSE: COMPLIANT

11.5.5.2 Compressed air systems, and systems used to store or dispense other gases used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

RESPONSE: COMPLIANT

11.6.1 Storage and Handling of Goods

FIFO principles applied for raw materials, packaging, chemicals and product. All products observed in cold store and dry store observed with identification and within code.

11.6.1.1 The site shall document and implement an effective storage plan that allows for the safe, hygienic storage of raw materials (i.e. frozen, chilled, and ambient), ingredients, packaging materials, equipment, and chemicals.

RESPONSE: COMPLIANT

11.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented.

RESPONSE: COMPLIANT

11.6.1.3 Procedures shall be in place to ensure that all ingredients, materials, work-in-progress, rework, and finished product are utilized within their designated shelf-life.

RESPONSE: COMPLIANT

11.6.1.4	<p>Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers.</p> <p>RESPONSE: COMPLIANT</p>
11.6.1.5	<p>Where goods described in 11.6.2 to 11.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No temporary or overflow conditions</p>
11.6.1.6	<p>Records shall be available to validate alternate or temporary control measures for the storage of raw materials, ingredients, packaging materials, equipment, chemicals, or finished products.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: No temporary or overflow conditions</p>
11.6.2	<p>Cold Storage, Freezing and Chilling of Foods</p> <p>Cold stores have been designed to effectively maintained product at the required temperatures. Cold stores were observed well maintained and clean. Loading and unloading of product is conducted under cover to protect products from damage. Storage of Lactoferrin prior to freeze drying is a CCP requirement and records sighted 4/08/20 to 2/01/20 compliant <4C</p>
11.6.2.1	<p>The site shall provide confirmation of the effective operational performance of freezing, chilling and cold storage facilities. Chillers, blast freezers and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of food and easily accessible for inspection and cleaning.</p> <p>RESPONSE: COMPLIANT</p>
11.6.2.2	<p>Sufficient refrigeration capacity shall be available to chill, freeze, store chilled or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.</p> <p>RESPONSE: COMPLIANT</p>
11.6.2.3	<p>Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.</p> <p>RESPONSE: COMPLIANT</p>
11.6.2.4	<p>Freezing, chilling and cold storage rooms shall be fitted with temperature monitoring equipment and located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible.</p> <p>RESPONSE: COMPLIANT</p>
11.6.2.5	<p>Loading and unloading docks shall be designed to protect the product during loading and unloading.</p> <p>RESPONSE: COMPLIANT</p>
11.6.3	<p>Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods</p> <p>Dry and cold storage facilities observed clean and tidy during the audit. Storage areas segregated via salt storage room, rennet storage in new cold room, cultures in designated freezers -45C, packaging stored in designated racking in enclosed hygienic storage areas.</p>
11.6.3.1	<p>Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration.</p> <p>RESPONSE: COMPLIANT</p>
11.6.3.2	<p>Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.</p> <p>RESPONSE: COMPLIANT</p>
11.6.3.3	<p>Vehicles used in food contact, handling or processing zones or in cold storage rooms shall be designed and operated so as not to present a food safety hazard.</p> <p>RESPONSE: COMPLIANT</p>

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Chemicals observed stored in segregated and designated facilities and secured with bulk chemicals stored in a caged area and locked, accessible to designated maintenance staff and with full cleaning operations completed at the end of day's production. SDS's maintained for chemicals used eg Proxitane 1/06/20, Reflux A230, 8/03/2016,--Dual Quat August 2016, ChlorKleena 31/05/16, CIP 600 31/05/16, CIP 300 30/06/17.

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to staff, product, packaging, product handling equipment or areas in which the product is handled, stored or transported.

RESPONSE: COMPLIANT

11.6.4.2 Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

RESPONSE: COMPLIANT

11.6.4.3 Daily supplies of chemicals used for continuous sanitizing of water or as a processing aid, or for emergency cleaning of food processing equipment or surfaces in food contact zones, may be stored within or in close proximity to a processing area provided that access to the chemical storage facility is restricted to authorized personnel.

RESPONSE: COMPLIANT

11.6.4.4 Pesticides, rodenticides, fumigants and insecticides shall be stored separate from sanitizers and detergents. All chemicals shall be stored in their original containers, or in clearly labelled and suitable secondary containers if allowed by applicable legislation.

RESPONSE: NOT APPLICABLE

EVIDENCE: No pest control chemicals stored on site, removed by the pest controller after service.

11.6.4.5 Hazardous chemical and toxic substance storage facilities shall: i. Be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals; ii. Be adequately ventilated; iii. Be provided with appropriate signage indicating the area is a hazardous storage area; iv. Be secure and lockable to restrict access only to those personnel with formal training in the handling and use of hazardous chemicals and toxic substances; v. Have instructions on the safe handling of hazardous chemicals and toxic substances readily accessible to staff; vi. Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility; vii. Have suitable first aid equipment and protective clothing available close to the storage area; viii. In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and ix. Be equipped with spillage kits and cleaning equipment.

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

Documented protocols are in place to ensure that loading, transport and unloading and storage maintains product integrity throughout via enclosed loading and unloading docks.

11.6.5.1 The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported and unloaded under conditions suitable to prevent cross-contamination.

RESPONSE: COMPLIANT

11.6.6 Loading

Loading and unloading and transport is completed as per documented requirements and observed during the audit at Jervois via sealed loading docks. Transport is inspected prior to loading and confirmed vehicle secured, clean free from extraneous matter, no odours, taints, pests, vehicle temperature <4C, product temperature <4C as sighted Eades Transport via Form FSP 4.11 F2, 29/07/20 to 9/04/20.

11.6.6.1 Vehicles (e.g. trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product.

RESPONSE: COMPLIANT

11.6.6.2 Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity during loading and transport.

RESPONSE: COMPLIANT

11.6.6.3 Vehicles (e.g. trucks/vans/containers) shall be secured from tampering using a seal or other agreed upon and acceptable device or system.

RESPONSE: COMPLIANT

11.6.7 Transport

The transport is undertaken by third party service providers and service specifications available outlining requirements for refrigeration, service and in the event of breakdowns. Communicated via sister site the required batches for loading and quantity, the temperature of the truck is checked via digital display to ensure that correct temperature and clean and hygienic, prior to loading. Transport is inspected prior to loading and confirmed vehicle secured, clean free from extraneous matter, no odours, taints, pests, vehicle temperature <4C, product temperature <4C as sighted Eades Transport via Form FSP 4.11 F2, 29/07/20 to 9/04/20.

11.6.7.1 Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and product temperatures recorded at regular intervals during loading as appropriate.

RESPONSE: COMPLIANT

11.6.7.2 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature at regular intervals during transit.

RESPONSE: COMPLIANT

11.6.8 Unloading

Loading and unloading and transport is completed as per documented requirements and observed during the audit at Jervois.

11.6.8.1 Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

RESPONSE: COMPLIANT

11.6.8.2 Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity.

RESPONSE: COMPLIANT

11.7.1 Process Flow

The process flow is from milk receivals and ingredient receivals, through to silo storage, and into pasteuriser processing room and into mozzarella processing facility, packing and cold store, through to loading and despatch of finished product. There is as high hygiene entry into the whey powder room, as well as ppe and clothing requirements in the pasteurised cream processing room. The flow of personnel is managed through training and staff movement policies.

11.7.1.1 The process flow shall be designed to prevent cross-contamination and organized so there is a continuous flow of product through the process. The flow of personnel shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

Dry ingredients and packaging were observed stored in designated areas i.e. enclosed packing store adjacent to cheese packing room, as well as the dry powders store all away from frozen and chilled raw materials.

11.7.2.1 Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross-contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross-contamination.

RESPONSE: COMPLIANT

11.7.3 Thawing of Food

NA - There is no thawing of food undertaken at the site.

<p>11.7.3.1</p>	<p>Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There is no thawing of food undertaken at the site.</p>
<p>11.7.3.2</p>	<p>Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature do not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There is no thawing of food undertaken at the site.</p>
<p>11.7.3.3</p>	<p>Air thawing facilities shall be designed to thaw food under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There is no thawing of food undertaken at the site.</p>
<p>11.7.3.4</p>	<p>Provision is to be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There is no thawing of food undertaken at the site.</p>
<p>11.7.4 High Risk Processes</p> <p>NA - There are no high risk foods manufactured at the facility.</p>	
<p>11.7.4.1</p>	<p>The processing of high risk food shall be conducted under controlled conditions such that sensitive areas in which high risk food has undergone a “kill” step, a “food safety intervention” or is subject to post process handling, are protected/segreated from other processes, raw materials or staff who handle raw materials to ensure cross-contamination is minimized.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no high risk foods manufactured at the facility.</p>
<p>11.7.4.2</p>	<p>Areas in which high risk processes are conducted shall only be serviced by staff dedicated to that function.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no high risk foods manufactured at the facility.</p>
<p>11.7.4.3</p>	<p>Staff access points shall be located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no high risk foods manufactured at the facility.</p>
<p>11.7.4.4</p>	<p>Staff engaged in high risk areas shall change into clean clothing or temporary protective outerwear when entering high risk areas.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no high risk foods manufactured at the facility.</p>
<p>11.7.4.5</p>	<p>Product transfer points shall be located and designed so as not to compromise high risk segregation and to minimize the risk of cross-contamination.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no high risk foods manufactured at the facility.</p>

11.7.5 Control of Foreign Matter Contamination

Foreign object bag audits are undertaken monthly as sighted in Mozzarella areas 27/07/2020, 15/06/20, 20/05/20, 14/04/20, 19/03/20, 18/02/20, 29/01/20 with items found individually documented and reported back via management meetings as well as daily meetings as sighted meetings held 20/03/20, 21/01/20, 1-4 items found per audit in 2020. Documented as Foreign Matter Prevention (FSP4.3.1.5) details the metal control policies in place inclusive of knife integrity checks (monitoring record i.e. Cooker Stretcher and Prat Wheel Checklist), wood controls with limited use of wooden pallets only in the enclosed product areas, glass and brittle plastics, other plastics, cardboard, paper, thread, stationary and corrective actions as the need arise. Equipment Breakage or Loss Policy (FSP4.3.1), includes policies for loose metal or non-metal equipment or tools, forming part of the equipment and inspected as part of the GMP Housekeeping Audit to ensure that items remains intact. The procedure details the protocols to be followed for equipment breakages or loss, with the notification of the Production Manager and Quality Manager, whom will inspect the affected area and isolation of products and collection of fragments and corrective action undertaken. Permitted items registers are maintained in each area as was sighted Multivac area allowable items registered and confirmed via prestart checklist 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19. Minor NCR: Tools observed (3 Allen keys) observed adjacent to the mozzarella X ray machine not controlled via the permitted items register GMP audits undertaken bi monthly and includes all areas including cheese plant, protein plant, maintenance, butter and cream plant, whey powder plant, cool rooms, amenities areas and includes review of walls, floors, ceilings, drains, foot baths, lighting, work benches, pest activity, cleanliness and hygiene, foreign objects, glass, ceramics and hard plastics, PPE, external areas. Sighted undertaken in the various areas 3-29/06/20,15-28/04/20, 19-28/02/20 with detailed corrective action requirements noted and work orders raised.

11.7.5.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff.

RESPONSE: MINOR

EVIDENCE: Tools observed (3 Allen keys) observed adjacent to the mozzarella X ray machine not controlled via the permitted items register

ROOT CAUSE: Allen keys required were not captured on the form. Update form to include allen keys. Allen Keys were added to the form 10/08/20 Review that corrective actions are effective at weekly management meeting under external audit results.

CORRECTIVE ACTION: The allen keys are required for adjusting the labelling machine at the Multivac and have been added to the Multivac Area Form 10/08/20

VERIFICATION OF CLOSEOUT: Sighted Allen Keys added to the Brine Tank and Multivac checklist FSP 5.14 F5-6 includes operator double sign off. Review of compliance to checklist also via GMP and FO bag audits, as well as Management Review of effectiveness. .

COMPLETION DATE: 08/10/2020 **CLOSEOUT DATE:** 09/04/2020

11.7.5.2 Inspections shall be performed to ensure plant and equipment remain in good condition, equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

11.7.5.3 All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location.

RESPONSE: COMPLIANT

11.7.5.4 Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing /contact zones.

RESPONSE: COMPLIANT

11.7.5.5 Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register.

RESPONSE: COMPLIANT

11.7.5.6 Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

RESPONSE: COMPLIANT

11.7.5.7 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.11.7.5.8 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

11.7.5.8 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

11.7.5.9 Knives and cutting instruments used in processing and packaging operations shall be controlled and kept clean and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

RESPONSE: COMPLIANT

11.7.6 Detection of Foreign Objects

Foreign Matter Detection (FSP4.3.1.6), outlines the foreign object detection parameters, validation of the units undertaken by an approved service provider, verification of the units based on risk assessment and corrective actions to be taken, use of test packs and memory tests. The verification of the X-Ray detector is completed at the start, middle and end of production using stainless steel test piece at 5.5mm AISI316. The fail safe systems on the X-Ray unit, includes a reject confirmation sensor, full bin, door lock and reject arm system into a bulk bin. In the event that the detector unit fails, the line must be stopped and review of the last confirmed successful test. The X-Ray detector is program is accessible only to key staff with defined access levels, with one administration rights, currently assigned to the site QA Manager. The detector also includes photos of each assessed product and can be readily retrieved for is review purposes and /or investigation. Rejections and investigations are recorded on the requisite forms as per HACCP Plans. X ray machine operation is described in FSP 5.14.13 and includes operations start up/shutdown, change of product type, sensitivity checks procedure (middle of top of block), rejected blocks procedure retest, supervisor notification, removal of foreign object for investigation, and also recording of reason for false positives. It was sighted records of X ray testing undertaken as per CCP requirements 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19, start, middle and end of production, compliant to CCP procedure requirements. Personnel have been trained in X Ray detector CCP requirements including personnel observed testing the metal detector at time of audit.

11.7.6.1 The responsibility, methods and frequency for monitoring, maintaining, calibrating and using screens, sieves, filters or other technologies to remove or detect foreign matter shall be documented and implemented.

RESPONSE: COMPLIANT

11.7.6.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

RESPONSE: COMPLIANT

11.7.6.3 Records shall be maintained of the inspection of foreign object detection devices and of any products rejected or removed by them. Records shall include any corrective actions resulting from the inspections.

RESPONSE: COMPLIANT

11.7.7 Managing Foreign Matter Contamination Incidents

Foreign Matter Detection (FSP4.3.1.6), outlines the foreign object detection parameters, validation of the units undertaken by an approved service provider, verification of the units based on risk assessment and corrective actions to be taken, use of test packs and memory tests. The verification of the X-Ray detector is completed at the start, middle and end of production using stainless steel test piece at 5.5mm AISI316. The fail safe systems on the X-Ray unit, includes a reject confirmation sensor, full bin, door lock and reject arm system into a bulk bin. In the event that the detector unit fails, the line must be stopped and review of the last confirmed successful test. The X-Ray detector is program is accessible only to key staff with defined access levels, with one administration rights, currently assigned to the site QA Manager. The detector also includes photos of each assessed product and can be readily retrieved for is review purposes and /or investigation. Rejections and investigations are recorded on the requisite forms as per HACCP Plans. X ray machine operation is described in FSP 5.14.13 and includes operations start up/shutdown, change of product type, sensitivity checks procedure (middle of top of block), rejected blocks procedure retest, supervisor notification, removal of foreign object for investigation, and also recording of reason for false positives. It was sighted records of X ray testing undertaken as per CCP requirements 3/08/20, 28/07/20, 9/06/20, 23/04/20, 25/02/20, 18/12/19 start, middle and end of production, compliant to CCP procedure requirements. Personnel have been trained in X Ray detector CCP requirements including personnel observed testing the metal detector at time of audit. Records reviewed for product rejects were false positives only and reasons recorded. Whey Powder plant metal detection is also routinely tested as per procedure SOP/WHP/PAC/15, and was sighted testing on day of audit 5/08/20 as well as records 4/08/20, 8/07/20, 29/05/20, 13/03/20, 20/01/20 compliant. Documented as per Equipment Breakage or Loss Policy (FSP4.3.1), includes policies for loose metal or non-metal equipment or tools, forming part of the equipment and inspected as part of the GMP Housekeeping Audit to ensure that items remains intact. The procedure details the protocols to be followed for equipment breakages or loss, with the notification of the Production Manager and Quality Manager, whom will inspect the affected area and isolation of products and collection of fragments and corrective action undertaken. There have been no instances of glass breakages recorded in the last 12 months, all equipment is mainly solid stainless steel structure.

11.7.7.1	<p>In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed.</p> <p>RESPONSE: COMPLIANT</p>
11.7.7.2	<p>In circumstances where glass or similar material breakage occurs, the affected area is to be isolated, cleaned and thoroughly inspected (including cleaning equipment and footwear) and cleared by a suitably responsible person prior to the commencement of operations.</p> <p>RESPONSE: COMPLIANT</p>
11.8.1	<p>Location</p> <p>NA - There are no onsite laboratories. The product is sent to the sister site for storage and testing.</p>
11.8.1.1	<p>On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no onsite laboratories. The product is sent to the sister site for storage and testing.</p>
11.8.1.2	<p>Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory wastewater outlet shall as a minimum be down stream of drains that service food processing and handling areas.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no onsite laboratories</p>
11.8.1.3	<p>Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel.</p> <p>RESPONSE: NOT APPLICABLE</p> <p>EVIDENCE: NA - There are no onsite laboratories</p>
11.9.1	<p>Dry and Liquid Waste Disposal</p> <p>Documented as per Waste and Environment (FSP4.18.4, 5/01/19), liquid waste stored in reservoir located away from the site for spray irrigation onto company farm land well as away from the factory and solid waste is collected by Veolia and removed twice weekly. Whey is processed through the whey powder drying plant or the lactoferrin extraction plant. There was no accumulated waste observed during the audit.</p>
11.9.1.1	<p>The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented.</p> <p>RESPONSE: COMPLIANT</p>
11.9.1.2	<p>Waste shall be removed on a regular basis and not build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.</p> <p>RESPONSE: COMPLIANT</p>
11.9.1.3	<p>Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition, cleaned and sanitized regularly so as not to attract pests and other vermin.</p> <p>RESPONSE: COMPLIANT</p>
11.9.1.4	<p>Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging.</p> <p>RESPONSE: COMPLIANT</p>
11.9.1.5	<p>Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.</p> <p>RESPONSE: COMPLIANT</p>
11.9.1.6	<p>Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing.</p> <p>RESPONSE: COMPLIANT</p>

11.9.1.7	<p>Waste held on site prior to disposal shall be stored in a separate storage facility and suitably insect proofed and contained so as not to present a hazard.</p> <p>RESPONSE: COMPLIANT</p>
11.9.1.8	<p>Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard.</p> <p>RESPONSE: COMPLIANT</p>
11.9.1.9	<p>Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.</p> <p>RESPONSE: COMPLIANT</p>
11.10.1	<p>Grounds and Roadways</p> <p>The facilities and immediate surrounds are concreted and the roadways are compacted earth /lime stone gravel compacted to minimize dust migration. Facilities were observed clean with no accumulation of waste and free from pests and vermin during the audit.</p>
11.10.1.1	<p>Measures shall be established to maintain a suitable external environment, and the effectiveness of the established measures shall be monitored and periodically reviewed.</p> <p>RESPONSE: COMPLIANT</p>
11.10.1.2	<p>The grounds and area surrounding the premises shall be maintained to minimize dust and kept free of waste, accumulated debris or standing water so as not to attract pests and vermin.</p> <p>RESPONSE: COMPLIANT</p>
11.10.1.3	<p>Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises.</p> <p>RESPONSE: COMPLIANT</p>
11.10.1.4	<p>Paths, roadways, loading and unloading areas shall be adequately drained to prevent ponding of water. Drains shall be separate from the site drainage system and regularly cleared of debris.</p> <p>RESPONSE: COMPLIANT</p>
11.10.1.5	<p>Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises.</p> <p>RESPONSE: COMPLIANT</p>
11.10.1.6	<p>Paths from amenities leading to site entrances are required to be effectively sealed.</p> <p>RESPONSE: COMPLIANT</p>