Australian Government
Department of Agriculture, Fisheries and Forestry

Application for Registration or Notification to the Secretary of Change of Details of an Establishment

Export Control (Prescribed Goods —General) Order 2005

APPLICATION CLASSIFICATIONS

Complete each section as indicated below (please type clearly or print all details)

	Sections to be completed
☑ New Registration	A, B, C, D, F
☐ Occupier Change of Name ☐ Change of Management and/or Authorised Signatories, Agents	A, C, D, F
☐ Change of Occupier Current Occupier (Section E only) Proposed Occupier (All other sections)	A, B, C, D, E, F

This application may attract a fee which is payable prior to registration being granted

SECTION A

Registration number or reserved number
(registration number if registered within last seven years if known)

Reserved Est 1405

Name of Occupier
if a corporation: registered company name;
if a partnership: name of each partner in full;
if an individual: person's name in full

GMP Pharmaceuticals Pty. Ltd.

ACN 063535006

ABN 80063535006

Alternative trading names of occupier
(registered business names only)

State RBN

Vessel name
(if the premises are a ship)

SECTION A (continued)

Address of establishment or home port

60 Huntingwood Drive
Huntingwood
State NSW Postcode 2148

Phone: c/- (02) 9631 9999 Fax: c/- (02) 9631 9888

Mobile: s. 22(1)(a)(ii)

Email s. 22(1)(a)(ii)

Business address of occupier

60 Huntingwood Drive
Huntingwood
State NSW Postcode 2148

Phone: c/- (02) 9631 9999 Fax: c/- (02) 9631 9888

Mobile: s. 22(1)(a)(ii)

Email s. 22(1)(a)(ii)

SECTION B

If establishment is a ship, the place in Australia where the ship can be inspected

SECTION C

Management Details

List all persons who manage or control the day to day operations of the establishment, or a substantial part of the operations, and any person who has the authority to direct such persons. Also include the person who will sign this application.

Note: For the purposes of the *Export Control (Prescribed Goods — General) Order 2005*, a person is taken to be a person who manages or controls, or is to manage or control, the operations carried on, or to be carried on, in an establishment if the person has or would have authority to:

(a) direct the operations, or an important or substantial part of the operations; or

(b) direct a person who has the kind of authority referred to in paragraph (a) in the exercise of that authority or proposed authority.

1. Approved Export Permit Issuer — Only tick for those persons who are approved to validate RFPs in EXDOC and who require an EXDOC AQA user ID.

2. Agent — Only tick those persons who you are nominating as an agent ie: they are not in direct management and control of the establishment, but will act as an agent for the purpose of validating RFPs for the establishment.

3. Authorised Signatories — persons who are authorised to sign export documentation for the establishment.

Note: At some establishments an individual may be nominated for approval as both an 'Approved Export Permit Issuer' and an 'Authorised Signatory'.

Note: Approval of authorised signatories and agents under the dairy program must be done on a separate form. Please contact Dairy Export Program.

Please attach a separate sheet if insufficient space.

Attachment Included?

☐ Yes
☑ No

1.

Name in full (please print) ☐ Adding

s. 22(1)(a)(ii)

Position (including company directors) and occupation

QA Manager

Home address

s. 22(1)(a)(ii)

Place of birth s. 22(1)(a)(ii) Date of birth s. 22(1)(a)(ii)

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☑ Authorised signatory

s. 22(1)(a)(ii) answered all questions in

2.

Name in full (please print) ☐ Adding

s. 22(1)(a)(ii)

Position (including company directors) and occupation

OPERATIONS MANAGER

Home address

s. 22(1)(a)(ii)

Place of birth Date of birth

s. 22(1)(a)(ii)

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☑ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

s. 22(1)(a)(ii)

3.

Name in full (please print) ☐ Adding

s. 22(1)(a)(ii)

Position (including company directors) and occupation

Q A MANAGER

Home address

s. 22(1)(a)(ii)

Place of birth s. 22(1)(a)(ii) Date of birth s. 22(1)(a)(ii)

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☑ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

s. 22(1)(a)(ii)

4.

Name in full (please print) ☐ Adding

s. 22(1)(a)(ii)

Position (including company directors) and occupation

Production Manager.

Home address

s. 22(1)(a)(ii)

Place of birth s. 22(1)(a)(ii) Date of birth

s. 22(1)(a)(ii)

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☑ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

s. 22(1)(a)(ii)

5.

Name in full (please print) ☐ Adding

s. 22(1)(a)(ii)

Position (including company directors) and occupation

Warehouse Manager

Home address

s. 22(1)(a)(ii)

Place of birth s. 22(1)(a)(ii) Date of birth s. 22(1)(a)(ii)

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☑ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature s. 22(1)(a)(ii)

6.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

7.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

8.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

9.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

PERSONS TO BE DELETED

SECTION d

For Persons Nominated in Management Details

1 Has the person completing this form, or any of the persons listed in Section C of this application; Yes No

1.1 been convicted of any offence against any law of the Commonwealth or a State or Territory? s. 22(1)(a)(ii)

1.2 in the last 10 years, been placed on a bond to be of good behaviour and/or been fined without a conviction being recorded against them?

1.3 to their knowledge have any charges outstanding against them?

1.4 had any convictions against a law of any country other than Australia?

1.5 either alone or jointly with another person, owe the Commonwealth any amount by way of:

(i) a fee for a service performed at a registered establishment; or

(ii) a charge or levy arising under a law of the Commonwealth; or

(iii) a penalty for failure to pay a charge or levy arising under a law of the Commonwealth?

1.6 either alone or jointly with another person failed to pay any fee, charge, levy or penalty of that kind within 30 days after the due date for payment?

1.7 previously made a false or misleading statement in any application or notice under the Export Control Act 1982 or under regulations or orders made under that Act?

1.8 either alone or jointly with another person:

(i) been refused a licence, permit or approval to export prescribed goods; or

(ii) been granted a licence, permit or approval to export prescribed goods which has been revoked, suspended or cancelled?

1.9 contravened any other notice, instruction, condition or restriction under the Export Control Act 1982, or under regulations or orders made under the Export Control Act 1982?

If the answer to any part of Section D, Q1 is YES then please specify person, offence penalty date and details. Please attach a separate sheet if insufficient space.

s. 22(1)(a)(ii)

Question 2 in this section relates to the applicant and persons named in Section C, and deals with "ASSOCIATES" of the applicant and persons named in Section C.

*IMPORTANT "associate" includes

(a) a person who is or was a consultant, adviser, partner, representative on retainer, employer or employee of the person concerned or of any corporation of which the person concerned is an officer or employee, or in which the person concerned holds shares; and

(b) the spouse or de facto partner (within the meaning of the Acts Interpretation Act 1901) of the person concerned; and

SECTION d (continued)

(c) any other person who is or was;

(i) directly or indirectly concerned in; or

(ii) in a position to control or influence the conduct of; a business or undertaking of the person concerned, or of a corporation of which the person concerned is an officer or employee, or in which the person concerned holds shares; and

(d) a corporation of which the person concerned, or any other person mentioned in paragraphs (a), (b) and (c), is, or was at a relevant date, an officer or employee, or in which the person concerned or any of those other persons holds shares or held shares on a relevant date.

For further information see section 4.05 of the Export Control (Prescribed Goods – General) Order 2005

2 Has the person completing this form, or any of the persons listed in Section C of this application have an associate*; Yes No

2.1 who has been convicted of an offence against a law of the Commonwealth or a State or a Territory or another country? s. 22(1)(a)(ii)

2.2 who either alone or jointly with another person, owe the Commonwealth any amount by way of:

(i) a fee for a service performed at a registered establishment; or

(ii) a charge or levy arising under a law of the Commonwealth; or

(iii) a penalty for failure to pay a charge or levy arising under a law of the Commonwealth?

2.3 who either alone or jointly with another person failed to pay any fee, charge, levy or penalty of that kind within 30 days after the due date for payment?

2.4 who previously made a false or misleading statement in any application or notice under the Export Control Act 1982, or under regulations or orders made under that Act?

2.5 who either alone or jointly with another person:

(i) been refused a licence, permit or approval to export prescribed goods; or

(ii) been granted a licence, permit or approval to export prescribed goods which has been revoked, suspended or cancelled?

2.6 who contravened any other notice, instruction, condition or restriction under the Export Control Act 1982, or under regulations or orders made under the Export Control Act 1982?

If the answer to any part of Section D, Q2 is YES then please specify person, offence penalty date and details. Also include full name, date of birth of associate and details of association. Please attach a separate sheet if insufficient space.

SECTION E

Transfer of Occupier

(To be completed by the current registered occupier)

The person who signs this declaration must be included in those listed in Management and Control of the establishment. I, being the current occupier of the registered export establishment, apply for transfer of occupier of;

Establishment number

TO — Name of proposed occupier

Reason for transfer

N/A

Proposed transfer date

Full name of current occupier

Signature of the current occupier | Date

Name in full (please print)

Position

SECTION F

Declaration

The person who signs this declaration must be included in those listed in Management and Control of the establishment.

(Before signing this declaration please ensure that you have completed each section requested in the application classifications box)

I, s. 22(1)(a)(ii)

being the person in whose name, or being the representative of the company in whose name the establishment is, or is sought to be registered **declare** that I have read the information and that the information provided in and with this application is true in every detail.

GIVING FALSE OR MISLEADING INFORMATION IS A SERIOUS OFFENCE

Name in full (please print)

s. 22(1)(a)(ii)

Position

OA Manager

s. 22(1)(a)(ii) Date 24 Sept 18

ADDITIONAL COMMENTS

Only storage required

OFFICE USE ONLY

FIELD OFFICER

Operations Recommending Officer

Recommended operations (Refer to code book) and comments affecting registration, where appropriate the charge category and expected volume of export should be included.

Registered operations	QA=	Yes	No
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Overseas Operations:

Commodity(ies):

Establishment Type:

Charge Category:

Is the establishment approved to validate export permit/RFP in accordance with instrument of approval? Yes ☐ No ☐

This establishment is operationally suitable for export registration under the *Export Control Act 1982* and an approved arrangement is in place.

Signature Date

Printed name in full and position

REGION REGISTRATION COORDINATOR

Evidence of legal existence received for:

- ☐ Occupier name
- ☐ Trading name(s)
- ☐ Fee / Payment received

File Number:

INVESTIGATION & ENFORCEMENT

Investigation & Enforcement has no objection to this application.

Signature Date

Printed name in full and position

ACCOUNTS CERTIFICATION

This establishment meets the financial requirements of Part 4 of the *Export Control (Prescribed Goods — General) Order 2005*

Account number

Signature Date

Printed name in full and position

CENTRAL OFFICE

Overseas Letters

Comments

Pursuant to Part 4 of the *Export Control (Prescribed Goods — General) Order 2005*, I hereby register the establishment designated in this application as an export establishment for the operations specified.

Signature Date

Name and position number

Action officer

- ☐ Transaction checked
- ☐ EXDOC

Initials and date

Explanatory Notes - To be Retained by Applicant

What is an EX26?	An approved form used to apply for export registration or notify a change of detail or arrangement to an export registered establishment.
What is an export establishment?	A premises (including a fishing vessel) where prescribed goods are prepared for export and includes slaughter, boning, processing, inspecting, chilling, freezing, holding, producing, packing, treating, handling, dismembering, loading or storing.
When does a premises need to be registered with DAFF?	When a premises, including a fishing vessel, intends to produce, prepare, store or handle prescribed goods for export.
Who should dairy establishments contact regarding registration of an establishment?	All enquiries regarding registration of a dairy export establishment should be forwarded to dairy@agriculture.gov.au
How can I reserve an establishment number?	A number can be reserved through contacting the export documentation section in the DAFF regional office in the capital city of your state - see contact numbers below.
What is a prescribed good?	An edible product defined by the Export Control Act 1982 as a prescribed good which includes commodity groups meat, game, poultry, rabbit, fish, dairy, fresh fruit and vegetables, plant and plant products, grains, dried fruit and eggs.
What is an occupier?	The legal entity that manages and controls the operations carried out at an establishment and in whose name the establishment is or will be registered. Note: Establishments will only be registered in a company name or the full name(s) of an individual(s) operating a business or in the name of a partnership. For partnerships a copy of the partnership agreement is required.
When do I need to complete an EX26?	- if you are seeking registration (including re-registration) - adding or amending persons in management and control - adding or amending authorised signatories or Approved Export Permit Issuers or Agents - a change in name of occupier - variation of operations* - transferring registration to another entity *Alternatively you may request this on company letterhead signed by a person in management and control.
Who should complete an EX26?	The person completing the application and declaration must be a person in management and control (for a Company the Company Secretary should make an application). For a new registration the person must be nominated in management and control of the application.
Who should be nominated in management and control?	Any and every person in a position to manage or control the day-to-day operation of the establishment.
Who is an 'Approved Export Permit Issuer'?	For all commodities, any and every person who is approved to validate RFPs submitted via the electronic certification system EXDOC and who requires an EXDOC AQA user ID.
Who are 'Authorised signatories'?	For non-meat establishments: any and every person who is authorised to sign export documentation for the establishment. For meat establishments: any and every person as defined as authorised signatories in the Approved Arrangement Guidelines - Meat. For dairy: approval as an authorised signatory or approved export permit issuer is completed via a separate process. Please contact the regional documentation section on dairy.exdoc@agriculture.gov.au for further details
Who are 'Agents'?	Any and every person who is nominated as an agent by the occupier of an establishment, who are not in direct management and control of an establishment, but act as an agent for the purpose of validating RFPs for the establishment.
FISH - Are agents required to complete an Agents Authorisation Form?	Yes. Agents validating RFPs for fish exports must complete an agent authorisation form. The form must accompany the EX26 obtained from foodexportdocumentation@agriculture.gov.au
Is there an application fee?	Depending on the type of establishment and application there may be a fee. Information regarding DAFF fees and charges can be obtained from the Biosecurity Office in your respective region or the DAFF website www.agriculture.gov.au
Important information which may effect the establishment's application or ability to process.	There are fees and charges which apply for DAFF inspection and inspection related services. Certification provided by DAFF will also attract a charge. Penalties may apply for late payments. Prior to transferring registration from one occupier to another all outstanding monies owed to DAFF in fees and charges and industry levies must be paid in accordance with legislative provisions. Persons nominated in management and control will be assessed for fit and proper status which may include criminal history checks. The establishment registration is subject to continuing compliance with the conditions as provided in the *Export Control (Prescribed Goods – General) Order 2005* and the relevant commodity Orders and it will be scrutinised from time to time for technical compliance, indebtedness and fit and proper purposes.
How long will application take to process?	Approximately 2 weeks unless further information is required. It should be noted that the application is not approved until the Secretary or their delegate signs the application.
When do I need to notify DAFF of any changes?	All changes made to an establishment or to anyone listed in management and control must be notified to DAFF within 7 days of the change occurring.

This information is provided as a guide only. A Biosecurity Officer will be able to provide more detailed advice and information concerning the legislative requirements and may be contacted on:

NSW	02 8334 7444	VIC	03 8318 6700	WA	08 9334 1555
QLD	07 3246 8755	SA	08 8201 6000	TAS	03 6223 2502
NT	08 8981 1211	CAIRNS	07 4030 7800	TOWNSVILLE	07 4789 7888

If you think someone you know is breaking Australian quarantine or food inspection laws, we want to hear from you.

THE DAFF BIOSECURITY REDLINE - 1800 803 006

Australian Government
Department of Agriculture, Fisheries and Forestry

Application for Registration or Notification to the Secretary of Change of Details of an Establishment

Export Control (Prescribed Goods —General) Order 2005

APPLICATION CLASSIFICATIONS	
Complete each section as indicated below (please type clearly or print all details)	
	Sections to be completed
☐ New Registration	A, B, C, D, F
☐ Occupier Change of Name ☐ Change of Management and/or Authorised Signatories, Agents	A, C, D, F
☐ Change of Occupier Current Occupier (Section E only) Proposed Occupier (All other sections)	A, B, C, D, E, F
This application may attract a fee which is payable prior to registration being granted	

SECTION A

Registration number or reserved number
(registration number if registered within last seven years if known)

1405

Name of Occupier
if a corporation: registered company name;
if a partnership: name of each partner in full;
if an individual: person's name in full

GMP PHARMACEUTICALS PTY LTD

ACN 0 6 3 3 5 3 0 0 6

ABN 8 0 0 6 3 3 5 3 0 0 6

Alternative trading names of occupier
(registered business names only)

NA

State RBN

Vessel name
(if the premises are a ship)

SECTION A (continued)

Address of establishment or home port

60, HUNTINGWOOD DRIVE
HUNTINGWOOD
State NSW Postcode 2148

Phone: 02 9852 3900 Fax:

Mobile: s. 22(1)(a)(ii)

Email

Business address of occupier

AS ABOVE

State Postcode

Phone: Fax:

Mobile:

Email

SECTION B

If establishment is a ship, the place in Australia where the ship can be inspected

NA.

SECTION C

Management Details

List all persons who manage or control the day to day operations of the establishment, or a substantial part of the operations, and any person who has the authority to direct such persons. Also include the person who will sign this application.

Note: For the purposes of the *Export Control (Prescribed Goods — General) Order 2005*, a person is taken to be a person who manages or controls, or is to manage or control, the operations carried on, or to be carried on, in an establishment if the person has or would have authority to:

(a) direct the operations, or an important or substantial part of the operations; or

(b) direct a person who has the kind of authority referred to in paragraph (a) in the exercise of that authority or proposed authority.

1. Approved Export Permit Issuer — Only tick for those persons who are approved to validate RFPs in EXDOC and who require an EXDOC AQA user ID.

2. Agent — Only tick those persons who you are nominating as an agent ie: they are not in direct management and control of the establishment, but will act as an agent for the purpose of validating RFPs for the establishment.

3. Authorised Signatories — persons who are authorised to sign export documentation for the establishment.

Note: At some establishments an individual may be nominated for approval as both an 'Approved Export Permit Issuer' and an 'Authorised Signatory'.

Note: Approval of authorised signatories and agents under the dairy program must be done on a separate form. Please contact Dairy Export Program.

Please attach a separate sheet if insufficient space.

Attachment Included?

☐ Yes
☐ No

1.

Name in full (please print) ☐ Adding
s. 22(1)(a)(ii)

Position (including company directors) and occupation
SITE MANAGER

Home address
s. 22(1)(a)(ii)

Place of birth
s. 22(1)(a)(ii)

Date of birth
s. 22(1)(a)(ii)

[please tick appropriate box(es)]
☐ Approved Export Permit Issuer ☐ Agent ☑ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature
s. 22(1)(a)(ii)

2.

Name in full (please print) ☐ Adding
s. 22(1)(a)(ii)

Position (including company directors) and occupation
HEAD OF QUALITY

Home address
s. 22(1)(a)(ii)

Place of birth
s. 22(1)(a)(ii)

Date of birth
s. 22(1)(a)(ii)

[please tick appropriate box(es)]
☐ Approved Export Permit Issuer ☐ Agent ☑ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature
s. 22(1)(a)(ii)

3.

Name in full (please print) ☐ Adding
s. 22(1)(a)(ii)

Position (including company directors) and occupation
WAREHOUSE MANAGER

Home address
s. 22(1)(a)(ii)

Place of birth
s. 22(1)(a)(ii)

Date of birth
s. 22(1)(a)(ii)

[please tick appropriate box(es)]
☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature
s. 22(1)(a)(ii)

4.

Name in full (please print) ☐ Adding
s. 22(1)(a)(ii)

Position (including company directors) and occupation
PRODUCTION SUPERVISER

Home address
s. 22(1)(a)(ii)

Place of birth
s. 22(1)(a)(ii)

Date of birth
s. 22(1)(a)(ii)

[please tick appropriate box(es)]
☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature
s. 22(1)(a)(ii)

5.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

6.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

7.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

8.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

9.

Name in full (please print) ☐ Adding

Position (including company directors) and occupation

Home address

State Postcode

Place of birth Date of birth

[please tick appropriate box(es)]

☐ Approved Export Permit Issuer ☐ Agent ☐ Authorised signatory

I, the undersigned, have read and answered all questions in Section D

Signature

PERSONS TO BE DELETED

SECTION D

For Persons Nominated in Management Details

1 Has the person completing this form, or any of the persons listed in Section C of this application; Yes No s. 22(1)(a)(ii)

1.1 been convicted of any offence against any law of the Commonwealth or a State or Territory?

1.2 in the last 10 years, been placed on a bond to be of good behaviour and/or been fined without a conviction being recorded against them?

1.3 to their knowledge have any charges outstanding against them?

1.4 had any convictions against a law of any country other than Australia?

1.5 either alone or jointly with another person, owe the Commonwealth any amount by way of:

(i) a fee for a service performed at a registered establishment; or

(ii) a charge or levy arising under a law of the Commonwealth; or

(iii) a penalty for failure to pay a charge or levy arising under a law of the Commonwealth?

1.6 either alone or jointly with another person failed to pay any fee, charge, levy or penalty of that kind within 30 days after the due date for payment?

1.7 previously made a false or misleading statement in any application or notice under the *Export Control Act 1982* or under regulations or orders made under that Act?

1.8 either alone or jointly with another person:

(i) been refused a licence, permit or approval to export prescribed goods; or

(ii) been granted a licence, permit or approval to export prescribed goods which has been revoked, suspended or cancelled?

1.9 contravened any other notice, instruction, condition or restriction under the *Export Control Act 1982*, or under regulations or orders made under the *Export Control Act 1982*?

If the answer to any part of Section D, Q1 is YES then please specify person, offence penalty date and details. Please attach a separate sheet if insufficient space.

Question 2 in this section relates to the applicant and persons named in Section C, and deals with "ASSOCIATES" of the applicant and persons named in Section C.

***IMPORTANT "associate" includes**

(a) a person who is or was a consultant, adviser, partner, representative on retainer, employer or employee of the person concerned or of any corporation of which the person concerned is an officer or employee, or in which the person concerned holds shares; and

(b) the spouse or de facto partner (within the meaning of the *Acts Interpretation Act 1901*) of the person concerned; and

SECTION D (continued)

(c) any other person who is or was;

(i) directly or indirectly concerned in; or

(ii) in a position to control or influence the conduct of; a business or undertaking of the person concerned, or of a corporation of which the person concerned is an officer or employee, or in which the person concerned holds shares; and

(d) a corporation of which the person concerned, or any other person mentioned in paragraphs (a), (b) and (c), is, or was at a relevant date, an officer or employee, or in which the person concerned or any of those other persons holds shares or held shares on a relevant date.

For further information see section 4.05 of the *Export Control (Prescribed Goods – General) Order 2005*

2 Has the person completing this form, or any of the persons listed in Section C of this application have an associate*; Yes No s. 22(1)(a)(ii)

2.1 who has been convicted of an offence against a law of the Commonwealth or a State or a Territory or another country?

2.2 who either alone or jointly with another person, owe the Commonwealth any amount by way of:

(i) a fee for a service performed at a registered establishment; or

(ii) a charge or levy arising under a law of the Commonwealth; or

(iii) a penalty for failure to pay a charge or levy arising under a law of the Commonwealth?

2.3 who either alone or jointly with another person failed to pay any fee, charge, levy or penalty of that kind within 30 days after the due date for payment?

2.4 who previously made a false or misleading statement in any application or notice under the *Export Control Act 1982*, or under regulations or orders made under that Act?

2.5 who either alone or jointly with another person:

(i) been refused a licence, permit or approval to export prescribed goods; or

(ii) been granted a licence, permit or approval to export prescribed goods which has been revoked, suspended or cancelled?

2.6 who contravened any other notice, instruction, condition or restriction under the *Export Control Act 1982*, or under regulations or orders made under the *Export Control Act 1982*?

If the answer to any part of Section D, Q2 is YES then please specify person, offence penalty date and details. Also include full name, date of birth of associate and details of association. Please attach a separate sheet if insufficient space.

SECTION E

Transfer of Occupier

(To be completed by the current registered occupier)

The person who signs this declaration must be included in those listed in Management and Control of the establishment. I, being the current occupier of the registered export establishment, apply for transfer of occupier of;

Establishment number

TO — Name of proposed occupier

Reason for transfer

Proposed transfer date

Full name of current occupier

Signature of the current occupier **Date**

Name in full (please print)

Position

SECTION F

Declaration

The person who signs this declaration must be included in those listed in Management and Control of the establishment.

(Before signing this declaration please ensure that you have completed each section requested in the application classifications box)

I, s. 22(1)(a)(ii)

being the person in whose name, or being the representative of the company in whose name the establishment is, or is sought to be registered **declare** that I have read the information and that the information provided in and with this application is true in every detail.

GIVING FALSE OR MISLEADING INFORMATION IS A SERIOUS OFFENCE

Name in full (please print)

s. 22(1)(a)(ii)

Position

SITE MANAGER

Signat s. 22(1)(a)(ii) **Date**

27/04/2020

ADDITIONAL COMMENTS

1405 currently licenced for storage.

Additional arrangements required for manufacturing, packing, testing and release of product for export.

OFFICE USE ONLY

FIELD OFFICER

Operations Recommending Officer

Recommended operations (Refer to code book) and comments affecting registration, where appropriate the charge category and expected volume of export should be included.

Registered operations	QA=	Yes	No
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Overseas Operations:

Commodity(ies):

Establishment Type:

Charge Category:

Is the establishment approved to validate export permit/RFP in accordance with instrument of approval? Yes ☐ No ☐

This establishment is operationally suitable for export registration under the *Export Control Act 1982* and an approved arrangement is in place.

Signature **Date**

Printed name in full and position

REGION REGISTRATION COORDINATOR

Evidence of legal existence received for:

- ☐ Occupier name
- ☐ Trading name(s)
- ☐ Fee / Payment received

File Number:

INVESTIGATION & ENFORCEMENT

Investigation & Enforcement has no objection to this application.

Signature **Date**

Printed name in full and position

ACCOUNTS CERTIFICATION

This establishment meets the financial requirements of Part 4 of the *Export Control (Prescribed Goods — General) Order 2005*

Account number

Signature **Date**

Printed name in full and position

CENTRAL OFFICE

Overseas Letters

Comments

Pursuant to Part 4 of the *Export Control (Prescribed Goods — General) Order 2005*, I hereby register the establishment designated in this application as an export establishment for the operations specified.

Signature **Date**

Name and position number

Action officer

- ☐ Transaction checked
- ☐ EXDOC

Initials and date

Australian Government
Department of Agriculture

Department of Agriculture: Food Program (Dairy) Bi-Annual Approved Arrangement Audit Report

Company:	GMP Pharmaceuticals PTY LTD		
Audit Location:	60 Huntingwood Drive, Huntingwood, NSW, 2148		
Compliance standard:	• Export Control (Milk & Milk Products) Orders 2005 • Export Control Act 1982 • Export Control (Prescribed Goods - General) Order 2005 • Establishments Approved Arrangement • Importing Country Requirements		
Auditee Representatives:	s. 22(1)(a)(ii) QA Team Leader		
Establishment No:	1405	**Audit Dates:**	01-05/02/ 2021
Lead auditor:	s. 22(1)(a)(ii)	Additional audit team members:	Nil
Total Audit Time: For charging purposes (if applicable) * Report writing time is also charged and will be included in the invoice issued	Audit Time: 16 hours Report Writing: 1.00hr	Day 1 01.02.2021: Start time: 09:00 Finish Time 13:30	Breaks: 30 mins
		Day 2 02.02.2021: Start time: 09:00 Finish Time 13:30	Breaks: 30mins Mins
		Day 3 02.02.2021: Start time: 09:00 Finish Time 13:30	Breaks: 30mins Mins
		Day 4 02.02.2021: Start time: 09:00 Finish Time 13:30	Breaks: 30mins Mins

Auditor Name: s. 22(1)(a)(ii)		**Signature:** s. 22(1)(a)(ii)	
Date Report Issued:	5th February 2021	**No# of Non-Compliances Issued This Audit:**	**80+**
No# NC Closed out from Previous Audit:	**n/a**	**No# of Non-Compliances Re-Issued:**	**n/a**

Additional Information (where applicable) can be found at the end of the report

Audit Scope and Objectives:

The scope of the desk audit included review of the following AA elements:

- Review all applicable 21 elements of the food safety program of GMP Pharmaceuticals for approval as an export registered establishment with the Department of Agriculture for dairy powder products.
- GMP Pharmaceuticals is seeking approval as an export registered establishment with the Department of Agriculture, Water and the Environment (DAWE) for the production of Dairy Powder Products- repacked dairy powder, freeze dried dairy and yoghurt products.

Summary of findings:

The food safety program reviewed does not currently meet all the requirements of the Export Control Milk and Milk Products Orders 2005. Those items required to be further actioned, amended or strengthened are detailed below (as noted in red writing, blue highlight sections are for further questioning).

Audit Outcome: Acceptable? Not Acceptable?	Acceptable

1. *Management Practices* **2.** *Internal Audits, Corrective Actions* **3.** *Plans & Specifications* **4.** *Cleaning* **5.** *Water*
6. *Pest Control* **7.** *Protection, Segregation & Waste* **8.** *Protective Clothing, Premise Construction, Hygiene and GMP/GHP*
9. *HACCP* **10.** *Testing* **11.** *Training* **12.** *Identification/Traceability & Recall* **13.** *Approved Supplier*
14. *Receiving & Dispatching* **15.** *Transfer & Declarations of Compliance* **16.** *Importing Country Requirements*
17. *Loading of Sea and Air* **18.** *Seals* **19.** *Pasteurisation* **20.** *Trade Descriptions* **21.** *Maintenance and Calibration*
22. *Miscellaneous*

Approved Arrangement Elements Audited

1. Management Practices, Commitment to Food Safety and Records	Compliant? (Yes / No/ NA- Not Assessed)	No

Summary of Findings:
The Declaration of Occupiers Commitment (FSM 1.5) sighted and details meeting export, importing country requirements and domestic requirements, Group CEO is responsible for signing. FSM 1.4 Food Safety and Quality Policy further details that the establishment will meet export and domestic requirements, Group CEO signs. FSM 1.4 also details that an annual management review is to occur.

Organisational structure is documented in FSM 1.6 sighted, showing staff from Group CEO to floor staff. Position descriptions are documented in FSM 1.7 for both the Huntingwood and Girwaween sites.

Management review procedures FSM 1.16 reviewed, annual review to occur, attendees and agenda items detailed including export requirements, management review meeting minutes are taken and filed, actions are assigned to attendees where required.

Document control procedures sighted in FSM 1.9, details process for approving new documents and amending current in use documents, includes seeking approval from the Department (DAWE- Department of Agriculture, Water and The Environment) for changes relating to export, importing country requirements or may affect the products integrity or fitness for human consumption. Master document list, amendment register and version control used to track documents. Retention period and persons who can amend/create and approve documents are detailed.

This element was found to be non-compliant due to the following findings.

Findings:

- FSM 1.5 Declaration of Occupiers Commitment and FSM 1.4 Food Safety and Quality Policy supplied are not signed and dated by the Group CEO.
- The QA Associate is held by a different person in the organisational structure FSM 1.6 issue date October 2020 versus the FSM 1.7 Position descriptions issue date October 2020
- It is unclear who has the main role in overseeing and management of the AA (FSM) as multiple QA roles are in place at the Huntingwood site, for example there is QA Team Leader and Senior QA Associate at the same level in the organisational chart – site to clarify.
- Positions description titles in FSM 1.7 do not consistently state which site the role is at, the Organisational structure 1.6 clearly shows two sites.
- Unclear what the retention period is for documents, differs in FSM 1.9 under section 6. States 4 years. and section 9.9.6- states 3 years, section 9.3.2 states 5 years. On review of procedures such as 1.15, 3.12 it details 4 years- please confirm retention and recommend review of retention period across all procedures.
- FSM 1.9 states that the QA Manager or delegate manages this procedure, whereas the organisational chart for Est1405 doesn't have a QA Manager. Please confirm correct role title, recommend reviewing all procedures to ensure correct QA title is used.
- Management review procedures FSM 1.16 detail management review is conducted as per QAF045, on review of QAF045 supplied it is not included in the table.

2. Internal Audits and Corrective Actions	Compliant? (Yes / No/ NA- Not Assessed)	No

Summary of Findings:
Internal audit procedure 1.15 reviewed, details process for external and internal audits (GMP and Non-GMP audits). GMP audits are conducted as per SOP QA 008 Internal GMP Audit. Non-GMP audits are done as per the internal audit schedule/ Verification schedule 1.14a. Compliance to the audit is to be recorded on the internal audit summary, objective evidence to be captured on documents being audited or on internal audit summary. Form49 Internal audit summary report is used to document the audits findings, corrective and preventative actions. Corrective actions procedures are detailed for when immediate action can be taken or not. A corrective action report and following the corrective and preventative action procedures are detailed. For external audits a person from management will accompany the auditor/s, a quality incident form QAF007 and corrective and preventative actions are to be taken.

Internal audit checklist QAF017 and QAF009 Internal GMP audit form templates sighted.

Internal audit schedule QAF045 reviewed details audits conducted over the calendar year.

1.14a Verification schedule sighted and details internal audits to be completed on activities such as; quality system documents, corrective action and non-conforming product procedures, HACCP, importing country requirements, trade description, approved suppliers.

SOP QA 008 Internal GMP Audit sighted and reviewed covers internal audit requirements and process of completing audits.

FSM 1.17Corrective and Preventative Action (CAPA) Procedure reviewed, capture processes for internal and external non-compliances. External non-compliances have CAPA and QID (quality incident deviation) form completed. Internal non-conformances follow CAPAs as per HACCP, if action can be taken immediately it is done so and recorded on the relevant monitoring form, if not CAPA and QID completed. Notification to the Department of QIDs is documented. CAPA process includes logging of incident into QID register, completing QID from and investigations, determine products status, determining corrective and preventive actions, timeframe for completion, verifying actions are acceptable, QID can only be closed once actions have been deemed acceptable, QA Manager to close, monthly review of QID occurs, QID maybe extended if a plan is in place to address and no food safety risk is present. If there is a risk to food safety or quality then immediate action must be taken to correct the non-compliance, non-urgent issue have up to 1 month for actioning.

This element was found to be non-compliant due to the following findings.

Findings:
The below findings have been identified for;
FSM 1.15:

- Unclear if the internal audit summary and internal audit summary report Form49 are the same form? As is not consistently referenced in 1.15.
- 1.15 Section 6.0 details records, however these records are not consistently referenced or used in the procedure, where a form or checklist is referenced its document code should be noted. For example; the Internal audit checklist QAF017 is only referenced in the corrective action by name, its not referenced to be used under section 9.2. Internal audit summary report is referenced as QAF036 under section 6.0, but as Form49 later on in the procedure.
- The external audit section doesn't refer to the Corrective and preventative procedure, only to complete QAF007 and take action- recommend referencing the CAPA procedure.
- FSM 1.15 doesn't reference SOPQA008 under non-GMP audits, on review of SOP QA 008 it provides details on the internal audit process and requirements for quality system related audits.

SOP QA 008 Internal GMP Audit:

- References AQIS, not current name of Department
- FSM 1.15 refers to this SOP for GMP audit requirements, section 6.7 doesn't elaborate on the frequency, how audits are completed, and how non-compliances are determined and actioned. Please add detail on GMP audits.
- Monthly GMP audit forms have been provided, these forms are not referenced in this SOP (QAF062, QAF063, QAF064), but IPAC checklist instead.

Internal audit schedule QAF045:

- Doesn't capture all elements of the AA including; importing country requirements, trade descriptions, HACCP, approved suppliers, the schedule also doesn't reflect internal audits referenced in 1.14a.

Verification procedure 1.14 not provided for review.

3. Plans & Specifications	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings: This element non-compliant at present due to the below finding.

Findings:

- Plans still under development, site to provide once finalised.

4. Cleaning & Sanitising	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

Sighted Cleaning and sanitising procedure FSM 3.12, covers all of site, daily pre-operational inspection to be completed. Cleaning effectiveness verified by in- house ATP swabs, monthly environmental swabbing, quarterly allergen swabbing and finished product testing. Production and Warehouse Manager or delegate are responsible for monitoring the effectiveness of cleaning daily. General overview of cleaning procedure and chemicals detailed. Cleaning equipment is colour coded for work area/equipment's, storage and cleaning requirements for cleaning equipment is detailed. Covers an overview of cleaning required and frequency, as well as monitoring.

SOP PFD013 General Cleaning procedure reviewed- provides cleaning procedure for bulk production, staging, packing areas for Freeze dry product.

FSM 3.13 Cleaning Schedule reviewed- captures areas of site to be cleaned and sanitised, frequency, chemicals to be used, how to clean, persons responsible and recording form.

FSM 3.14 Cleaning and Approved Chemicals List sighted- details chemicals at site, usage, SDS on file, allergen status and where stored.

SOPQA0018- Environmental Monitoring Procedure reviewed- details air monitoring and environmental swabs to be taken, temperature monitoring, sampling maps are included. Air monitoring to be completed monthly, limits, how to sample and corrective action requirements detailed. Listeria swabbing to be done monthly from a direct and non-direct contact surfaces, sampling process documented, sent to external lab for analysis. Corrective actions for positive listeria detections documented, includes- intensive clean, testing product, raising CAPA, notify NSW Food Authority, customer, instigating clearance programme.

FSM 3.5 reviewed and details that chemical containers are not to be used for any other purpose and are checked at receival to ensure that they are not damaged, labelled and clean.

QAF040 reviewed.

Sighted SOPPFD019 Portable CIP Machine Procedure sighted and is in place and used for hard to clean equipment such as the heat exchanger.

This element was found to be non-compliant due to the following findings.

Findings: The following findings have been noted for each document reviewed:

FSM 3.12:

- No frequency is documented in FSM 3.12 for ATP and finished product testing.
- Section 9.5 of procedure 3.12 refers to a cleaning schedule at the end of the document, but no schedule is included in 3.12.
- No reference to the Environmental monitoring procedure SOPQA0018 is documented

SOP PFD013 General Cleaning procedure:

- Doesn't refer to a pre-operational inspection occurring after cleaning has been completed or who is cleaning.
- No reference to ensuring product and or packaging is removed before cleaning commences is documented.
- The frequency of cleaning is unclear, as it refers to daily, as needed or as per the schedule- see sections 6.1.1 and 6.2.1.
- No reference to the cleaning schedule 3.13 is documented.
- Triple S is documented to be used in the bulk storage and staging area, no sanitiser is documented to be used in the bulk storage and staging area. this differs to chemicals to be used in 3.13.
- Only sanitiser is referenced to be used in the packing area, whereas as FSM 3.13 lists Ultramax and Alcohol.
- Unclear if SOP PFD013 General Cleaning procedure is the only SOP for cleaning.

FSM 3.14 Cleaning and Approved Chemicals List:

- Does not refer to Triple 2 or 70% Alcohol

SOPQA0018- Environmental Monitoring Procedure:

- Under listeria swabbing it refers to QAF040 for when areas are to be swabbed, on review of QA040 it doesn't detail when areas are to be swabbed. Is there another sampling document capturing this?
- Not clear if air monitoring is tested internally or externally.
- Doesn't refer to notifying the Department environment for out of specification results
- Doesnt capture if product at site will be placed on hold if results are out of specification.
- Doesnt reference when QAF048 Sampling room environmental monitoring plan is used, please clarify and provide.

Unclear from procedures how many CIPS systems are used at site- clarify with site

SOPPFD019 Portable CIP Machine Procedure—

- validation data to be provided for this unit, must capture each piece of equipment or process line it is used on
- SOP doesn't include any monitoring or verification checks on equipment/process lines after using the portable unit
- FSM 3.13 Cleaning Schedule only refers to use of this on the cooking tank system- unclear if this includes the heat exchanger. No heat exchanges is noted in the HACCP plans.

FSM 3.13 Cleaning Schedule

- Unclear if the anti room and ante room are the same area?
- Ante room and bins are to be cleaned monthly on the schedule- frequency may not reflect use of area.

Procedures provided do not capture how compliance is determined after cleaning via a preoperational inspection, does another procedure capture this? Clarify with site.

No reference to ATP swabs being undertaken after cleaning is documented in any procedure provided.

5. Water Sampling	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
Sighted FSM 1.2 Product Assessment, Inspection and Testing Procedure- covers general overview of testing done at site, including water. Water at site is potable, supplied by Sydney water, Sydney water monitors chemical and physical testing against the ADWG. The quarterly Sydney Water Quality report will be reviewed, issues with chemical and physical parameters will be investigated. Monthly ecoli testing of water occurs at site.

SOP QA0014 Water Quality Monitoring Programme reviewed, one sample per calendar month is taken, tested for Ecoli at NATA lab, sampling process defined, water sampling map and sample location list is included, corrective action documented for out of specification results covers notification to the department and investigations. Site obtains the annual Sydney water quality report or completes the testing if the report is not available.

This element is non-compliant due to the following findings.

Findings:
The following findings have been noted with relation to:
FSM 1.2;

- Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager or technical Officer.
- Persons who review the Sydney water quality report and the process for investigating issues with the report is not documented.

SOP QA0014 Water Quality Monitoring Programme:

- Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager.
- Sampling states one sample per month, rotating through the location list table 2, however there are > 12 samples. Are there occasions when more than one sample is taken per month?
- SOP QA0014 details that the annual Sydney Water quality report is obtained, whereas FSM 1.2 states the report is reviewed quarterly- are both monitoring activities being carried out?
- Retention period of water quality records is 7 years, this differs to FSM 1.9. Is this correct?

6. Pest Control	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
FSM 3.6 Pest Control Procedure sighted, monthly external services by a pest control technician are carried out, additionally staff are to report pest sightings, these are entered into the pest control log and a monthly Warehouse GMP audit is conducted. Procedure details hygiene and maintenance requirements to ensure compliance to pest control. FSM 1.18 Control of Non-conforming product is to be instigated if product is affected with pests. Recommendations from the pest control technician are to be actioned by the site.
Pest control service requirements are defined, including target pests/vermin. The technician conducts routine services and treatments, including actioning any issues noted in the pest sighting log, a pest control manual is on place that contains SDS, licences, bait station map.

This element is non-compliant due to the following finding.

Findings:

1. Section 7 only refers to a monthly Warehouse GMP audit, no reference to factory (production & packing GMP audits has been included)

7. Protection, Segregation, Waste and Other Products	Compliant? (Yes / No/ NA-Not Assessed)	No

Summary of Findings:

FSM 3.5 Waste procedures sighted, GMP audits and cleaning to be conducted to ensure compliance to waste procedures. Waste is to be identified and separated from food product. Procedure captures requirements for handling and hygiene requirements of solid (recyclable and non-recyclable waste) and liquid waste. Non-conforming product is to be clearly labelled as so.

See section 4 for information on chemicals.

Refer to sections 8 and section 12 on product handling and identifications.

FSM 1.18 Non-conforming product procedure reviewed, details process of identifying non-conforming product/equipment/material and process of determining disposition of them, notification to the department has been included. Process includes isolation, labelling of affected product and placing on hold in the computer system so that it cannot be used.

This element is non-compliant due to the following findings

Findings:

Findings for FSM 3.5:

- Section states no rework, however FSM 1.14 details rework is used at site. Please clarify if rework is being used and detail this in the procedure and HACCP plan.

Findings for FSM 1.18 Non-conforming product;

- Refers to the title of a QA Manager, but no role is listed in the organisational chart or position descriptions for Est1405.
- Procedures detail product maybe rejected, released, but they do not capture if CAPA process is ever required.
- Procedures to be followed for product being processed or received is not clearly defined. Does it follow the same process? Site to clarify
- No reference to non-conforming products for export is detailed? Need to detail or reference supporting procedures.

Unclear in AA/FSM at present how export vs domestic product is processed.

For additional findings see element 8 below

8. Protective Clothing, Premise Construction, Personnel Hygiene and GMP/GHP	Compliant? (Yes / No/ NA-Not Assessed)	No

Summary of Findings:

FSM 3.1 GMP procedures reviewed, covers production, packaging and ware house areas as follows;
Monitoring of GMP occurs via daily GMP inspections and cleaning, and monthly GMP audits. Major changes to the premises are to be approved by the DAWE. Three hygiene zones are in place at site and details entry, equipment and PPE requirements in each. Procedure captures where warehouse staff store personal items and lunch.
Equipment is to be kept clean and maintained, refers to the cleaning procedure 3.12 and maintenance procedure 3.8 for equipment requirements.
Further controls of GMP are via procedures; 3.6 Pest Control, 3.5 Waste Management, 3.3 Personal Hygiene, 3.4 Storage Procedure, 3.11 Allergen Control Procedure and work area SOPs.
All raw materials and finished products are to be fully enclosed, any damaged product is to disposed of. Controls are in place for introducing packing or raw materials into staging- outer packaging on raw materials is removed or cleaned. Only human food product is produced at site.
Doors, positive air pressure and air locks in high and medium risk areas are in place to prevent air born contamination. No animals are permitted at site. Compressed filtered air is used, not for direct contact with product, maintenance manages air filters.
Tools are to be stored in designated containers
Procedure defines requirements for glass, soft and hard plastics, wood and metal.
Cleaning chemicals are to be approved for use, stored in designated area, staff are trained in chemical handling and are to follow cleaning procedures/SOPS/schedules.
Tools used daily are kept in the work areas in designated containers.
Maintenance / contractors also bring tools into these areas but are checked for condition and cleanliness before and after use, the work area is also checked for debri and cleanliness.

Products are to be stored off the floor- applies to raw materials and finished products.
Stock transfers are recorded for product moved between both GMP sites.
Export product us transferred using approved suppliers, department seals are currently not required at site.
Site uses FEFO for stock rotation, the computer warehouse system manages this via the batch number.
Sighted GMP templates; QAF064, QAF062 and QAF063.

FSM 3.3 Personal Hygiene requirements sighted; covers health, handwashing and hygiene requirements of staff and visitors. General overview of uniform and PPE requirements is included. Uniforms and PPE are checked before use to ensure they are fit for use. QID and CAPA to be followed for any breaches of personal hygiene requirements.

See training element for details on GMP training.

SOPPRO013 Gowning Procedure sighted, captures procedures for adorning uniforms/PPE when entering and existing production/packing areas.

FSM 3.4 Storage reviewed, details procedure relating to storage of raw materials and finished products at site, daily and monthly monitoring occurs to determine compliance to the procedures. Details storage requirements of raw materials and finished products from time of receival to dispatch, all dairy products are pasteurised and received from Department registered establishments with transfer certificates. Corrective actions for damaged or quarantined stock is detailed Storage requirements of packaging, chemicals for cleaning, maintenance and pest control are documented.

FSM 3.11 Allergen Management Procedure reviewed, procedures for control of allergens at site, various allergens at site, specific storage, labelling and handling controls are in place for allergens except dairy, as dairy is the main allergen in products at site it is not treated as an allergen product. Risk matrix of allergens is in place, processing and cleaning procedures are in place for allergen and non-allergen products, verification is via ATP & environmental swabbing and product testing.

This element is non-compliant due to the following findings

Findings:

FSM 3.1 areas that require addressing:

- Corrective actions for GMP audits dont capture preventative actions or reference to SOP QA 008 Internal GMP Audit.
- Amenities are only referenced as being separate to the storage area, does not cover where they are.
- Unclear where production and packing staff lockers are. Clarify if production and packing staff store lunch in the staff kitchen.
- Section 9.11 doesn't refer to product that is damaged being isolated or held or following corrective action procedures.
- Dropped product procedure is not clearly articulated states- 'will be disposed transferred to designated area for review by QA, prior to disposal immediately. Also, doesn't detail if the product goes on hold while awaiting assessment or if other actions are required.
- Permitted items in production and packing are not clearly defined under foreign matter section.
- Is there a record kept to show the line or equipment has been cleared after a maintenance intervention?

FSM 3.4 Storage Procedure findings.

- Procedure has contradictory statements about storage requirements; Section 9.1 paragraph 3 details how some products require temperature control, paragraphs 5 then states no products or ingredients require temperature control, section 9.2 details different temperature requirements as well.
- No details have been included for storage of export vs. domestic product.
- Procedural section of the document doesn't make reference to non-conforming product or CAPA procedures- should reference them for further details.

3.11 Allergen Control Procedure findings;

- Scope section only refers to the warehouse, not production and packing areas
- Under storage and handling (dot point 2) it refers to a pink label for allergens, but in the table it states orange.
- Provide allergen validation data for each product line/area

FSM 3.3 Findings:

- Scope only refers to the warehouse, not production and packing areas
- Doesn't reference FSM 3.1 or reflect PPE requirements per hygiene zone, or personal effects as per FSM 3.1
- No reference to contacting the Department in the event staff have a reportable illness and export product is affected.

- Procedure states an informal assessment is completed on uniform and PPE fitness for use- need a formal assessment as evidence it has been carried out.
- Lacking details on footwear requirements, only states they are provided and to be stored, or covers are provided.
- Monitoring of GMP compliance doesn't include reference to preoperational inspection or GMP audits.

SOPPRO013 Gowning Procedure findings:

- This procedure is not reference in either FSM 3.1 or 3.3.
- Procedures in this SOP do not align with zones or clothing requirements in FSM 3.1 or 3.3. For example the SOP refers to 2 zones, while FSM 3.1 refers to 3 zones.
- Unclear is the SOP applies to the warehouse staff and packing areas.
- Section 6.6 requires review to details exact requirements for entering and exiting all zones listed.
- Further details on when/where PPE, boots are changed, stored, and cleaned is required – refeence to procedure on wall is not acceptable.
- Section 6.7 States uniforms are to be placed in the storage unit if leaving area temporarily, but then states if unform is clean to place in locker. Under FSM 3,1/ 3.3 only personal items are to be in lockers.

9. HACCP	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

The establishment has the following HACCP supporting documents in place;
FSM 2.02- HACCP Team – details persons at site who are part of the team, roles, experience and training are detailed. s. 22(1)(a)(ii) is the HACCP Team Leader.
FSM 2.03- HACCP Supporting Information – provides an overview of products produced at site and summary of hazards. New products are to be reviewed by the HACCP team and approved by the NSWFA or DAWE. Information details how hazard significance is determined via a risk matrix and a CCP decision tree is documented to be used.
FSM 2.04- Food Ingredient and Packaging Hazard Analysis – details hazards for ingredients and packaging used at site.
FSM 2.05- HACCP Verification Schedule- details HACCP verification activities at site, covering elements such as review of records, HACCP review, testing of product and environmental sources and more.

The establishment stores and processes blended dairy powder products, as well as transfers/receives products from their second site (Girraween). All dairy and eggs ingredients supplied and used at site are pasteurised and dried by approved suppliers.

4 HACCP plans in place for export related products are:
FSM 2.1.1-2.1.4- Dairy Products- covers receivals, storage and dispatch of packed dairy products
FSM 2.2.1- 2.2.4- Repacked Dairy products- covers repacking of dairy product powders into bottles/ sachets
FSM 2.3.1-2.3.4- Milk Dice Freeze Dried Products- covers processing of freeze-dried milk-based products with additional ingredients
FSM 2.4.1-2.4.4- Freeze dried yoghurt-based products- covers processing of freeze-dried milk yoghurt powders, with or without fruit/flavours.

As part of this desk audit the HACCP plan 2.3.1-2.3.4- Milk Dice Freeze Dried Products was reviewed.

- 2.3.1 Product Description and intended use- Milk Dice Freeze Dried Products – details cooking a blend of products with milk powder, anhydrous milk fat, egg, colours and flavours, product is aerated and freeze dried. Both milk and egg products used are pasteurised, the water activity of finished product is no more than 0.83. Product is packed into sachets and deemed ready to eat for general population, notes not for persons who are allergic to dairy and eggs.
- 2.3.2 Process Flow Chart - Milk Dice Freeze Dried Products- captures steps from receivals to dispatch/delivery, CCPS and RCPS detailed. Some inputs and output points are noted.
- 2.3.3.3.3 Milk Dice Freeze Dried Products- Hazard analysis- general hazards and hazards specific to the processing of milk dice freeze dried products has been documented, hazards identified into biological, physical, chemical, regulatory, traceability, hazards are risk rated, control measures listed and if a CCP or not has been described.
- 2.3.4- Milk Dice Freeze Dried Products- HACCP audit table- CCPs and RCPs identified and reflect the flow chart and hazard tables- hazard, control, critical limit, monitoring, records, corrective actions detailed.

- RCPs/CCPS across flow chart, hazard and HACCP audit tables align.

This element is non-compliant due to the following findings.

Findings:

FSM 2.02 HACCP Team-

- s. 22(1)(a)(ii) is listed as the QA Team Leader whereas the Organisation Chart lists s. 22(1)(a)(ii)
- Qualifications of staff are not consistently listed in the HACCP team table. For example: s. 22(1)(a)(ii) has an engineering degree as mentioned in the procedure but is not included in the table.

FSM 2.03- HACCP Supporting Information

- Does not capture if products produced at site are all GMP Pharmaceutical products or if contract packaging is also conducted at site- further details on scope and purpose required.
- Does not clearly detail that site is handling/processing product for domestic and export markets.
- Processing hazard section doesn't include repack product section.

FSM 2.04- Food Ingredient and Packaging Hazard Analysis

- Controls are detailed, but don't reference specific procedures/SOPs
- Hazard significance has not been determined for each hazard identified
- No reference to verification table 1.14a or HACCP verification schedule

FSM 2.3.1 Product Description and intended use- Milk Dice Freeze Dried Products –

- Shelf life of product states 24 months, whereas FSM 1.14 states products have a 12 month best before from DOM.
- Product description doesn't detail what species the milk is originating from
- Unclear if milk is still the main ingredient of this product – clarify with site.
- Doesn't state the destination markets/ countries
- Microbiological testing requirements do not reflect those in 1.20a
- Labelling sections doesn't refer to the relevant procedures for labelling, product identification and traceability or importing country requirements
- Final preparation and use states product is ready to eat, is the product required to be reconstituted with liquid ?

FSM 2.32- Process Flow Chart - Milk Dice Freeze Dried Products-

- Inputs and waste are not included at all relevant steps. For example; no rework has been noted (but FSM procedures refer to rework being used), no inputs of ingredients shown (food ingredients is shown as an unnumbered steps, sachets are shown as an output to step 5), waste output at step 14 (when product is held at correct temps the hazard table states is rejected)
- Air is an input, is this compressed air? And is it contacting product? FSM had noted air does not contact product.
- Flow chart is dated from 2019, has it been reviewed in 2020?

FSM 2.3.3 Milk Dice Freeze Dried Products- Hazard analysis

- No supporting document was reviewed that defines the key/legend code for types of hazards (with the exception of CCPs/CPs)
- Key: B – Biological hazard, C – Chemical hazard, P – Physical hazard, Q – Quality, T- Product Traceability (regulatory), R- Regulatory (other), SP – Support program, CCP- Critical Control Point, QCP- Quality Control Point, RCP - Regulatory Control Point. No-SP – Adequately covered by Support program.
- Hazard analysis only contains 31 steps, flow chart has 32 steps (missing label sachets in hazard table)
- Control measures do not consistently refer to a FSM procedure/SOP/Form- for example step 10 water hazard doesn't reference SOP QA0014 or 1.2, step 3 printed packaging hazard refers to Sop receivals, not SOPWHS002- recommend adding references to the procedures as well as the description of the control measure
- Step 11 Cooking doesn't reference a hold time, is this correct?
- Not all control measures may have been considered, for example: all steps- equipment/utensils hasn't considered maintenance activities, steps where temperature control is required haven't considered storage/calibration procedures, training not considered as a control for some hazards such as CCP points.
- CIP is referenced as a control measure for cleaning of the heat exchanger and buffer tanks, is there other equipment's/lines where CIP is used? No CIP information has been received- procedure or validation material- please provide.
- Some control measures for hazards have been recorded as 'refer to earlier steps' but no relevant step is named
- Step 8 in the hazard table is sanitise with wipes, whereas the flow chart is Sanitise UV tunnel
- Receivals steps refer to the GIN code, whereas 1.13 refers to the GIN and item code- is just he GIN code used for traceability.
- Step 25 in the hazard table is listed as xray, whereas the flow chart calls step 25 metal detection

FSM 2.3.42.3.4- Milk Dice Freeze Dried Products- HACCP audit table

- Step 1- RCP 2 details product will be rejected if export documentation is not received, whereas FSM procedures (e.g 1.10) indicate product will be used for domestic product.

- Recommend reference to SOPS or FSM procedures for corrective actions
- Justification of critical limits doesn't reference annual revalidation of CCPs

General HACCP and FSM findings:

- Verification table 1.14a or the HACCP verification table is not referenced in the HACCP plans provided
- It is unclear after review of the above HACCP plan and FSM procedures (1.20, 1.18, 1.13) if raw materials are placed on hold, labelled until inspection and testing is completed; HACCP plan states they are inspected and tested
- Water activity testing of product is not included in FSM 1.20a

10. Sampling and Testing	Compliant? (Yes / No/ NA-Not Assessed)	**No**

Summary of Findings:
Sighted FSM 1.2 Product Assessment, Inspection and Testing Procedure sighted, raw material, finished product and water testing requirements. Form QAF28 to completed for out of specification product. QA Manager or Technical officer reviews records relating to food safety, production, product, water and environmental testing.
An overview of testing is referenced, then refers to SOPS in place for testing of products, water, environmental testing; SOP QA0021 Sampling and Testing of Export Products, SOP QA0014 Water Quality Monitoring Programme, SOP QA0018 Environmental Monitoring Programme. All testing to be completed a NATA approved lab, only trained persons are to sample product. Any out of specification product is to follow SOP QA 0023 Out of Specification Procedure. Raw materials and finished products are inspected before and during production. Finished product testing is done to meet domestic and importing country/ customer requirements. Corrective actions detailed and include notification to the Department.
Quarterly allergen swabbing to occur, determine no presence of eggs
Air quality testing procedure are detailed, an annual positive air pressure check is completed by an external contractor. Establishment also completed air quality testing as well.

SOP QA0021 Sampling and Testing of Export Products reviewed- details microbiological testing requirements for export product.

FSM 1.20a Product Testing reviewed, captures domestic and export testing requirements (China and Hong Kong).

This element is non-compliant due to the following findings.

Findings:
The following findings have been noted with relation to FSM 1.2;

- Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager or technical Officer.
- SOP QA0021 is referred to as 'Sample and Testing of Dairy Goods' and 'Sampling and Testing of Export Products' in section 9.1.
- Section 9.3 details that raw materials are tested as per order requirements or Laboratory Sample Plan, but 1.20 a states raw materials are not tested routinely, only done of CoC or CoA is not received- procedures need to be clear and be aligned, ensure HACCP plan reflects this.
- Documents Enterobacteriaceae testing is completed as part of monthly environmental testing under SOP QA0018 Environmental Monitoring Programme, but SOP QA0018 supplied does not reference this testing.
- Several corrective action sections in the procedure, under different headings, processes do not always align between the section. For example; corrective actions for out of specification product is not clear if the product is placed on hold, only reference to product going on hold is for allergen affected product. Under section 6.0 is refers to Form QAF28 to completed for out of specification product, but then under section 9.5 it refers to QAF28 and QAF007, Corrective actions for allergen, salmonella and Enterobacteriaceae detections, but doesn't reference placing product on hold or corrective action/ non-conforming product procedures or forms.
- Persons who review the Sydney water quality report is not documented and the process for investigating issues with the report is not documented.
- Section 9.8 details environmental swabbing for salmonella and Enterobacteriaceae, but this is not documented in SOP QA0018 Environmental Monitoring Programme. Corrective actions are detailed but doesn't reference placing product on hold or corrective action/ non-conforming product procedures or forms.
- Allergens to be sampled as per QA0018 Environmental Monitoring Programme, but this programme when reviewed did not include allergen swabbing.
- Section 9.9 Air Quality testing doesn't refer to and reflect SOP QA0018 Environmental Monitoring Programme; different frequency, limits, sampling locations and corrective actions.

SOP QA0021 Sampling and Testing of Export Products does not reference contacting the Department for out of specification product.

11. Training	Compliant? (Yes / No/ NA-Not Assessed)	**No**

Summary of Findings:
FSM Training 3.2 reviewed, all staff to completed induction before commencing work, inductions covers workplace induction, food safety, employee responsibility, contamination. Further Sop training completed in; personal hygiene, GMP, gowning procedure. Staff to complete an attendance record at induction, once staff are competent the training matrix is updated. Further training is conducted per department area, this training is based on department SOPS. Each staff member will have a training plan in place, training plans incorporate, induction, GMP, HACCP, food safety and external/special training. A training matrix/ register is used to capture staff and training plans completed/in process. Training records are in use and are to include staffs competency assessment which is based on discussion, observation, execution or achieving 85% pass mark in a test. Refresh training on SOPS is to occur every 3 years or when changes occur, GMP training annually, additional training can be carried out as needed if deemed required. Procedure details export signatories will have knowledge of export, import country requirements, persons who are using Exdoc will also be trained.

This element is non-compliant due to the following findings.

Findings:
- Under the SOP training states staff will be observed and then deemed competent - unclear if this is occurring at induction and how competency is determined? Further on in Section 9.6 clearly details how staff are assessed, is this section applicable to induction as well?
- Sample of training matrix and or records not provided
- Training is completed by either; read only, read and understand, onserved, observed, testing/quiz- how is this determined for each SOP/training package?
- No details about how export signatories attain their knowledge in export, import country requirements etc is detailed.

12. Identification/Traceability & Recall	Compliant? (Yes / No/ NA-Not Assessed)	**No**

Summary of Findings:
FSM 1.14 Product Identification and traceability reviewed, all raw materials are assigned a traceable item code when received this is linked to the receival register, is a sequential number. The traceable item code is used for traceability via the companys stock system and for the production process. A GIN (goods inward Notebook) captures information on the product. Product is transferred once received to it's a designated area, colour coded labels are applied to signify product status. Details export and domestic product to be labelled and segregated. Non-export products have different names and codes. Stored and WIP products labelling requirements are captured. Batch numbers of raw materials are recorded on production and packing work orders (these are generated for each batch. Finished products are issued a manually generated batch number and best before date (12 months from date of manufacture), these are printed onto packaging, HW signifies Huntingwood site, work orders and packaging document confirm batch number/best before date, these are checked for each run. Rework is allocated a work order and rework form and checklist are to be used. Finished products are traceable via; best before date, batch number and production and packing work orders and documents. When products are dispatched, dispatch docket is generated, links to computer system and captures traceability of product.

FSM 1.19 Recall and Withdrawal procedure reviewed, covers process for all products to be recalled and withdrawn, includes notification to the department for export product.

This element is non-compliant due to the following findings.

Findings:
FSM 1.14 Product Identification and traceability findings:
Unclear if the GIN and the item code are the same and how are they are linked (section 9.1.1)
Unclear how the traceable item code, GIN, manual batch number and receival register are linked to computer stock system?
Raw material batch details are recorded on production and packing work orders, but where does the GIN/ traceable item code come into it?
Details export and domestic product to be labelled, but doesn't define how export product is labelled.
Procedure doesn't capture scheduling requirements of export and domestic product? How do you ensure that non export product doesn't cross over to export production?

13. Approved Supplier Program; Ingredients and Packaging	Compliant? (Yes / No/ NA-Not Assessed)	No

Summary of Findings:
FSM 1.22 Approved Supplier Procedure sighted, is supported by SOP QA0026 and Approved Supplier List. Only products on the approved supplier list are to be purchased. Procedures defines requirements for approval of suppliers for ingredients (dairy, non-dairy), packaging, service suppliers for maintenance, labs and chemicals. Procedure details the requirements for Australian and imported dairy ingredients suppliers (reflects requirements as detailed in FSM 1.10- see section 15. If products do not have enough documentation to show that it meets export requirements, then it is not used for export product. Eu supplier and product information must be met in order for the ingredients to be used not EU finished product. Dairy suppliers must also provide documentation such as: CoAs, Department Export Registration (or similar for imported product), HACCP certificate or equivalent, Supplier questionnaire. An annual review of suppliers occurs.

This element is non-compliant due to the following findings.

Findings:
Procedure doesn't capture process of routine monitoring of suppliers and goods at time of receivals, or non-conformance process for suppliers.
Approved Supplier Register/list and SOP QA0026 not provided.

14. Receiving and Dispatching Milk & Milk Products	Compliant? (Yes / No/ NA-Not Assessed)	No

Summary of Findings:
SOPWHS009- Dispatching Goods reviewed, covers steps when dispatch goods at site, see findings as below.

Sighted SOPWHS0002- Receiving Items covers steps when receiving goods at site, findings have been noted below.

See sections 13 15- Information on receiving and dispatching of product

This element is non-compliant due to the following findings.

Findings:

SOPWHS009- Dispatching Goods findings:
- Section 7.9 details checking of truck for dairy goods, but doesn't elaborate on what the checks are or if these are recorded
- Section 7.9 is the only part that references a transfer certificate, no specific mention of what checks are required for export product, should reflect requirements under FSM 1.10 and the HACCP plan. Product should be checked against the transfer cert/dec at time of dispatch.
- Unclear in the SOP if a dispatch checklist is completed
- Corrective actions and Non-conforming product procedures not referenced in the SOP

SOPWHS0002- Receiving Items:
- No reference to checking dairy products for export compliance is noted in the SOP, should reflect requirements in HACCP and FSM 1.10
- FSM 1.13 refers to a traceable item code being issue first then a GIN, but SOP just refers to the GIN- which is correct?
- Corrective actions and Non-conforming product procedures not referenced in the SOP
- HACCP plan reviewed refers to a receival checklist, but this SSOP doesn't not reference such as checklist.
- Is part b undertaken for all products received?

15. Transfer & Manufacturers Declarations of Compliance	Compliant? (Yes / No/ NA-Not Assessed)	No

Summary of Findings:
Reviewed FSM 1.10 Export Documentation Procedure covers roles and responsibilities in completing export documentation at site. Documentation and information is reviewed by eligible persons to ensure export documentation & importing country requirements are met, this includes; Completed & received Transfer certificates, decs of compliances, RFPs, Micor, CoAs, product testing results. Procedures define the requirements for export permit, health certificates and prohibited goods, and when these cannot be generated. Persons who can complete transfer certificates and declaration of compliance are detailed and are trained in the procedure.

Procedure details the requirements for completing and checking transfer certificates and declarations of compliance by eligible staff, as well as when they are required (at receival and dispatch).
Procedure details Australian dairy ingredients received are for domestic and export use, export product is required to have a transfer certificate and come from an export registered establishment, export product is labelled and segregated from domestic product. Requirements for Imported dairy ingredients are defined and include; must be registered, meet importing country requirements, provide COAs or health certificates. Only product that has documentation stating that it meets Eu requirements can be used in EU product. Additionally, if documentation is not sufficient to indicate product meets a specific importing country or general export requirements it is deemed not suitable for export- computer system and labelling will capture this information.

This element is non-compliant due to the following findings.

Findings:
No template has provided for transfer certificate or declaration of compliance.
Under section 9.3 if refers to checking the product has come from an export registered establishment, but not how it is done.
Section 9.4 is not clear when a transfer certificate is required or not; Girraween is referenced as not requiring a transfer certificate (dot point 1), but then requires one in dot point 2, dot point 2 is requires rephrasing (repeated wording)
Retention period is stated as 7 years for export documentation, this differs to FSM 1.9.

16. Importing Country Requirements	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

Sighted FSM 1.11 Importing Country requirements and FSM 1.11a Importing Country Requirements schedule reviewed.
FSM 1.11 references export products will meet export and importing country requirements, including China and EU. All products will meet export requirements and are deemed export until they are labelled domestic- both on the label and in the computer system. Importing country requirements is obtained when order is received, by review of Micor, department emails, market advice notices, contacting importing country customer and regulatory authorities. Products are checked to ensure they meet importing country requirements at the time a transfer certificate or declaration is to be completed, QAF056 Product HACCP Verification Form and QAF057 Export Documentation Checklist are completed.

FSM 1.11a reviewed, specific importing country requirements for China and Hong Kong.

Verification table 1.14a captures review of importing country requirements prior to shipment and or when changes have occurred.

This element is non-compliant due to the following findings.

Findings:
- Verification table 1.14 states importing country requirements are checked prior to shipment, but then states that it is completed as part of an internal audit in February- unclear if this is the one activity or two?
- 1.11 references EU exports and to review 1.11a for further on specific importing country requirements, on review of 1.11a no EU information is detailed. Only China and Hong Kong are detailed in 1.11a- please confirm importing countries, and if EU is one update procedures to include EU requirements.
- 1.11 states that EU production is not routine, but site will ensure EU requirements are met, Eu checklist to be completed- no EU checklist received.
- No reference to training in export or importing country requirements for staff is detailed in 1.11.
- Unclear if all raw materials and finished product are all export grade, on interpretation of 1.11 section 9.4 all products meet export requirements, unless theres documentation issue, whereas 1.10 details products when received are classed as export or domestic (section 9.3) , which depends on documentation received. So does the site receive all raw materials with export documentation from export registered establishments?

17. Loading of Sea and Air Freight Containers	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

This element is non-compliant due to the following finding.

Findings:
Unclear from evidence received if establishment is loading containers.

18. Department of Agriculture Seals	Compliant? (Yes / No/ NA- Not Assessed)	**N/A**

Summary of Findings: Not required at this stage for the establishment, as documented in FSM 3.1

Findings:
- Not Applicable

19. Pasteurisation	Compliant? (Yes / No/ NA- Not Assessed)	**n/a**

Summary of Findings:

Sighteed FSM 3.1 GMP it documents that all dairy and egg products received at site are pasteurised and HACCP plans also detail product is pasteurised by suppliers, CoA or CoC is to be received.

Findings:
Nil

20. Trade Descriptions	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
FSM reviewed 1.12 Trade Descriptions is in place, roles and responsibilities for checking and approving labels before use, as well as ensuring all goods (raw materials, finished products) are labelled during storage and use/production is described. A transfer cert/ dec of compliance is only generated and signed once it is in the computer system. Labelling requirements are detailed for export and domestic products, foreign translations for export product when required (China labels product must be approved by Chinese authorities)- Labels to be reviewed when changes occur or at least annually. SOPS are in place for printing labels & packaging.

FSM 1.12a Labelling Requirements details labelling requirements for product for retail and non-retail sale.

Verification table incorporates an annual review or review when changes occur for trade descriptions.

FSM 1.10 Export Documentation details that foreign language translation for labels/artwork are kept on file, are completed by a translator, each delivery is checked and logged onto QAF027.

This element is non-compliant due to the following finding.

Findings:
- Goat milk powder artwork provided, but doesn't list the Est1405.

21. Maintenance and Calibration	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

Establishment has FSM 3.8 Maintenance Procedure in place, covers scheduled (preventative) and unscheduled maintenance activities at site. Staff to report any issues with the plant/ equipment to manger/supervisor so that it can be addressed. Both planned and unplanned maintenance activities are recorded on either Preventative Maintenance Form (FDPM) or QAF-037 Maintenance Form. Procedure captures ensuring work area is checked before use to ensure it is cleaned and sanitised, no debri. The plant and equipment (including tools) are to be fit for use, kept clean and sanitised. Tool hygiene and reconciliation is checked as part of daily GMP audits or QAF-037. Repairs to plant or equipment's are risk rated in terms on priority- low to critical. Any major changes to the plant are to be approved by the department. FSM 3.9 Maintenance schedule is in place. Maintenance staff and contractors are trained in GMP and Hygiene requirements.

FSM 3.7 Calibration procedure sighted, covers equipment that is required to be calibrated at site and persons responsible, calibration register is in place and further details equipment calibration requirements. Equipment is to be labelled with calibration details, procedures are in place for when calibration fails- label not to use, repair, cease production if it relates to CCP. Calibrations can be completed by internal staff or external service contractors, the establishment retains records of calibrations. Overview of scale and thermometers calibrations is detailed. Sighted Calibration register.

This element is non-compliant due to the following findings.

Findings:
Findings to be addressed for FSM 3.8:

- Section 7 monitoring only refers to a monthly GMP audit in the Warehouse, no reference to thsi occurring in the production & packing areas.
- Procedure doesn't capture how equipment/fixtures are addressed to ensure they are fit for use.

Findings to be addressed for FSM 3.7:

- Scope only captures the warehouse, does not cover production and packaging areas, but these areas are mentioned later on in the procedure

22. Miscellaneous (Alterations & additions to premise & FSP since last visit, AA approval/conditions, Registration details, Exemptions, Outstanding Non-Conformances raised during the previous audit not previously closed out or required to be verified)	Compliant? (Yes / No/ NA-Not Assessed)	**N/a**
Summary of Findings: Not applicable this audit		
Findings: Not applicable this audit		

Additional items of Concern identified during the audit and not mentioned above:

- No additional items, all issues of concern have been documented above

Notes:

- Not all the elements identified in the scope of the audit determined prior to the visit were able to be looked at during this visit. Effective review of those elements that were audited during this visit took longer than anticipated and those elements not reviewed this visit will be included in the next bi-annual audit.
- It has been identified that the current day allocated to undertake verification of your approved arrangement is insufficient to effectively verify compliance with legislative and importing country requirements, as such future audits of your site will be undertaken over two consecutive days for each of the Bi-Annual audits undertaken over the year.

Observations:

- All observations (where applicable) have been included in the report above

Non Compliances:

- Where a non-compliance has been documented in the report above, the information provided in the findings "as evidenced by" are those items identified that support why the element has been found non-compliant. It is not necessarily exhaustive and is not an itemised "to do" list, rather examples to support why a program/element is not effective. The expectation is that the non-conformance will be thoroughly reviewed to determine the root cause and actions taken to address both the root cause to why it happened as well as rectifying the "finding" (where applicable) and verification to ensure the failure does not re-occur.
- If you require further clarification please contact myself or in my absence dairy@agriculture.gov.au

Australian Government
Department of Agriculture

Department of Agriculture: Food Program (Dairy) Bi-Annual Approved Arrangement Audit Report

Company:	GMP Pharmaceuticals PTY LTD		
Audit Location:	60 Huntingwood Drive, Huntingwood, NSW, 2148		
Compliance standard:	• Export Control (Milk & Milk Products) Orders 2005 • Export Control Act 1982 • Export Control (Prescribed Goods - General) Order 2005 • Establishments Approved Arrangement • Importing Country Requirements		
Auditee Representatives:	s. 22(1)(a)(ii)- QA Team Leader , s. 22(1)(a)(ii) Site Manager, s. 22(1)(a)(ii)- Senior QA Associate.		
Establishment No:	1405	**Audit Dates:**	01-05, 16-17/02, 19/02-2021
Lead auditor:	s. 22(1)(a)(ii) (DAWE)	Additional audit team members:	Nil

Total Audit Time: For charging purposes (if applicable) * Report writing time is also charged and will be included in the invoice issued	Audit Time: 16 hours Report Writing: 1.00hr	01.02.2021:4 hrs
		02.02.2021: 4hrs
		02.02.2021: 4hrs
		03.02.2021: 5hrs (includes 1hr reporting)
	Audit Time: 14 hours Report Writing: 2.00hr	16.02.2021: 5.45hrs (on and off-site)
		17.02.2021: 8.15hrs (on and off-site)
		24.02.2021- 2hrs

Auditor Name: s. 22(1)(a)(ii)		**Signature:** s. 22(1)(a)(ii)	
Date Report Issued:	5th February 2021 24th February 2021	**No# of Non-Compliances Issued This Audit:**	**80+**
No# NC Closed out from Previous Audit:	**n/a**	**No# of Non-Compliances Re-Issued:**	**n/a**

Additional Information (where applicable) can be found at the end of the report

Audit Scope and Objectives:

The audit of Est1405 was carried out via a combination of desk audit and site audits, adhoc meetings, dates and scope covered are detailed as below.

The scope of the desk audit on 01-05/02/2021 included review of the following AA elements:

- Review all applicable 21 elements of the food safety program of GMP Pharmaceuticals for approval as an export registered establishment with the Department of Agriculture for dairy powder products.
- GMP Pharmaceuticals is seeking approval as an export registered establishment with the Department of Agriculture, Water and the Environment (DAWE) for the production of Dairy Powder Products- repacked dairy powder, freeze dried dairy and yoghurt products.

16-17/02/2021- a site audit was conducted to confirm process, structure, equipment and hygiene. A review of the desk audit findings also occurred. The establishment was only packing freeze dried yoghurt sachets at time of audit, freeze dry production and milk repack production-packing was not occurring, another site audit is required to further review the production and packing.

A review of additional evidence has occurred over adoc dates, dates of such reviews are noted in the summary of findings/ and findings as below.

Summary of findings:

As of 05.02.20201 the food safety program reviewed does not currently meet all the requirements of the Export Control Milk and Milk Products Orders 2005. Those items required to be further actioned, amended or strengthened are detailed below (as noted in red writing, blue highlight sections are for further questioning).

After the site audit conducted on 16-17/02/2021 the food safety program reviewed does not currently meet all the requirements of the Export Control Milk and Milk Products Orders 2005. Items required to be further actioned, amended or strengthened are detailed below in red-yellow highlight from this visit. Any findings that have been actioned and closed have been noted as so in green, previous desk audit findings noted in red are still to be addressed.

Audit Outcome: Acceptable? Not Acceptable?	Not Acceptable

1. *Management Practices* **2.** *Internal Audits, Corrective Actions* **3.** *Plans & Specifications* **4.** *Cleaning* **5.** *Water*
6. *Pest Control* **7.** *Protection, Segregation & Waste* **8.** *Protective Clothing, Premise Construction, Hygiene and GMP/GHP*
9. *HACCP* **10.** *Testing* **11.** *Training* **12.** *Identification/Traceability & Recall* **13.** *Approved Supplier*
14. *Receiving & Dispatching* **15.** *Transfer & Declarations of Compliance* **16.** *Importing Country Requirements*
17. *Loading of Sea and Air* **18.** *Seals* **19.** *Pasteurisation* **20.** *Trade Descriptions* **21.** *Maintenance and Calibration*
22. *Miscellaneous*

Approved Arrangement Elements Audited

1. Management Practices, Commitment to Food Safety and Records	Compliant? (Yes / No/ NA-Not Assessed)	**No**

Summary of Findings:
The Declaration of Occupiers Commitment (FSM 1.5) sighted and details meeting export, importing country requirements and domestic requirements, Group CEO is responsible for signing. FSM 1.4 Food Safety and Quality Policy further details that the establishment will meet export and domestic requirements, Group CEO signs. FSM 1.4 also details that an annual management review is to occur.

Organisational structure is documented in FSM 1.6 sighted, showing staff from Group CEO to floor staff. Position descriptions are documented in FSM 1.7 for both the Huntingwood and Girwaween sites.

Management review procedures FSM 1.16 reviewed, annual review to occur, attendees and agenda items detailed including export requirements, management review meeting minutes are taken and filed, actions are assigned to attendees where required.

Document control procedures sighted in FSM 1.9, details process for approving new documents and amending current in use documents, includes seeking approval from the Department (DAWE- Department of Agriculture, Water and The Environment) for changes relating to export, importing country requirements or may affect the products integrity or fitness for human consumption. Master document list, amendment register and version control used to track documents. Retention period and persons who can amend/create and approve documents are detailed.

This element was found to be non-compliant due to the following findings.

Findings:

1. FSM 1.5 Declaration of Occupiers Commitment and FSM 1.4 Food Safety and Quality Policy supplied are not signed and dated by the Group CEO.
2. The QA Associate is held by a different person in the organisational structure FSM 1.6 issue date October 2020 versus the FSM 1.7 Position descriptions issue date October 2020
3. It is unclear who has the main role in overseeing and management of the AA (FSM) as multiple QA roles are in place at the Huntingwood site, for example there is QA Team Leader and Senior QA Associate at the same level in the organisational chart.
4. Positions description titles in FSM 1.7 do not consistently state which site the role is at, the Organisational structure 1.6 clearly shows two sites.
5. Documentation retention period varies between procedures. For example in FSM 1.9 it states 3, 4 and 5 years, FSM 1.15, 3.12 details 4 years.
6. FSM 1.9 states that the QA Manager or delegate manages this procedure, whereas the organisational chart for Est1405 doesn't have a QA Manager.
7. 17.02.2021- further discussed management review procedures at site. Management review procedure FSM 1.16 does not clearly describe that management review is conducted done 6 monthly as per the verification schedule and the annual management review internal audit is conducted as per QAF045- Internal Audit Schedule.

2. Internal Audits and Corrective Actions	Compliant? (Yes / No/ NA-Not Assessed)	**No**

Summary of Findings:

Internal audit procedure 1.15 reviewed, details process for external and internal audits (GMP and Non-GMP audits). GMP audits are conducted as per SOP QA 008 Internal GMP Audit. Non-GMP audits are done as per the internal audit schedule/ Verification schedule 1.14a. Compliance to the audit is to be recorded on the internal audit summary, objective evidence to be captured on documents being audited or on internal audit summary. Form49 Internal audit summary report is used to document the audits findings, corrective and preventative actions. Corrective actions procedures are detailed for when immediate action can be taken or not. A corrective action report and following the corrective and preventative action procedures are detailed. For external audits a person from management will accompany the auditor/s, a quality incident form QAF007 and corrective and preventative actions are to be taken.

Internal audit checklist QAF017 and QAF009 Internal GMP audit form templates sighted.

Internal audit schedule QAF045 reviewed details audits conducted over the calendar year.

1.14a Verification schedule sighted and details internal audits to be completed on activities such as; quality system documents, corrective action and non-conforming product procedures, HACCP, importing country requirements, trade description, approved suppliers.

SOP QA 008 Internal GMP Audit sighted and reviewed covers internal audit requirements and process of completing systems and spot audits.

FSM 1.17Corrective and Preventative Action (CAPA) Procedure reviewed, capture processes for internal and external non-compliances. External non-compliances have CAPA and QID (quality incident deviation) form completed. Internal non-conformances follow CAPAs as per HACCP, if action can be taken immediately it is done so and recorded on the relevant monitoring form, if not CAPA and QID completed. Notification to the Department of QIDs is documented. CAPA process includes logging of incident into QID register, completing QID from and investigations, determine products status, determining corrective and preventive actions, timeframe for completion, verifying actions are acceptable, QID can only be closed once actions have been deemed acceptable, QA Manager to close, monthly review of QID occurs, QID maybe extended if a plan is in place to address and no food safety risk is present. If there is a risk to food safety or quality then immediate action must be taken to correct the non-compliance, non-urgent issue have up to 1 month for actioning.

17.02.2021 sighted Internal Audit Summary Report QAF036 for 27.01.2021- GMP Area and Pest control monthly audits for Jan 2021- CAPA 21001 raised for pest control sightings in January, closed 05.02.2021. Sighted 22.12.2020- IA on SOPQA0019 Receiving, SOPQA0021- Sampling and Testing of Dairy Goods- FSM 1.11 Importing Country requirements, FSM 1.10 Export Docs, FSM 1.12 Trade Description - QAF036 and QAF0017 completed. Also conformed with site that they undertake systems audits which are scheduled, and monthly GMP audits and spot audits. Spot audits are adhoc, are conducted during process and use IPQC forms.

This element was found to be non-compliant due to the following findings.

Findings:

The below findings have been identified for;

FSM 1.15:

1. Does not consistently describe forms and reports used as part of the internal audit process. 17.02.2021- discussed with site, site is using QAF036 as the Internal audit summary and QAF017 for the Internal Audit checklist.
2. Corrective and preventative procedures for external audits do not describe the CAPA process.
3. 17.02.2021 – on review of the Internal audits on SOPQA0019 Receiving, SOPQA0021- Sampling and Testing of Dairy Goods- FSM 1.11 Importing Country requirements, FSM 1.10 Export Docs, FSM 1.12 Trade Description no supporting evidence to show that procedures had been checked against process and or current requirements was documented, QAF017 did not capture Export documentation procedures.

SOP QA 008 Internal GMP Audit:

4. Does not describe GMP audit frequency, process, and how non-compliances are determined and actioned. 17.02.2021- discussed audit process with site, systems audits done as per QAF045, GMP audits done monthly, and spot audits are adhoc.
5. Monthly GMP audit forms have been provided, these forms are not captured in this SOP (QAF062, QAF063, QAF064)

Internal audit schedule QAF045:

6. Doesn't capture all elements of the AA including; importing country requirements, trade descriptions, HACCP, approved suppliers, the schedule also doesn't reflect internal audits referenced in 1.14a. 17.02.2021- CLOSED- clarified with site, QAF045 lists audits as an overview, SOP QA008 further details what is covered under each audit.

7. Verification procedure 1.14 not provided for review. 17.02.2021- CLOSED.- verification procedure FSM 1.14 reviewed and captures verification activities at site including review of importing country requirements, trade description and those as per 1.14a.

3. Plans & Specifications	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

01-05.02.2021- This element non-compliant at present due to plans not being finalised.

16.02.2021- reviewed under SMF001- Section 3.2- includes overview of site layout of process, packing and warehouse areas. Plans then split per production/packing area for; freeze dry goods processing and packing (milk powder packing under this chart), powder and sachet line flow chart for processing and packing (still under construction), tablet lines, chem and micro labs, warehouse. Plans show entry/exit points, product flow, raw materials entry points, equipment locations.

Plans sighted for shows water lines; cooling return line, cooling supply line, cold water, compressed air dated 05.09.19, Drainage plan map: 12.09.18- shows drain lines, vents and air service lines, Sewer Service diagram- 06.11.19- shows all sewer lines at site.

This element is deemed non-compliant due to the below finding;

Findings:

1. Plans provided do not clearly identify water inlets points, drains inlets, HEPA air outlets/inlets for all of site.

4. Cleaning & Sanitising	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

Sighted Cleaning and sanitising procedure FSM 3.12, covers all of site, daily pre-operational inspection to be completed. Cleaning effectiveness verified by in- house ATP swabs, monthly environmental swabbing, quarterly allergen swabbing and finished product testing. Production and Warehouse Manager or delegate are responsible for monitoring the effectiveness of cleaning daily. General overview of cleaning procedure and chemicals detailed. Cleaning equipment is colour coded for work area/equipment's, storage and cleaning requirements for cleaning equipment is detailed. Covers an overview of cleaning required and frequency, as well as monitoring.

SOP PFD013 General Cleaning procedure reviewed- provides cleaning procedure for bulk production, staging, packing areas for Freeze dry product.

FSM 3.13 Cleaning Schedule reviewed- captures areas of site to be cleaned and sanitised, frequency, chemicals to be used, how to clean, persons responsible and recording form.

FSM 3.14 Cleaning and Approved Chemicals List sighted- details chemicals at site, usage, SDS on file, allergen status and where stored.

SOPQA0018- Environmental Monitoring Procedure reviewed- details air monitoring and environmental swabs to be taken, temperature monitoring, sampling maps are included. Air monitoring to be completed monthly, limits, how to sample and corrective action requirements detailed. Listeria swabbing to be done monthly from a direct and non-direct contact surfaces, sampling process documented, sent to external lab for analysis. Corrective actions for positive listeria detections documented, includes- intensive clean, testing product, raising CAPA, notify NSW Food Authority, customer, instigating clearance programme.

FSM 3.5 reviewed and details that chemical containers are not to be used for any other purpose and are checked at receival to ensure that they are not damaged, labelled and clean.

QAF040 reviewed.

Sighted SOPPFD019 Portable CIP Machine Procedure sighted and is in place and used for hard to clean equipment such as the heat exchanger.
This element was found to be non-compliant due to the following findings.

On 11/02/2021 The establishment provided SOPS (SOPFPD030, SOPPK001) and checklists(forms- PRF001, PRF002, PRF028, PKF018) for Line Startups and clearance, these are to used be before starting assembly of equipment and materials and before starting manufacturing. SOPS detail procedures such as checking areas/equipment are clean,

documentation/tags completed, product-packaging is removed, forms are used to verify rooms are acceptable and ready for use. SOPQA0031 Operation of Hygiena Ensure Touch- documents procedures for use ATP swabs and the acceptable limit.

A site audit occurred on 16-17/02/2021, a walk through of the premises occurred within the warehousing, freeze dry production & packing, milk repack, staff amenities areas, the facility was found to be clean and tidy, no waste overflow or product buildup/spills noted, unused equipment, production/packing rooms, warehousing, amenities, change room areas were visibly clean. Signage of rooms was also in use to show that they had been cleaned. Further discussion on cleaning procedures and monitoring occurred, the establishment uses cleaning and room usage logs, signage, prestart clearance checklist and forms to capture cleaning conducted. Cleaning chemicals were stored away from product, and colour coded cleaning equipment and signage was noted with production and packing areas. The establishment has SOPS in place for equipment use and cleaning, a sample of SOPS reviewed included. SOPPFD003- Cooking Machine Standard, SOPPRFD014- Freezer and Freeze Dryer Cleaning and SOPPFD025- Powder Mixer Liquid. PRF009- Production Cleaning Validation sighted at 16.02.2021- done after cleaning and includes ATP swabs-

This element has been non-compliant due to the below findings;

Findings:

The following findings have been noted for each document reviewed:
FSM 3.12:

1. No frequency is documented in FSM 3.12 for ATP and finished product testing. 16.02.2021- site advised this occurs after cleaning or change of product.
2. Section 9.5 of procedure 3.12 refers to a cleaning schedule at the end of the document, but no schedule is included in 3.12.

SOP PFD013 General Cleaning procedure:

3. Chemicals to be used in the SOP do not align with FSM 3.13. For example Triple S is to be used in the bulk storage area within the SOP, whereas FSM 3.1.3 refers to Ultramax.
4. Unclear if SOP PFD013 General Cleaning procedure is the only SOP for cleaning. 17.02.2021- CLOSED- site confirmed SOPS are in place for equipment use and cleaning, sighted SOPPFD003- Cooking Machine Standard, SOPPRFD014- Freezer and Freeze Dryer Cleaning and SOPPFD025- Powder Mixer Liquid, SOPS either covered cleaning, or cleaning and use of the equipment.

FSM 3.14 Cleaning and Approved Chemicals List:

5. Does not include Triple S or 70% Alcohol
6. Does not show location of chemicals in dishwasher area

SOPQA0018- Environmental Monitoring Procedure:

7. Under listeria swabbing it refers to QAF040 for when areas are to be swabbed, on review of QA040 it doesn't detail when areas are to be swabbed. 05/02/2021- CLOSED establishment confirmed that QAF040 is the correct form, location swabs are coded E,F -listeria swabs, A and B settle plates, the legend code is included in SOPQA0018.

8. Procedures provided have not captured what CIPS systems are used at site. 05/02/2021- clarified with site, the only CIP system is for the cooking tanks only. Moulds are cleaned via dishwashing system- site to send validation data through for both.

SOPPFD019 Portable CIP Machine Procedure— not used anymore- CLOSED

9. validation data to be provided for this unit, must capture each piece of equipment or process line it is used on
10. SOP doesn't include any monitoring or verification checks on equipment/process lines after using the portable unit
11. FSM 3.13 Cleaning Schedule only refers to use of this on the cooking tank system- unclear if this includes the heat exchanger. No heat exchanger is noted in the HACCP plans.

FSM 3.13 Cleaning Schedule

12. Unclear if the air lock and ante room are the same area? Air lock is an areas where you pass between warehouse and packing/production, ante room= change rooms. 05.02.2021- Site clarified that the ante room = change room. And cleaning is done daily and weekly.
13. Ante room and bins are to be cleaned monthly on the schedule- frequency may not reflect use of area.- Bag is changed daily, bin cleaned weekly. 05/02/2021- Site clarified that the bins have bags, these are changed daily or when full, cleaning of bin is weekly. NC closed.

14. Procedures provided do not capture how compliance is determined after cleaning via a preoperational inspection, does another procedure capture this? 05/02/2021- clarified with establishment via teams meeting, line startup and clearance procedure and checklists are in place, site to provide. 11/02/2021- establishment provided line startup and clearance SOPS and checklists- SOPS (SOPFPD030, SOPPK001)

and checklists(forms- PRF001, PRF002, PRF028, PKF018) however these procedures have not been included in FSM 3.12 for use.

15. No reference to ATP swabs being undertaken after cleaning is documented in any procedure provided. 11/02/2021- SOPQA0031 Operation of Hygiena Ensure Touch provided for review does not detail when ATP swabs are to be done, where results are recorded, corrective actions only capture reclean and reswab- no further actions detailed if failure still occurs. 16.02.2021- site advised that they redo until result ok, procedure does not capture process for when multiple failures occur.

5. Water Sampling	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
Sighted FSM 1.2 Product Assessment, Inspection and Testing Procedure- covers general overview of testing done at site, including water. Water at site is potable, supplied by Sydney water, Sydney water monitors chemical and physical testing against the ADWG. The quarterly Sydney Water Quality report will be reviewed, issues with chemical and physical parameters will be investigated. Monthly ecoli testing of water occurs at site.

SOP QA0014 Water Quality Monitoring Programme reviewed, one sample per calendar month is taken, tested for Ecoli at NATA lab, sampling process defined, water sampling map and sample location list is included, corrective action documented for out of specification results covers notification to the department and investigations. Site obtains the annual Sydney water quality report or completes the testing if the report is not available.

This element is non-compliant due to the following findings.

Findings:
The following findings have been noted with relation to:
FSM 1.2;

1. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager or technical Officer.
2. Persons who review the Sydney water quality report and the process for investigating issues with the report is not documented.

SOP QA0014 Water Quality Monitoring Programme:

3. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager.
4. Sampling states one sample per month, rotating through the location list table 2, however there are > 12 samples. 05/02/2021- establishment confirmed that they are completing all test points each month, SOP to be updated to reflect this, site to resubmit.
5. SOP QA0014 details that the annual Sydney Water quality report is obtained, whereas FSM 1.2 states the report is reviewed quarterly. 05/02/2021- site confirmed that they are conducting both activities. NC CLOSED
6. Retention period of water quality records is 7 years, this differs to FSM 1.9. 05.02.2021- site confirmed it should be 3 years, procedure to be updated.

6. Pest Control	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
FSM 3.6 Pest Control Procedure sighted, monthly external services by a pest control technician are carried out, additionally staff are to report pest sightings, these are entered into the pest control log and a monthly Warehouse GMP audit is conducted. Procedure details hygiene and maintenance requirements to ensure compliance to pest control. FSM 1.18 Control of Non-conforming product is to be instigated if product is affected with pests. Recommendations from the pest control technician are to be actioned by the site.
Pest control service requirements are defined, including target pests/vermin. The technician conducts routine services and treatments, including actioning any issues noted in the pest sighting log, a pest control manual is on place that contains SDS, licences, bait station map.

A site audit walk through occurred on 16.02.2021 within warehousing, amenities, production and processing areas, no pest and vermin issues were noted. Pest and vermin controls are located outside of the production and processing areas. Sighted bait stations within the warehouse area and building perimeter. Doors into the facility were closed when not in use, air locks (rapid doors) and personal doors are in place and are sealed/closed after use.

This element is non-compliant due to the following finding.

Findings:

1. Section 7 does not include GMP audits for the production & packing areas.

7. Protection, Segregation, Waste and Other Products	Compliant? (Yes / No/ NA-Not Assessed)	**No**

Summary of Findings:

FSM 3.5 Waste procedures sighted, GMP audits and cleaning to be conducted to ensure compliance to waste procedures. Waste is to be identified and separated from food product. Procedure captures requirements for handling and hygiene requirements of solid (recyclable and non-recyclable waste) and liquid waste. Non-conforming product is to be clearly labelled as so.

See section 4 for information on chemicals.

Refer to sections 8 and section 12 on product handling and identifications.

FSM 1.18 Non-conforming product procedure reviewed, details process of identifying non-conforming product/equipment/material and process of determining disposition of them, notification to the department has been included. Process includes isolation, labelling of affected product and placing on hold in the computer system so that it cannot be used.

A site audit walk through occurred on 16.02.2021, product and packaging within the warehouse areas was sighted to be labelled and contained in packaging. Waste bins were noted within the sachet packing room, and were separated from product, external kin bins for waste were sighted outside the milk repack area, were labelled and no overflow was noted. Raw materials and finished products were labelled and stored in areas for quarantine and final release, labels were in place to reflect status of these products. WIP sachet product was sighted in the freeze dry production & packing areas in labelled and covered tubs. Chemicals storage was separated from the product in the warehouse and dishwashing room. Products (raw materials, finished products) and cleaned equipment were stored off the floor and covered.

This element is non-compliant due to the following findings

Findings:

Findings for FSM 3.5:

1. Section states no rework, however FSM 1.13 details rework is used at site. 16.02.2021- site confirmed no rework at site, all goes to waste.

Findings for FSM 1.18 Non-conforming product;

2. Refers to the title of a QA Manager, but no role is listed in the organisational chart or position descriptions for Est1405.
3. Procedures to be followed for product being processed or received is not clearly defined. 05/02/2021- site confirmed that it WIP and received product follow the same process, procedure to be amended to incorporate reference to WIP and received product.
4. Does not include procedures for handling non-conforming export products.
5. Procedures provided no not include how and if export product will be processed differently to domestic product.
6. For additional findings see element 8 below
7. 17.02.2021- no operations were occurring in the freeze dry production area and the milk repack production- packing area at audit, further review of these areas is required to further verify compliance to this element.

8. Protective Clothing, Premise Construction, Personnel Hygiene and GMP/GHP	Compliant? (Yes / No/ NA-Not Assessed)	No

Summary of Findings:

FSM 3.1 GMP procedures reviewed, covers production, packaging and warehouse areas as follows;
Monitoring of GMP occurs via daily GMP inspections and cleaning, and monthly GMP audits. Major changes to the premises are to be approved by the DAWE. Three hygiene zones are in place at site and details entry, equipment and basic overview of PPE requirements in each. Procedure captures where warehouse staff store personal items and lunch. Refers to FSM 3.3 for details on Personal hygiene and PPE.
Equipment is to be kept clean and maintained, refers to the cleaning procedure 3.12 and maintenance procedure 3.8 for equipment requirements.
Further controls of GMP are via procedures; 3.6 Pest Control, 3.5 Waste Management, 3.3 Personal Hygiene, 3.4 Storage Procedure, 3.11 Allergen Control Procedure and work area SOPs.
All raw materials and finished products are to be fully enclosed, any damaged product is to disposed of. Controls are in place for introducing packing or raw materials into staging- outer packaging on raw materials is removed or cleaned. Only human food product is produced at site.
Doors, positive air pressure and air locks in high and medium risk areas are in place to prevent air born contamination. No animals are permitted at site. Compressed filtered air is used, not for direct contact with product, maintenance manages air filters.
Tools are to be stored in designated containers
Procedure defines requirements for glass, soft and hard plastics, wood and metal.
Cleaning chemicals are to be approved for use, stored in designated area, staff are trained in chemical handling and are to follow cleaning procedures/SOPS/schedules.
Tools used daily are kept in the work areas in designated containers.
Maintenance / contractors also bring tools into these areas but are checked for condition and cleanliness before and after use, the work area is also checked for debri and cleanliness.
Products are to be stored off the floor- applies to raw materials and finished products.
Stock transfers are recorded for product moved between both GMP sites.
Export product us transferred using approved suppliers, department seals are currently not required at site.
Site uses FEFO for stock rotation, the computer warehouse system manages this via the batch number.
Sighted GMP templates; QAF064, QAF062 and QAF063.

FSM 3.3 Personal Hygiene requirements sighted; covers health, handwashing and hygiene requirements of staff and visitors. General overview of uniform and PPE requirements is included. Uniforms and PPE are checked before use to ensure they are fit for use. QID and CAPA to be followed for any breaches of personal hygiene requirements.

See training element for details on GMP training.

SOPPRO013 Gowning Procedure sighted, captures procedures for adorning uniforms/PPE when entering and existing production/packing areas.

FSM 3.4 Storage reviewed, details procedure relating to storage of raw materials and finished products at site, daily and monthly monitoring occurs to determine compliance to the procedures. Details storage requirements of raw materials and finished products from time of receival to dispatch, all dairy products are pasteurised and received from Department registered establishments with transfer certificates. Corrective actions for damaged or quarantined stock is detailed Storage requirements of packaging, chemicals for cleaning, maintenance and pest control are documented.

FSM 3.11 Allergen Management Procedure reviewed, procedures for control of allergens at site, various allergens at site, specific storage, labelling and handling controls are in place for allergens except dairy, as dairy is the main allergen in products at site it is not treated as an allergen product. Risk matrix of allergens is in place, processing and cleaning procedures are in place for allergen and non-allergen products, verification is via ATP & environmental swabbing and product testing.

A site audit walk through occurred on 16.02.2021, areas reviewed as part of this walk included the; milk repack and Freeze dry production and packing, warehousing, amenities and cold storage area. At the time of the site walk through only one room within the freeze dry production area was running, freeze dry yoghurt sachets were being packed and staff within this area were observed to be wearing the required PPE and uniforms. Change rooms and air lock rooms where staff and products are moved into/out of production/packing were sighted, air showers are in place for when staff enter the freeze dry production and packing areas. Both milk repack and freeze production change rooms had PPE and uniforms available, gowning procedures were in place. Areas reviewed were found to be maintained and clean, and waste was separated from edible product and identified. Cold storage units (chillers and chest freezers) were sighted with monitoring controls in place. No specific allergen procedures were reviewed as part of the site walk. Raw materials, WIP and finished products were identified/labelled, were covered/packed and were stored off the floor. No maintenance issues were noted with equipment or structures at the time of the audit. Within the milk repack area on entering/exiting staff change and apply/remove PPE such as striped poncho, hair net, snood, shoe covers, wash and sanitise hands, once inside repack area staff cannot cross over the redline, same applies to warehouse staff bringing product into the area.

On entering the freeze dry production and packing areas, similar PPE and uniforms are applied, with different boots and poncho for packing versus production, no cross over between areas, staff must enter and exit via change room protocols. Each production, packing and storage room has a cleaning log, and where required an air pressure and humidity log, these are completed am and pm when in use, sighted samples of these logs at audit. Further review of the freeze dry production process is required to verify GMP controls in these areas.

This element is non-compliant due to the following findings

Findings:

FSM 3.1 areas that require addressing:

1. Corrective actions for GMP audits don't capture preventative actions or reference to SOP QA 008 Internal GMP Audit.
2. Amenities are only referenced as being separate to the storage area- section 9.8- 17.02.2021- discussed with site, missing reference to production (process and packing areas)in this statement.
3. Unclear where production and packing staff lockers are.16.02.2021-CLOSED procedures refers to staff kitchen, area was sighted at audit and reflect the procedure.
4. Section 9.11 does not include if damaged product is isolated or held or if CAPA process is followed.
5. Dropped product procedure is not clearly described and if product goes on hold- states 'will be disposed transferred to designated area for review by QA, prior to disposal immediately.
6. Is there a record kept to show the line or equipment has been cleared after a maintenance intervention. 18.02.2020- CLOSED- QAF037- Maintenance form is in place, referenced in FSM 3.8 Maintenance procedures.
7. 17.02.2021- discussed Hygiene zoning table with site, it is used to classify the hygiene and cleaning requirements at site, the table currently doesn't capture the definition of what constitutes the high, medium or low risk zones.

FSM 3.4 Storage Procedure findings.

8. Procedure does not clearly explain storage requirements; Section 9.1 paragraph 3 details how some products require temperature control, paragraph 5 then states no products or ingredients require temperature control, section 9.2 details different temperature requirements as well. 16.02.2021- sighted a chiller and chest freezers storing ingredients at site, monitoring controls are in place, FSM 3.4 requires amendment under paragraph 5 where it states no products or ingredients require temperature control
9. Storage requirements of export product have not been included.

3.11 Allergen Control Procedure findings;

10. Scope does not include production and packing areas.
11. Under storage and handling (dot point 2) it refers to a pink label for allergens, but in the table it states orange.
12. Provide allergen validation data for each product line/area.

FSM 3.3 Findings:

13. Scope only refers to the warehouse, not production and packing areas.
14. Doesn't reference FSM 3.1 or reflect PPE requirements per hygiene zone, or personal effects as per FSM 3.1 or SOPPRO013 17.02.2021- discussed with site, reference to FSM 3.1 and SOPPRO013 to be added.
15. Procedure states an informal assessment is completed on uniform and PPE fitness for use- need a formal assessment as evidence it has been carried out. 17.02.2021- establishment confirmed that no formal assessment is in place, site to complete and provide.
16. Lacking detail on footwear requirements, only states they are provided and to be stored, or covers are provided. 17.02.2021- CLOSED- discussed with site, footwear requirements are captured under FSM 3.1 and SOPPRO013.

SOPPRO013 Gowning Procedure findings:

17. Procedures in this SOP do not align with zones or clothing requirements in FSM 3.1 or 3.3. For example the SOP refers to 2 zones, while FSM 3.1 refers to 3 zones. 17.02.2021- CLOSED- further discussion with site on zoning, FSM 3.1 zones are risk rated for hygiene and cleaning, zones in FSM 3.3. are specific to clothing & PPE requirements for each area, the site walk through verified compliance to the FSM 3.3 requirements for clothing and PPE.
18. Unclear if the SOP applies to the warehouse staff and packing area as only refers to production. 17.02.2021- discussed with site, applies to all staff and areas at site, clothing and PPE requirements for warehouse and packing staff has not been included.
19. Section 6.6 requires review to detail exact requirements for entering and exiting all zones listed. 17.02.2021- after review of procedures at site, procedure does not clearly capture PPE/clothing requirements for milk repack, freeze dry production and packing areas.

20. Further details on when/where PPE, boots are changed, stored, and cleaned is required. 17.02.2021- the documented procedure does not currently reflect requirements for each area and how they are stored/changed.
21. Section 6.7 States uniforms are to be placed in the storage unit if leaving area temporarily, but then states if unform is clean to place in locker. 17.02.2021- at audit confirmed that uniforms are stored on hooks if provided or in bin for cleaning.

9. HACCP	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

The establishment has the following HACCP supporting documents in place;
FSM 2.02- HACCP Team – details persons at site who are part of the team, roles, experience and training are detailed. s. 22(1)(a)(ii) is the HACCP Team Leader.
FSM 2.03- HACCP Supporting Information – provides an overview of products produced at site and summary of hazards. New products are to be reviewed by the HACCP team and approved by the NSWFA or DAWE. Information details how hazard significance is determined via a risk matrix and a CCP decision tree is documented to be used.
FSM 2.04- Food Ingredient and Packaging Hazard Analysis – details hazards for ingredients and packaging used at site.
FSM 2.05- HACCP Verification Schedule- details HACCP verification activities at site, covering elements such as review of records, HACCP review, testing of product and environmental sources and more.

The establishment stores and processes blended dairy powder products, as well as transfers/receives products from their second site (Girraween). All dairy and eggs ingredients supplied and used at site are pasteurised and dried by approved suppliers.

4 HACCP plans in place for export related products are:
FSM 2.1.1-2.1.4- Dairy Products- covers receivals, storage and dispatch of packed dairy products
FSM 2.2.1- 2.2.4- Repacked Dairy products- covers repacking of dairy product powders into bottles/ sachets
FSM 2.3.1-2.3.4- Milk Dice Freeze Dried Products- covers processing of freeze-dried milk-based products with additional ingredients
FSM 2.4.1-2.4.4- Freeze dried yoghurt-based products- covers processing of freeze-dried milk yoghurt powders, with or without fruit/flavours.

As part of this desk audit the HACCP plan 2.3.1-2.3.4- Milk Dice Freeze Dried Products was reviewed.

- 2.3.1 Product Description and intended use- Milk Dice Freeze Dried Products – details cooking a blend of products with milk powder, anhydrous milk fat, egg, colours and flavours, product is aerated and freeze dried. Both milk and egg products used are pasteurised, the water activity of finished product is no more than 0.83. Product is packed into sachets and deemed ready to eat for general population, notes not for persons who are allergic to dairy and eggs.
- 2.3.2 Process Flow Chart - Milk Dice Freeze Dried Products- captures steps from receivals to dispatch/delivery, CCPS and RCPS detailed. Some inputs and output points are noted.
- 2.3.3.3.3 Milk Dice Freeze Dried Products- Hazard analysis- general hazards and hazards specific to the processing of milk dice freeze dried products has been documented, hazards identified into biological, physical, chemical, regulatory, traceability, hazards are risk rated, control measures listed and if a CCP or not has been described.
- 2.3.4- Milk Dice Freeze Dried Products- HACCP audit table- CCPs and RCPs identified and reflect the flow chart and hazard tables- hazard, control, critical limit, monitoring, records, corrective actions detailed.
- RCPs/CCPS across flow chart, hazard and HACCP audit tables align.

A site audit walk through occurred on 16.02.2021 to verify production processes, both FSM 2.4.2 Freeze Dried Yoghurt Bases Products and 2.2.2 Repacked Dairy Products Flow chart were reviewed, and findings have been noted. As only one room was in operation (freeze dry yoghurt sachets were being packed into retail packs and cartons), FSM 2.4.2 steps 24 to 27 were only able to be verified at audit against the process being undertaken. Another site audit is required to verify the remainder of the production process for FSM 2.4.2.

This element is non-compliant due to the following findings.

Findings:

FSM 2.01- Food Safety and Quality (HACCP) Scope and Purpose 17.02.2021 reviewed;

1. Does not capture the scope of the intended markets of products made at site.
2. Does not detail that the establishment is a contract manufacturer.

FSM 2.02 HACCP Team- 17.02.2021- discussed with site, still in process of update.

3. s. 22(1)(a)(ii) is listed as the QA Team Leader whereas the Organisation Chart lists s. 22(1)(a)(ii)
4. Qualifications of staff are not consistently listed in the HACCP team table. For example: s. 22(1)(a)(ii) has an engineering degree as mentioned in the procedure but is not included in the table.

FSM 2.03- HACCP Supporting Information

5. Does not capture if products produced at site are all GMP Pharmaceutical products or if contract packaging is also conducted at site- further details on scope and purpose required. 17.02.2021- CLOSED- to be captured under FSM 2.01, FSM 2.01 was not provided as part of the original desk audit,
6. Does not clearly detail that site is handling/processing product for domestic and export markets. 17.02.2021- CLOSED- to be captured under FSM 2.01, FSM 2.01 was not provided as part of the original
7. Processing hazard section doesn't include repack product section.

FSM 2.04- Food Ingredient and Packaging Hazard Analysis

8. Hazard significance has not been determined for each hazard identified.

FSM 2.3.1 Product Description and intended use- Milk Dice Freeze Dried Products – site to review findings against all HACCP plans.

9. Shelf life of product states 24 months, whereas FSM 1.13 states products have a 12 month best before from DOM- 16.02.2021- CLOSED- site confirmed that shelf life is 24 months, FSM 1.1.3 is an example only, noted as e.g. 12months
10. Doesn't state the destination markets/ countries-17.02.2021- on review of 2.4.1 Freeze Dried Yoghurt based products the shipping section does not reflect the current process of the customer storing domestic product at site and they organise shipping.
11. Microbiological testing section does not reflect testing conducted under FSM 1.20a.
12. Final preparation and use states product is ready to eat- 16.02.2021- CLOSED- sighted freeze dry yoghurt product at audit, product is ready to eat, no reconstitution required.

FSM 2.3.2- Process Flow Chart - Milk Dice Freeze Dried Products-– site to review findings against other HACCP plans as well.

13. Inputs and outputs are not included at all relevant steps or linked to relevant steps. For example; no reject output has been noted at xray steps, not all inputs included (labels) step 5), waste output at step 14 (when product is held at correct temps the hazard table states is rejected).
14. Flow chart verification date is 2019, FSM procedures required an annual review. 17.02.2021-no review occurred in 2020, additionally FSM 2.2.2 has no review in 2020.

FSM 2.3.3 Milk Dice Freeze Dried Products- Hazard analysis

15. No supporting document was reviewed that defines the key/legend code for types of hazards (with the exception of CCPs/CPs). 17.02.2021- CLOSED- FSM 2.01 reviewed and includes definition of hazard types.

Key: B – Biological hazard, C – Chemical hazard, P – Physical hazard, Q – Quality, T- Product Traceability (regulatory), R- Regulatory (other), SP – Support program, CCP- Critical Control Point, QCP- Quality Control Point, RCP - Regulatory Control Point. No-SP – Adequately covered by Support program.

16. Hazard analysis only contains 31 steps, flow chart has 32 steps (missing label sachets in hazard table)
17. Step 11 Cooking include a hold time 17.02.2021- CLOSED site confirmed that no hold time as is not a CCP, product work orders detail steps for making each product which includes times for cooking/mixing ingredients.
18. Not all control measures have been considered, for example: all steps- equipment/utensils hasn't considered maintenance activities, steps where temperature control is required haven't considered storage/calibration procedures, training not considered as a control for some hazards such as CCP points. 17.02.2021- discussed finding with site, confirmed not all control measures have been included.
19. CIP is referenced as a control measure for cleaning of the heat exchanger and buffer tanks, is there other equipment's/lines where CIP is used? No CIP information has been received- validation material is required for review.
20. Some control measures for hazards have been recorded as 'refer to earlier steps' but no relevant step is named- 17.02.2021- site confirmed this is to do with specific steps, hazard table does not clearly define the specific steps.
21. Step 8 in the hazard table is sanitise with wipes, whereas the flow chart is Sanitise UV tunnel. 17.02.2021- no UV is used at site, flow charts FSM 2.3.2 and 2.2.2 currently include UV for sanitising.

22. Receivals steps refer to the GIN code, whereas 1.13 refers to the GIN and item code- is just the GIN code used for traceability 17.02.2021- CLOSED- site confirmed both can be used to trace, but GIN is the main identifier, GIN book captures products received, GIN and item code etc.
23. Step 25 in the hazard table is listed as xray, whereas the flow chart calls step 25 metal detection 17.02.2021- confirmed via site walk that xray is in used at site.

FSM 2.3.4- Milk Dice Freeze Dried Products- HACCP audit table

24. Step 1- RCP 2 details product will be rejected if export documentation is not received, whereas FSM procedures (e.g 1.10) indicate product will be used for domestic product.
25. Justification of critical limits doesn't reference annual revalidation of CCPs

General HACCP and FSM findings:

26. It is unclear after review of the above HACCP plan and FSM procedures (1.20, 1.18, 1.13- go back and check these) if raw materials are placed on hold (quarantine label), labelled until inspection and testing is completed; HACCP plan states they are inspected and tested. 17.02.2021- HACCP plan does not clearly detail the product is placed on hold under sample & inspect.
27. Water activity testing of product is not included in FSM 1.20a. 17.02.2021- CLOSED- discussed with site, not included as is a CCP covered under HACCP verification table

16.02.2021- A review of FSM 2.2.2 Process Flow Chart and 2.2.3- Hazard table for Repacked Dairy Products at site, the line was not in use. A review of FSM 2.4.2 and FSM 2.4.3 Freeze Dried Yoghurt based products also occurred (note only steps 24-27 were in operation), the following findings were noted;

28. Not all steps have been included in the process flow chart and hazard table. For example; decant/debag step not covered for all inputs (seals and scoops), transfers from storage to process areas (and back) or between process areas, or interim storage of WIP product are not all included.
29. The documented process flow steps do not reflect current process. For example; step 13 code container is not conducted at the current point on flow chart, no coding machine was in place at this step.
30. Process steps do not clearly describe what is occur at the step. For example; assemble order steps do not explain what is occurring at the step
31. Process flow steps do not align with those in the hazard table. For example, Step 16 on FSM 2.2.2 is 'carton', whereas step 16 on FSM 2.2.3 hazard table has pack in cartons/shipper.
32. The process flow charts and hazard tables do not clearly detail the steps when the carton and pallet is labelled.
33. Not all steps in the process are required for all products. For example; blending step is not required for all products.

10. Sampling and Testing	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

Sighted FSM 1.20 Product Assessment, Inspection and Testing Procedure sighted, raw material, finished product and water testing requirements. Form QAF28 to completed for out of specification product. QA Manager or Technical officer reviews records relating to food safety, production, product, water and environmental testing.
An overview of testing is referenced, then refers to SOPS in place for testing of products, water, environmental testing; SOP QA0021 Sampling and Testing of Export Products, SOP QA0014 Water Quality Monitoring Programme, SOP QA0018 Environmental Monitoring Programme. All testing to be completed a NATA approved lab, only trained persons are to sample product. Any out of specification product is to follow SOP QA 0023 Out of Specification Procedure. Raw materials and finished products are inspected before and during production. Finished product testing is done to meet domestic and importing country/ customer requirements. Corrective actions detailed and include notification to the Department.
Quarterly allergen swabbing to occur, determine no presence of eggs
Air quality testing procedure are detailed, an annual positive air pressure check is completed by an external contractor. Establishment also completed air quality testing as well.

SOP QA0021 Sampling and Testing of Export Products reviewed- details microbiological testing requirements for export product.

FSM 1.20a Product Testing reviewed, captures domestic and export testing requirements (China and Hong Kong).

This element is non-compliant due to the following findings.

Findings:
The following findings have been noted with relation to FSM 1.2;

1. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager or technical Officer.
2. Corrective action procedures are not clearly documented to reflect forms and processes followed when test results are out of specification.
3. The procedure does not reflect who reviews Sydney water quality reports and actions when issues are identified with the report.
4. Section 9.8 details environmental swabbing for salmonella and Enterobacteriaceae, but this is not documented in SOP QA0018 Environmental Monitoring Programme.
5. Allergens to be sampled as per SOPQA0018 Environmental Monitoring Programme, but this programme when reviewed did not include allergen swabbing.
6. Section 9.9 Air Quality testing doesn't refer to and reflect SOP QA0018 Environmental Monitoring Programme; different frequency, limits, sampling locations and corrective actions.

1. SOP QA0021 Sampling and Testing of Export Products does not reference contacting the Department for out of specification product.

11. Training	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
01-05.02.2021- FSM Training 3.2 reviewed, all staff to completed induction before commencing work, inductions covers workplace induction, food safety, employee responsibility, contamination. Further Sop training completed in; personal hygiene, GMP, gowning procedure. Staff to complete an attendance record at induction, once staff are competent the training matrix is updated. Further training is conducted per department area, this training is based on department SOPS. Each staff member will have a training plan in place, training plans incorporate, induction, GMP, HACCP, food safety and external/special training. A training matrix/ register is used to capture staff and training plans completed/in process. Training records are in use and are to include staffs competency assessment which is based on discussion, observation, execution or achieving 85% pass mark in a test. Refresh training on SOPS is to occur every 3 years or when changes occur, GMP training annually, additional training can be carried out as needed if deemed required. Procedure details export signatories will have knowledge of export, import country requirements, persons who are using Exdoc will also be trained.
This element is non-compliant due to the following findings.

11/02/2021- additional evidence was provided by the establishment to support FSM 3.2, this element is now compliant.

Findings:

1. Under the SOP training states staff will be observed and then deemed competent - unclear if this is occurring at induction and how competency is determined? Further on in Section 9.6 clearly details how staff are assessed, is this section applicable to induction as well? 11/02/2021- CLOSED- training matrix provided and includes Induction modules, training method and level of competency required. Information in the SOP is now understood and supported by the training matrix.
2. Sample of training matrix and or records not provided- 11/02/2021- CLOSED- a sample of the training matrix was provided, details training modules, method of training required per work area and the level of competency required. Sample of training records supplied for induction, HACCP, export and CAPA training.
3. Training is completed by either; read only, read and understand, onserved, observed, testing/quiz- how is this determined for each SOP/training package? 11/02/2021- CLOSED- training matrix details the method and level of competency required for each training module at site.
4. No details about how export signatories attain their knowledge in export, import country requirements etc is detailed. 11/02/2021- CLOSED- training matrix includes Export Dairy Control section, covers all modules (SOPS) staff are to be trained in, the method of training and level of competency required.

12. Identification/Traceability & Recall	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
FSM 1.14 Product Identification and traceability reviewed, all raw materials are assigned a traceable item code when received this is linked to the receival register, is a sequential number. The traceable item code is used for traceability via the companys stock system and for the production process. A GIN (goods inward Notebook) captures information on the product. Product is transferred once received to it's a designated area, colour coded labels are applied to signify product status. Details export and domestic product to be labelled and segregated. Non-export products have different names and codes. Stored and WIP products labelling requirements are captured. Batch numbers of raw materials are recorded on production and packing work orders (these are generated for each batch. Finished products are issued a manually generated batch number and best before date (12 months from date of manufacture), these are printed onto packaging, HW signifies Huntingwood site, work

orders and packaging document confirm batch number/best before date, these are checked for each run. Rework is allocated a work order and rework form and checklist are to be used. Finished products are traceable via; best before date, batch number and production and packing work orders and documents. When products are dispatched, dispatch docket is generated, links to computer system and captures traceability of product.

FSM 1.19 Recall and Withdrawal procedure reviewed, covers process for all products to be recalled and withdrawn, includes notification to the department for export product.

A site audit occurred on 16-17.02.2021 where further review of procedures both documented and on floor operations occurred. Products (raw materials, WIP and finished goods) were found to be labelled and segregated as hold and release procedures required. An overview of the receivals process occurred, GIN book and the dairy transfer log books were sighted, one book capture non-dairy ingredients and the other captures dairy goods received at site (batch, item codes, GIN id, supplier, est) were recorded in this book. Once the GIN is allocated the products/pallets are labelled with a quarantine label, once tested/inspected a release label is applied. QA also capture goods received in the sampling register, they notify the warehouse once product has been released. Details of goods received are also entered in the computer stock system (Pronto). The Pronto system was reviewed, the system captures raw material and finished goods hold and release details, and work orders for production-packing. Planning department create productions and packing batch numbers from the planning database and are a sequential number, these are then entered into the Pronto system for relevant work orders, the warehouse then uses the work orders and GIN ID to pick product required. Production and packing work orders are issued for each new batch of a product, captures ingredients used as per the BOM, the process steps of producing/packing product detailed, staff are to check off each step is completed on the work order, CCP and QCP monitoring is also included. A packing work order was sighted for Freeze dried Berry Vmore yoghurt sachet product at audit, records had been completed as required for cleaning, hygiene and QCP monitoring. A review of a Mock Recall completed on 05.08.2020 occurred for a packaging complaint of product, wrong cap used on product MV powder, product affected was traced and root cause was determined and actions were taken.

This element is non-compliant due to the following findings.

Findings:

FSM 1.13 Product Identification and traceability findings:

1. Unclear if the GIN and the item code are the same and how are they are linked (section 9.1.1) (item code is the raw material code , product code) 17.02.2021- CLOSED- site confirmed GIN and item code (product code) are separate, when goods are received, GIN is issued in GIN book and item code is recorded with it as well. Can track GIN and item code in the computer stock system (Pronto)
2. Unclear how the traceable item code, GIN, manual batch number and receival register are linked to computer stock system? 05/02/2021- establishment confirmed all link to the computer stock system, further review of the trace process to occur at site visit. 17.02.2021- CLOSED- discussed with site details of the product are entered in the Pronto system using information from the GIN book, receival register and production-packing work orders. Sighted example of Finished goods in Pronto system- records batch code, item code, work orders and quarantine/release status.
3. Raw material batch details are recorded on production and packing work orders, but where does the GIN/ traceable item code come into it? 05/02/2021- establishment confirmed that both the GIN and traceable item code (product codes) are recorded. NC CLOSED.
4. Procedure does not define how export product is labelled.
5. Procedure doesn't capture scheduling requirements of export and domestic product? 05 & 16/02/2021- site confirmed that Sales receive orders, sales confirm if export or not then arrange ingredients as required, production then scheduled, export then domestic production to occur, and export products will have a different code to non-export product- FSM 1.1.3 currently does not clearly capture this process.

13. Approved Supplier Program; Ingredients and Packaging	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

FSM 1.22 Approved Supplier Procedure sighted, is supported by SOP QA0026 and Approved Supplier List. Only products on the approved supplier list are to be purchased. Procedures defines requirements for approval of suppliers for ingredients (dairy, non-dairy), packaging, service suppliers for maintenance, labs and chemicals. Procedure details the requirements for Australian and imported dairy ingredients suppliers (reflects requirements as detailed in FSM 1.10- see section 15. If products do not have enough documentation to show that it meets export requirements, then it is not used for export product. Eu supplier and product information must be met in order for the ingredients to be used not EU finished product. Dairy suppliers must also provide documentation such as: CoAs, Department Export Registration (or similar for imported product), HACCP certificate or equivalent, Supplier questionnaire. An annual review of suppliers occurs.

At the site audit on 16.02.2021 the site confirmed that they are not intending to export to the EU and that export products will have a different product code to non-export product.

This element is non-compliant due to the following findings.

Findings:

1. Procedure doesn't capture process of routine monitoring of suppliers and goods at time of receivals, or non-conformance process for suppliers- 16.02.2021- procedure does not include monitoring of receivals or corrective action process for non-compliant suppliers.

2. Approved Supplier Register/list and SOP QA0026 is still in process of being developed.

3. 16.02.2021- FSM 1.22 includes EU requirements, site is not intending to export to the EU.

14. Receiving and Dispatching Milk & Milk Products	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
SOPWHS009- Dispatching Goods reviewed, covers steps when dispatch goods at site, see findings as below.

Sighted SOPWHS0002- Receiving Items covers steps when receiving goods at site, findings have been noted below.

See sections 13 15- Information on receiving and dispatching of product

This element is non-compliant due to the following findings.

Findings:

SOPWHS009- Dispatching Goods findings:

1. Section 7.9 details checking of truck for dairy goods, but doesn't elaborate on what the checks are or if these are recorded- 17.02.2021- no dispatch checklist is currently in place.
2. Section 7.9 is the only part that references a transfer certificate, procedure does not include what checks are required for export product.
3. Unclear in the SOP if a dispatch checklist is completed. 17.02.2021- no dispatch checklist is currently in place.

SOPWHS0002- Receiving Items:

4. No reference to checking dairy products for export compliance is noted in the SOP.
5. FSM 1.13 refers to a traceable item code being issue first then a GIN, but SOP just refers to the GIN- which is correct. 17.02.2021- CLOSED confirmed with establishment that the GIN is issued at receivals, is recorded in the GN book with item code.
6. HACCP plan reviewed refers to a receival checklist, but this SOP doesn't not reference such as checklist. 17.02.2021- CLOSED- site confirmed that the checklist is 'QAF034' and is completed by QA for products requiring temp control only.
7. Is part b undertaken for all products received? 17.02.2021- closed site confirmed that part b is completed via the sampling sheet for each product, sample of these were sighed at audit.

15. Transfer & Manufacturers Declarations of Compliance	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
Reviewed FSM 1.10 Export Documentation Procedure covers roles and responsibilities in completing export documentation at site. Documentation and information is reviewed by eligible persons to ensure export documentation & importing country requirements are met, this includes; Completed & received Transfer certificates, decs of compliances, RFPs, Micor, CoAs, product testing results. Procedures define the requirements for export permit, health certificates and prohibited goods, and when these cannot be generated. Persons who can complete transfer certificates and declaration of compliance are detailed and are trained in the procedure. Procedure details the requirements for completing and checking transfer certificates and declarations of compliance by eligible staff, as well as when they are required (at receival and dispatch).
Procedure details Australian dairy ingredients received are for domestic and export use, export product is required to have a transfer certificate and come from an export registered establishment, export product is labelled and segregated from domestic product. Requirements for Imported dairy ingredients are defined and include; must be registered, meet importing country requirements, provide COAs or health certificates. Only product that has

documentation stating that it meets Eu requirements can be used in EU product. Additionally, if documentation is not sufficient to indicate product meets a specific importing country or general export requirements it is deemed not suitable for export- computer system and labelling will capture this information.

This element is non-compliant due to the following findings.

Findings:

1. No template has provided for transfer certificate or declaration of compliance. 18.02.2021- QAF025 – Transfer certificate sighted and was compliant. QAF026 Manufacturers Declaration of Compliance to be provided for review.
2. Under section 9.3 if refers to checking the product has come from an export registered establishment, but not how it is done.
3. Section 9.4 is not clear when a transfer certificate is required or not; Girraween is referenced as not requiring a transfer certificate (dot point 1), but then requires one in dot point 2, dot point 2 is requires rephrasing (repeated wording) 17.02.2021-wording of this statement is unclear.
4. Retention period is stated as 7 years for export documentation, this differs from document control procedures.

16. Importing Country Requirements	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

Sighted FSM 1.11 Importing Country requirements and FSM 1.11a Importing Country Requirements schedule reviewed.
FSM 1.11 references export products will meet export and importing country requirements, including China and EU. All products will meet export requirements and are deemed export until they are labelled domestic- both on the label and in the computer system. Importing country requirements is obtained when order is received, by review of Micor, department emails, market advice notices, contacting importing country customer and regulatory authorities. Products are checked to ensure they meet importing country requirements at the time a transfer certificate or declaration is to be completed, QAF056 Product HACCP Verification Form and QAF057 Export Documentation Checklist are completed.

FSM 1.11a reviewed, specific importing country requirements for China and Hong Kong.

Verification table 1.14a captures review of importing country requirements prior to shipment and or when changes have occurred.

Site confirmed 16.02.2021 that they will not be exporting to the EU. Additionally, the site confirmed export product is bought in as required for export orders, product will be checked at receival to ensure if meets export requirements and then logged into system as export or domestic.

This element is non-compliant due to the following findings.

Findings:

1. Verification table 1.14 states importing country requirements are checked prior to shipment, but then states that it is completed as part of an internal audit in February. 05/02/2021- establishment confirmed that they do carry out both activities- NC closed.
2. 1.11 references EU exports and to review 1.11a for further on specific importing country requirements, on review of 1.11a no EU information is detailed. Only China and Hong Kong are detailed in 1.11a- please confirm importing countries, and if EU is one update procedures to include EU requirements. 16.02.2021- procedure includes EU requirements at present, site confirmed they will not export to EU.
3. 1.11 states that EU production is not routine, but site will ensure EU requirements are met, Eu checklist to be completed- no EU checklist received. 16.02.2021- 16.02.2021- procedure includes EU requirements at present, site confirmed they will not export to EU.
4. No reference to training in export or importing country requirements for staff is detailed in 1.11.
5. Unclear if all raw materials and finished product are all export grade, on interpretation of 1.11 section 9.4 all products meet export requirements, unless theres documentation issues, whereas 1.10 details products when received are classed as export or domestic (section 9.3), which depends on documentation received. 16.02.2021- export product codes are still to be set-up.

17. Loading of Sea and Air Freight Containers	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

This element is non-compliant due to the following finding.

Findings:
01-05.02.2021- Unclear from evidence received if establishment is loading containers.
16.02.2021- FSM Procedures reviewed have not captured if loading of containers is to occur at site.

18. Department of Agriculture Seals	Compliant? (Yes / No/ NA- Not Assessed)	**N/A**

Summary of Findings: Not required at this stage for the establishment, as documented in FSM 3.1

Findings:
- Not Applicable

19. Pasteurisation	Compliant? (Yes / No/ NA- Not Assessed)	**n/a**

Summary of Findings:

Sighted FSM 3.1 GMP it documents that all dairy and egg products received at site are pasteurised and HACCP plans also detail product is pasteurised by suppliers, CoA or CoC is to be received.

Findings:
Nil

20. Trade Descriptions	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM reviewed 1.12 Trade Descriptions is in place, roles and responsibilities for checking and approving labels before use, as well as ensuring all goods (raw materials, finished products) are labelled during storage and use/production is described. A transfer cert/ dec of compliance is only generated and signed once it is in the computer system. Labelling requirements are detailed for export and domestic products, foreign translations for export product when required (China labels product must be approved by Chinese authorities)- Labels to be reviewed when changes occur or at least annually. SOPS are in place for printing labels & packaging.

FSM 1.12a Labelling Requirements details labelling requirements for product for retail and non-retail sale.

Verification table incorporates an annual review or review when changes occur for trade descriptions.

FSM 1.10 Export Documentation details that foreign language translation for labels/artwork are kept on file, are completed by a translator, each delivery is checked and logged onto QAF027.

This element is non-compliant due to the following finding.

Findings:
01-05.2021- Goat milk powder artwork provided, but doesn't list the Est1405

16.02.2021- sighted sample of Full Cream Milk Powder 1kg Jar- BBD date, batch number, est number, manufature date are printed via ink jet on base of the Jar. Sighted label checks for freeze dry yoghurt sachets production at audit- done at start of run, this is checked against label sample and the production work order.

21. Maintenance and Calibration	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

Establishment has FSM 3.8 Maintenance Procedure in place, covers scheduled (preventative) and unscheduled maintenance activities at site. Staff to report any issues with the plant/ equipment to manger/supervisor so that it can be addressed. Both planned and unplanned maintenance activities are recorded on either Preventative Maintenance Form (FDPM) or QAF-037 Maintenance Form. Procedure captures ensuring work area is checked before use to ensure it is cleaned and sanitised, no debri. The plant and equipment (including tools) are to be fit for use, kept clean and sanitised. Tool hygiene and reconciliation is checked as part of daily GMP audits or QAF-

037. Repairs to plant or equipment's are risk rated in terms on priority- low to critical. Any major changes to the plant are to be approved by the department. FSM 3.9 Maintenance schedule is in place. Maintenance staff and contractors are trained in GMP and Hygiene requirements.

FSM 3.7 Calibration procedure sighted, covers equipment that is required to be calibrated at site and persons responsible, calibration register is in place and further details equipment calibration requirements. Equipment is to be labelled with calibration details, procedures are in place for when calibration fails- label not to use, repair, cease production if it relates to CCP. Calibrations can be completed by internal staff or external service contractors, the establishment retains records of calibrations. Overview of scale and thermometers calibrations is detailed. Sighted Calibration register.

A site audit walk through occurred on 16.02.2021, the establishment was found to of a satisfactory standard for structures and equipment., no issues were noted.

This element is non-compliant due to the following findings.

Findings:

Findings to be addressed for FSM 3.8:

1. Section 7 does not include monitoring of the production & packing areas.
2. Procedure doesn't capture how equipment/fixtures are addressed to ensure they are fit for use- is a risk assessment completed. 17.02.2021-CLOSED- site confirmed assessment process is in place, SOP VAL00001 Site Validation Master Plan is used and was sighted.

Findings to be addressed for FSM 3.7:

3. Scope does not cover production and packaging areas.

22. Miscellaneous (Alterations & additions to premise & FSP since last visit, AA approval/conditions, Registration details, Exemptions, Outstanding Non-Conformances raised during the previous audit not previously closed out or required to be verified)	Compliant? (Yes / No/ NA-Not Assessed)	**N/a**

Summary of Findings: Not applicable this audit

Findings: Not applicable this audit

Additional items of Concern identified during the audit and not mentioned above:

- No additional items, all issues of concern have been documented above

Notes:

- Not all the elements identified in the scope of the audit determined prior to the visit were able to be looked at during this visit. Effective review of those elements that were audited during this visit took longer than anticipated and those elements not reviewed this visit will be included in the next bi-annual audit.
- It has been identified that the current day allocated to undertake verification of your approved arrangement is insufficient to effectively verify compliance with legislative and importing country requirements, as such future audits of your site will be undertaken over two consecutive days for each of the Bi-Annual audits undertaken over the year.

Observations:

- All observations (where applicable) have been included in the report above

Non Compliances:

- Where a non-compliance has been documented in the report above, the information provided in the findings "as evidenced by" are those items identified that support why the element has been found non-compliant. It is not necessarily exhaustive and is not an itemised "to do" list, rather examples to support why a program/element is not effective. The expectation is that the non-conformance will be thoroughly reviewed to determine the root cause and actions taken to address both the root cause to why it happened as well as rectifying the "finding" (where applicable) and verification to ensure the failure does not re-occur.
- If you require further clarification please contact myself or in my absence dairy@agriculture.gov.au

Australian Government
Department of Agriculture, Water and the Environment

Department of Agriculture: Food Program (Dairy) Bi-Annual Approved Arrangement Audit Report

Company:	GMP Pharmaceuticals PTY LTD		
Audit Location:	60 Huntingwood Drive, Huntingwood, NSW, 2148		
Compliance standard:	• Export Control (Milk & Milk Products) Rules 2021 • Export Control Act 2020 • Establishments Approved Arrangement (currently approved Est's) • Importing Country Requirements		
Auditee Representatives: Entry Meeting	s. 22(1)(a)(ii) QA Team Leader , s. 22(1)(a)(ii) Site Manager, s. 22(1)(a)(ii)- Senior QA Associate.		
Auditee Representatives: Exit Meeting	s. 22(1)(a)(ii)- QA Team Leader , s. 22(1)(a)(ii) - Site Manager, s. 22(1)(a)(ii)r- Senior QA Associate.		
Establishment No:	1405	**Audit Dates:**	01-05, 16-17/02, 24//02, 15/03 , 12/04/2021
Lead auditor:	s. 22(1)(a)(ii) (DAWE)	Additional audit team members:	Nil

Total Audit Time: For charging purposes (if applicable) * Report writing time is also charged and will be included in the invoice issued	Audit Time: 16 hours Report Writing: 1.00hr	01.02.2021:4 hrs
		02.02.2021: 4hrs
		02.02.2021: 4hrs
		03.02.2021: 4hrs (includes 1hr reporting)
	Audit Time: 14 hours Report Writing: 2.00hr	16.02.2021: 5.45hrs (on and off-site)
		17.02.2021: 8.15hrs (on and off-site)
	Audit & Report Time: 2 hours	24.02.2021- 2hrs
	Audit time: 30 mins	15.03.2021- 30 mins
	Audit & report Time: 1.5 hours	12.04.2021- 1.5 hours

Auditor Name: s. 22(1)(a)(ii)		**Signature:** s. 22(1)(a)(ii)	
Date Report Issued:	5th February 2021 24th February 2021 12th April 2021	**No# of Non-Compliances Issued This Audit:**	**46**
No# NC Closed out from Previous Audit:	**n/a**	**No# of Non-Compliances Re-Issued:**	**n/a**

Additional Information (where applicable) can be found at the end of the report

Audit Scope and Objectives:

The audit of Est1405 was carried out via a combination of desk audit and site audits, adhoc meetings, dates and scope covered are detailed as below.

The scope of the desk audit on 01-05/02/2021 included review of the following AA elements:

- Review all applicable 21 elements of the food safety program of GMP Pharmaceuticals for approval as an export registered establishment with the Department of Agriculture for dairy powder products.
- GMP Pharmaceuticals is seeking approval as an export registered establishment with the Department of Agriculture, Water and the Environment (DAWE) for the production of Dairy Powder Products- repacked dairy powder, freeze dried dairy and yoghurt products.

16-17/02/2021- a site audit was conducted to confirm process, structure, equipment and hygiene. A review of the desk audit findings also occurred. The establishment was only packing freeze dried yoghurt sachets at time of audit, freeze dry production and milk repack production-packing was not occurring, another site audit is required to further review the production and packing.

A review of additional evidence has occurred over adoc dates, dates of such reviews are noted in the summary of findings/ and findings as below.

Summary of findings:

As of 05.02.20201 the food safety program reviewed does not currently meet all the requirements of the Export Control Milk and Milk Products Orders 2005. Those items required to be further actioned, amended or strengthened are detailed below (as noted in red writing, blue highlight sections are for further questioning).

After the site audit conducted on 16-17/02/2021 the food safety program reviewed does not currently meet all the requirements of the Export Control Milk and Milk Products Orders 2005. Items required to be further actioned, amended or strengthened are detailed below in red-yellow highlight from this visit. Any findings that have been actioned and closed have been noted as so in green, previous desk audit findings noted in red are still to be addressed.

Further review of updated food safety programme documentation occurred on 24.02, 15.03 and 12.04.2021, findings that are now compliant are highlighted in green, those still to be addressed are highlighted red/yellow. Grey highlighted areas are not applicable.

A second site visit was planned for 29.03.2021 but was postponed due to COVID19 lockdown in Brisbane.

Audit Outcome: Acceptable? Not Acceptable?	Not Acceptable

1. *Management Practices* **2.** *Internal Audits, Corrective Actions* **3.** *Plans & Specifications* **4.** *Cleaning* **5.** *Water*
6. *Pest Control* **7.** *Protection, Segregation & Waste* **8.** *Protective Clothing, Premise Construction, Hygiene and GMP/GHP*
9. *HACCP* **10.** *Testing* **11.** *Training* **12.** *Identification/Traceability & Recall* **13.** *Approved Supplier*
14. *Receiving & Dispatching* **15.** *Transfer & Declarations of Compliance* **16.** *Importing Country Requirements*
17. *Loading of Sea and Air* **18.** *Seals* **19.** *Pasteurisation* **20.** *Trade Descriptions* **21.** *Maintenance and Calibration*
22. *Miscellaneous*

Approved Arrangement Elements Audited

1. Management Practices, Commitment to Food Safety and Records	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
The Declaration of Occupiers Commitment (FSM 1.5) sighted and details meeting export, importing country requirements and domestic requirements, Group CEO is responsible for signing. FSM 1.4 Food Safety and Quality Policy further details that the establishment will meet export and domestic requirements, Group CEO signs. FSM 1.4 also details that an annual management review is to occur.

Organisational structure is documented in FSM 1.6 sighted, showing staff from Group CEO to floor staff. Position descriptions are documented in FSM 1.7 for both the Huntingwood and Girwaween sites.

Management review procedures FSM 1.16 reviewed, annual review to occur, attendees and agenda items detailed including export requirements, management review meeting minutes are taken and filed, actions are assigned to attendees where required.

Document control procedures sighted in FSM 1.9, details process for approving new documents and amending current in use documents, includes seeking approval from the Department (DAWE- Department of Agriculture, Water and The Environment) for changes relating to export, importing country requirements or may affect the products integrity or fitness for human consumption. Master document list, amendment register and version control used to track documents. Retention period and persons who can amend/create and approve documents are detailed.

This element was found to be non-compliant due to the following findings.

Findings:

1. FSM 1.5 Declaration of Occupiers Commitment and FSM 1.4 Food Safety and Quality Policy supplied are not signed and dated by the Group CEO. 12.04.2021- NC reviewed and closed- version of both documents provided showing Group CEO s. 22(1)(a)(ii) has signed them.
2. The QA Associate is held by a different person in the organisational structure FSM 1.6 issue date October 2020 versus the FSM 1.7 Position descriptions issue date October 2020
3. It is unclear who has the main role in overseeing and management of the AA (FSM) as multiple QA roles are in place at the Huntingwood site, for example there is QA Team Leader and Senior QA Associate at the same level in the organisational chart.
4. Positions description titles in FSM 1.7 do not consistently state which site the role is at, the Organisational structure 1.6 clearly shows two sites.
5. Documentation retention period varies between procedures. For example in FSM 1.9 it states 3, 4 and 5 years, FSM 1.15, 3.12 details 4 years. 12.04.2021- NC reviewed and closed- procedures now corrected, retention period now 5 years.

6. FSM 1.9 states that the QA Manager or delegate manages this procedure, whereas the organisational chart for Est1405 doesn't have a QA Manager. 12.04.2021- NC reviewed and closed- procedure 1.9 updated, QA officer to make changes to documents.
7. 17.02.2021- further discussed management review procedures at site. Management review procedure FSM 1.16 does not clearly describe that management review is conducted done 6 monthly as per the verification schedule and the annual management review internal audit is conducted as per QAF045- Internal Audit Schedule. 12.04.2021- NC reviewed and closed- procedure now clearly details that management review is done twice a year.

2. Internal Audits and Corrective Actions	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
Internal audit procedure 1.15 reviewed, details process for external and internal audits (GMP and Non-GMP audits). GMP audits are conducted as per SOP QA 008 Internal GMP Audit. Non-GMP audits are done as per the internal audit schedule/ Verification schedule 1.14a. Compliance to the audit is to be recorded on the internal audit summary, objective evidence to be captured on documents being audited or on internal audit summary. Form49 Internal audit summary report is used to document the audits findings, corrective and preventative actions. Corrective actions procedures are detailed for when immediate action can be taken or not. A corrective action report and following the corrective and preventative action procedures are detailed. For external audits a person from management will accompany the auditor/s, a quality incident form QAF007 and corrective and preventative actions are to be taken.

Internal audit checklist QAF017 and QAF009 Internal GMP audit form templates sighted.

Internal audit schedule QAF045 reviewed details audits conducted over the calendar year.

1.14a Verification schedule sighted and details internal audits to be completed on activities such as; quality system documents, corrective action and non-conforming product procedures, HACCP, importing country requirements, trade description, approved suppliers.

SOP QA 008 Internal GMP Audit sighted and reviewed covers internal audit requirements and process of completing systems and spot audits.

FSM 1.17Corrective and Preventative Action (CAPA) Procedure reviewed, capture processes for internal and external non-compliances. External non-compliances have CAPA and QID (quality incident deviation) form completed. Internal non-conformances follow CAPAs as per HACCP, if action can be taken immediately it is done so and recorded on the relevant monitoring form, if not CAPA and QID completed. Notification to the Department of QIDs is documented. CAPA process includes logging of incident into QID register, completing QID from and investigations, determine products status, determining corrective and preventive actions, timeframe for completion, verifying actions are acceptable, QID can only be closed once actions have been deemed acceptable, QA Manager to close, monthly review of QID occurs, QID maybe extended if a plan is in place to address and no food safety risk is present. If there is a risk to food safety or quality then immediate action must be taken to correct the non-compliance, non-urgent issue have up to 1 month for actioning.

17.02.2021 sighted Internal Audit Summary Report QAF036 for 27.01.2021- GMP Area and Pest control monthly audits for Jan 2021- CAPA 21001 raised for pest control sightings in January, closed 05.02.2021. Sighted 22.12.2020- IA on SOPQA0019 Receiving, SOPQA0021- Sampling and Testing of Dairy Goods- FSM 1.11 Importing Country requirements, FSM 1.10 Export Docs, FSM 1.12 Trade Description - QAF036 and QAF0017 completed. Also conformed with site that they undertake systems audits which are scheduled, and monthly GMP audits and spot audits. Spot audits are adhoc, are conducted during process and use IPQC forms.

This element was found to be non-compliant due to the following findings.

Findings:
The below findings have been identified for;
FSM 1.15:

1. Does not consistently describe forms and reports used as part of the internal audit process. 17.02.2021- discussed with site, site is using QAF036 as the Internal audit summary and QAF017 for the Internal Audit checklist. 12.04.2021- NC reviewed and closed- procedure now details QA036 and QAF017 to be used for internal audits.
2. Corrective and preventative procedures for external audits do not describe the CAPA process. 12.04.2021- NC reviewed and closed- procedure now details CAPA process for corrective actions.
3. 17.02.2021 – on review of the Internal audits on SOPQA0019 Receiving, SOPQA0021- Sampling and Testing of Dairy Goods- FSM 1.11 Importing Country requirements, FSM 1.10 Export Docs, FSM 1.12 Trade Description no supporting evidence to show that procedures had been checked against process and or current requirements was documented, QAF017 did not capture Export documentation procedures.

SOP QA 008 Internal GMP Audit:

4. Does not describe GMP audit frequency, process, and how non-compliances are determined and actioned. 17.02.2021- discussed audit process with site, systems audits done as per QAF045, GMP audits done monthly, and spot audits are adhoc.
5. Monthly GMP audit forms have been provided, these forms are not captured in this SOP (QAF062, QAF063, QAF064) 12.04.2021- NC reviewed and closed- GMP forms to be used are now referenced in FSM 1.15.

Internal audit schedule QAF045:

6. Doesn't capture all elements of the AA including; importing country requirements, trade descriptions, HACCP, approved suppliers, the schedule also doesn't reflect internal audits referenced in 1.14a. 17.02.2021- CLOSED- clarified with site, QAF045 lists audits as an overview, SOP QA008 further details what is covered under each audit.

7. Verification procedure 1.14 not provided for review. 17.02.2021- CLOSED.- verification procedure FSM 1.14 reviewed and captures verification activities at site including review of importing country requirements, trade description and those as per 1.14a.

3. Plans & Specifications	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

01-05.02.2021- This element non-compliant at present due to plans not being finalised.

16.02.2021- reviewed under SMF001- Section 3.2- includes overview of site layout of process, packing and warehouse areas. Plans then split per production/packing area for; freeze dry goods processing and packing (milk powder packing under this chart), powder and sachet line flow chart for processing and packing (still under construction), tablet lines, chem and micro labs, warehouse. Plans show entry/exit points, product flow, raw materials entry points, equipment locations.

Plans sighted for shows water lines; cooling return line, cooling supply line, cold water, compressed air dated 05.09.19, Drainage plan map: 12.09.18- shows drain lines, vents and air service lines, Sewer Service diagram- 06.11.19- shows all sewer lines at site.

This element is deemed non-compliant due to the below finding;

Findings:

1. Plans provided do not clearly identify water inlets points, drains inlets, HEPA air outlets/inlets for all of site.

4. Cleaning & Sanitising	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

Sighted Cleaning and sanitising procedure FSM 3.12, covers all of site, daily pre-operational inspection to be completed. Cleaning effectiveness verified by in- house ATP swabs, monthly environmental swabbing, quarterly allergen swabbing and finished product testing. Production and Warehouse Manager or delegate are responsible for monitoring the effectiveness of cleaning daily. General overview of cleaning procedure and chemicals detailed. Cleaning equipment is colour coded for work area/equipment's, storage and cleaning requirements for cleaning equipment is detailed. Covers an overview of cleaning required and frequency, as well as monitoring.

SOP PFD013 General Cleaning procedure reviewed- provides cleaning procedure for bulk production, staging, packing areas for Freeze dry product.

FSM 3.13 Cleaning Schedule reviewed- captures areas of site to be cleaned and sanitised, frequency, chemicals to be used, how to clean, persons responsible and recording form.

FSM 3.14 Cleaning and Approved Chemicals List sighted- details chemicals at site, usage, SDS on file, allergen status and where stored.

SOPQA0018- Environmental Monitoring Procedure reviewed- details air monitoring and environmental swabs to be taken, temperature monitoring, sampling maps are included. Air monitoring to be completed monthly, limits, how to sample and corrective action requirements detailed. Listeria swabbing to be done monthly from a direct and

non-direct contact surfaces, sampling process documented, sent to external lab for analysis. Corrective actions for positive listeria detections documented, includes- intensive clean, testing product, raising CAPA, notify NSW Food Authority, customer, instigating clearance programme.

FSM 3.5 reviewed and details that chemical containers are not to be used for any other purpose and are checked at receival to ensure that they are not damaged, labelled and clean.

QAF040 reviewed.

Sighted SOPPFD019 Portable CIP Machine Procedure sighted and is in place and used for hard to clean equipment such as the heat exchanger.
This element was found to be non-compliant due to the following findings.

On 11/02/2021 The establishment provided SOPS (SOPFPD030, SOPPK001) and checklists(forms- PRF001, PRF002, PRF028, PKF018) for Line Startups and clearance, these are to used be before starting assembly of equipment and materials and before starting manufacturing. SOPS detail procedures such as checking areas/equipment are clean, documentation/tags completed, product-packaging is removed, forms are used to verify rooms are acceptable and ready for use. SOPQA0031 Operation of Hygiena Ensure Touch- documents procedures for use ATP swabs and the acceptable limit.

A site audit occurred on 16-17/02/2021, a walk through of the premises occurred within the warehousing, freeze dry production & packing, milk repack, staff amenities areas, the facility was found to be clean and tidy, no waste overflow or product buildup/spills noted, unused equipment, production/packing rooms, warehousing, amenities, change room areas were visibly clean. Signage of rooms was also in use to show that they had been cleaned. Further discussion on cleaning procedures and monitoring occurred, the establishment uses cleaning and room usage logs, signage, prestart clearance checklist and forms to capture cleaning conducted. Cleaning chemicals were stored away from product, and colour coded cleaning equipment and signage was noted with production and packing areas. The establishment has SOPS in place for equipment use and cleaning, a sample of SOPS reviewed included. SOPPFD003- Cooking Machine Standard, SOPPRFD014- Freezer and Freeze Dryer Cleaning and SOPPFD025- Powder Mixer Liquid. PRF009- Production Cleaning Validation sighted at 16.02.2021- done after cleaning and includes ATP swabs-

This element has been non-compliant due to the below findings;

Findings:

The following findings have been noted for each document reviewed:
FSM 3.12:

1. No frequency is documented in FSM 3.12 for ATP and finished product testing. 16.02.2021- site advised this occurs after cleaning or change of product.
2. Section 9.5 of procedure 3.12 refers to a cleaning schedule at the end of the document, but no schedule is included in 3.12.

SOP PFD013 General Cleaning procedure:

3. Chemicals to be used in the SOP do not align with FSM 3.13. For example Triple S is to be used in the bulk storage area within the SOP, whereas FSM 3.1.3 refers to Ultramax. 12.04.2021- Triple removed from chemical list FSM 3.14.
4. Unclear if SOP PFD013 General Cleaning procedure is the only SOP for cleaning. 17.02.2021- CLOSED- site confirmed SOPS are in place for equipment use and cleaning, sighted SOPPFD003- Cooking Machine Standard, SOPPRFD014- Freezer and Freeze Dryer Cleaning and SOPPFD025- Powder Mixer Liquid, SOPS either covered cleaning, or cleaning and use of the equipment.

FSM 3.14 Cleaning and Approved Chemicals List:

5. Does not include Triple S or 70% Alcohol 12.04.2021- NC reviewed and closed- Triple S removed from list, 70% alcohol added into the chemical list for use.
6. Does not show location of chemicals in dishwasher area 12.04.2021- NC reviewed and closed- now includes locations of chemicals in the dishwasher area.

SOPQA0018- Environmental Monitoring Procedure:

7. Under listeria swabbing it refers to QAF040 for when areas are to be swabbed, on review of QA040 it doesn't detail when areas are to be swabbed. 05/02/2021- CLOSED establishment confirmed that QAF040 is the correct form, location swabs are coded E,F -listeria swabs, A and B settle plates, the legend code is included in SOPQA0018.

8. Procedures provided have not captured what CIPS systems are used at site. 05/02/2021- clarified with site, the only CIP system is for the cooking tanks only. Moulds are cleaned via dishwashing system- site to send validation data through for both. 15.03.2021- establishment provided Qualification Protocol procedure for the CIP tank (FDIQ004 and FDOQ004), but both documents do not capture validation process or data.

SOPPFD019 Portable CIP Machine Procedure— not used anymore- CLOSED

9. validation data to be provided for this unit, must capture each piece of equipment or process line it is used on
10. SOP doesn't include any monitoring or verification checks on equipment/process lines after using the portable unit
11. FSM 3.13 Cleaning Schedule only refers to use of this on the cooking tank system- unclear if this includes the heat exchanger. No heat exchanger is noted in the HACCP plans.

FSM 3.13 Cleaning Schedule

12. Unclear if the air lock and ante room are the same area? Air lock is an areas where you pass between warehouse and packing/production, ante room= change rooms. 05.02.2021- NC closed- Site clarified that the ante room = change room. And cleaning is done daily and weekly.
13. Ante room and bins are to be cleaned monthly on the schedule- frequency may not reflect use of area.- Bag is changed daily, bin cleaned weekly. 05/02/2021- Site clarified that the bins have bags, these are changed daily or when full, cleaning of bin is weekly. NC closed.
14. Procedures provided do not capture how compliance is determined after cleaning via a preoperational inspection, does another procedure capture this? 05/02/2021- clarified with establishment via teams meeting, line startup and clearance procedure and checklists are in place, site to provide. 11/02/2021- establishment provided line startup and clearance SOPS and checklists- SOPS (SOPFPD030, SOPPK001) and checklists(forms- PRF001, PRF002, PRF028, PKF018) however these procedures have not been included in FSM 3.12 for use.
15. No reference to ATP swabs being undertaken after cleaning is documented in any procedure provided. 11/02/2021- SOPQA0031 Operation of Hygiena Ensure Touch provided for review does not detail when ATP swabs are to be done, where results are recorded, corrective actions only capture reclean and reswab- no further actions detailed if failure still occurs. 16.02.2021- site advised that they redo until result ok, procedure does not capture process for when multiple failures occur. 12.04.2021- SOPQA0031- Operation of Ensure Hgienia Unit- NC reviewed - SOP now details that QID to be raised for repeat failures, however procedures reviewed still not clear on frequency of ATP swabs, swab location or records used.

5. Water Sampling	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
Sighted FSM 1.2 Product Assessment, Inspection and Testing Procedure- covers general overview of testing done at site, including water. Water at site is potable, supplied by Sydney water, Sydney water monitors chemical and physical testing against the ADWG. The quarterly Sydney Water Quality report will be reviewed, issues with chemical and physical parameters will be investigated. Monthly ecoli testing of water occurs at site.

SOP QA0014 Water Quality Monitoring Programme reviewed, one sample per calendar month is taken, tested for Ecoli at NATA lab, sampling process defined, water sampling map and sample location list is included, corrective action documented for out of specification results covers notification to the department and investigations. Site obtains the annual Sydney water quality report or completes the testing if the report is not available.

This element is non-compliant due to the following findings.

Findings:
The following findings have been noted with relation to:
FSM 1.2;

1. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager or technical Officer. 12.04.2021- NC reviewed and closed- procedure refers to QA Manager/Delegate, Technical Officer, or QA Officer throughout the procedure.
2. Persons who review the Sydney water quality report and the process for investigating issues with the report is not documented. 12.04.2021- NC Reviewed and closed- details QA Manager or Technical officer to review results.

SOP QA0014 Water Quality Monitoring Programme:

3. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager. 12.04.2021- NC reviewed and closed- procedure refers to QA Manager/Delegate, or QA Officer throughout the procedure.

4. Sampling states one sample per month, rotating through the location list table 2, however there are > 12 samples. 05/02/2021- establishment confirmed that they are completing all test points each month. 12.04.2021- procedure has not been changed.
5. SOP QA0014 details that the annual Sydney Water quality report is obtained, whereas FSM 1.2 states the report is reviewed quarterly. 05/02/2021- site confirmed that they are conducting both activities. NC CLOSED
6. Retention period of water quality records is 7 years, this differs to FSM 1.9. 05.02.2021- site confirmed it should be 3 years, procedure to be updated. 12.04.2021- NC reviewed and closed- retention period changed to 5 years and reflects FSM 1.9 requirements.

6. Pest Control	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM 3.6 Pest Control Procedure sighted, monthly external services by a pest control technician are carried out, additionally staff are to report pest sightings, these are entered into the pest control log and a monthly Warehouse GMP audit is conducted. Procedure details hygiene and maintenance requirements to ensure compliance to pest control. FSM 1.18 Control of Non-conforming product is to be instigated if product is affected with pests. Recommendations from the pest control technician are to be actioned by the site.
Pest control service requirements are defined, including target pests/vermin. The technician conducts routine services and treatments, including actioning any issues noted in the pest sighting log, a pest control manual is on place that contains SDS, licences, bait station map.

A site audit walk through occurred on 16.02.2021 within warehousing, amenities, production and processing areas, no pest and vermin issues were noted. Pest and vermin controls are located outside of the production and processing areas. Sighted bait stations within the warehouse area and building perimeter. Doors into the facility were closed when not in use, air locks (rapid doors) and personal doors are in place and are sealed/closed after use.

This element is non-compliant due to the following finding.

Findings:
1. Section 7 does not include GMP audits for the production & packing areas. 12.04.2021- NC reviewed and closed- procedure now reference to internal audit schedule.

7. Protection, Segregation, Waste and Other Products	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

FSM 3.5 Waste procedures sighted, GMP audits and cleaning to be conducted to ensure compliance to waste procedures. Waste is to be identified and separated from food product. Procedure captures requirements for handling and hygiene requirements of solid (recyclable and non-recyclable waste) and liquid waste. Non-conforming product is to be clearly labelled as so.

See section 4 for information on chemicals.

Refer to sections 8 and section 12 on product handling and identifications.

FSM 1.18 Non-conforming product procedure reviewed, details process of identifying non-conforming product/equipment/material and process of determining disposition of them, notification to the department has been included. Process includes isolation, labelling of affected product and placing on hold in the computer system so that it cannot be used.

A site audit walk through occurred on 16.02.2021, product and packaging within the warehouse areas was sighted to be labelled and contained in packaging. Waste bins were noted within the sachet packing room, and were separated from product, external kin bins for waste were sighted outside the milk repack area, were labelled and no overflow was noted. Raw materials and finished products were labelled and stored in areas for quarantine and final release, labels were in place to reflect status of these products. WIP sachet product was sighted in the freeze dry production & packing areas in labelled and covered tubs. Chemicals storage was separated from the product in the warehouse and dishwashing room. Products (raw materials, finished products) and cleaned equipment were stored off the floor and covered.

This element is non-compliant due to the following findings

Findings:

Findings for FSM 3.5:

1. Section states no rework, however FSM 1.13 details rework is used at site. 12.04.2021- NC reviewed and closed- procedure now details rework procedure.

Findings for FSM 1.18 Non-conforming product;

2. Refers to the title of a QA Manager, but no role is listed in the organisational chart or position descriptions for Est1405. 12.04.2021- NC reviewed and closed- updated to reference QA Manager or delegate.
3. Procedures to be followed for product being processed or received is not clearly defined. 05/02/2021- site confirmed that it WIP and received product follow the same process, procedure to be amended to incorporate reference to WIP and received product. 12.04.2021- NC reviewed and closed- procedure scope now covers receivals through to dispatch.
4. Does not include procedures for handling non-conforming export products. 12.04.2021- NC reviewed and closed- procedure reviewed , same NC process applies but different colour code and labelled applied for export products.
5. Procedures provided no not include how and if export product will be processed differently to domestic product. 12.04.2021- procedure FSM 1.13 covers handling of export vs. domestic product.

Note: 17.02.2021- no operations were occurring in the freeze dry production area and the milk repack production- packing area at audit, further review of these areas is required to further verify compliance to this element.

8. Protective Clothing, Premise Construction, Personnel Hygiene and GMP/GHP	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

FSM 3.1 GMP procedures reviewed, covers production, packaging and warehouse areas as follows;
Monitoring of GMP occurs via daily GMP inspections and cleaning, and monthly GMP audits. Major changes to the premises are to be approved by the DAWE. Three hygiene zones are in place at site and details entry, equipment and basic overview of PPE requirements in each. Procedure captures where warehouse staff store personal items and lunch. Refers to FSM 3.3 for details on Personal hygiene and PPE.
Equipment is to be kept clean and maintained, refers to the cleaning procedure 3.12 and maintenance procedure 3.8 for equipment requirements.
Further controls of GMP are via procedures; 3.6 Pest Control, 3.5 Waste Management, 3.3 Personal Hygiene, 3.4 Storage Procedure, 3.11 Allergen Control Procedure and work area SOPs.
All raw materials and finished products are to be fully enclosed, any damaged product is to disposed of. Controls are in place for introducing packing or raw materials into staging- outer packaging on raw materials is removed or cleaned. Only human food product is produced at site.
Doors, positive air pressure and air locks in high and medium risk areas are in place to prevent air born contamination. No animals are permitted at site. Compressed filtered air is used, not for direct contact with product, maintenance manages air filters.
Tools are to be stored in designated containers
Procedure defines requirements for glass, soft and hard plastics, wood and metal.
Cleaning chemicals are to be approved for use, stored in designated area, staff are trained in chemical handling and are to follow cleaning procedures/SOPS/schedules.
Tools used daily are kept in the work areas in designated containers.
Maintenance / contractors also bring tools into these areas but are checked for condition and cleanliness before and after use, the work area is also checked for debri and cleanliness.
Products are to be stored off the floor- applies to raw materials and finished products.
Stock transfers are recorded for product moved between both GMP sites.
Export product us transferred using approved suppliers, department seals are currently not required at site.
Site uses FEFO for stock rotation, the computer warehouse system manages this via the batch number.
Sighted GMP templates; QAF064, QAF062 and QAF063.

FSM 3.3 Personal Hygiene requirements sighted; covers health, handwashing and hygiene requirements of staff and visitors. General overview of uniform and PPE requirements is included. Uniforms and PPE are checked before use to ensure they are fit for use. QID and CAPA to be followed for any breaches of personal hygiene requirements.

See training element for details on GMP training.

SOPPRO013 Gowning Procedure sighted, captures procedures for adorning uniforms/PPE when entering and existing production/packing areas.

FSM 3.4 Storage reviewed, details procedure relating to storage of raw materials and finished products at site, daily and monthly monitoring occurs to determine compliance to the procedures. Details storage requirements of raw materials and finished products from time of receival to dispatch, all dairy products are pasteurised and received from Department registered establishments with transfer certificates. Corrective actions for damaged or quarantined stock is detailed Storage requirements of packaging, chemicals for cleaning, maintenance and pest control are documented.

FSM 3.11 Allergen Management Procedure reviewed, procedures for control of allergens at site, various allergens at site, specific storage, labelling and handling controls are in place for allergens except dairy, as dairy is the main allergen in products at site it is not treated as an allergen product. Risk matrix of allergens is in place, processing and cleaning procedures are in place for allergen and non-allergen products, verification is via ATP & environmental swabbing and product testing.

A site audit walk through occurred on 16.02.2021, areas reviewed as part of this walk included the; milk repack and Freeze dry production and packing, warehousing, amenities and cold storage area. At the time of the site walk through only one room within the freeze dry production area was running, freeze dry yoghurt sachets were being packed and staff within this area were observed to be wearing the required PPE and uniforms. Change rooms and air lock rooms where staff and products are moved into/out of production/packing were sighted, air showers are in place for when staff enter the freeze dry production and packing areas. Both milk repack and freeze production change rooms had PPE and uniforms available, gowning procedures were in place. Areas reviewed were found to be maintained and clean, and waste was separated from edible product and identified. Cold storage units (chillers and chest freezers) were sighted with monitoring controls in place. No specific allergen procedures were reviewed as part of the site walk. Raw materials, WIP and finished products were identified/labelled, were covered/packed and were stored off the floor. No maintenance issues were noted with equipment or structures at the time of the audit. Within the milk repack area on entering/exiting staff change and apply/remove PPE such as striped poncho, hair net, snood, shoe covers, wash and sanitise hands, once inside repack area staff cannot cross over the redline, same applies to warehouse staff bringing product into the area. On entering the freeze dry production and packing areas, similar PPE and uniforms are applied, with different boots and poncho for packing versus production, no cross over between areas, staff must enter and exit via change room protocols. Each production, packing and storage room has a cleaning log, and where required an air pressure and humidity log, these are completed am and pm when in use, sighted samples of these logs at audit. Further review of the freeze dry production process is required to verify GMP controls in these areas.

This element is non-compliant due to the following findings

Findings:

FSM 3.1 areas that require addressing:

1. Corrective actions for GMP audits don't capture preventative actions or reference to SOP QA 008 Internal GMP Audit. 12.04.2021- NC reviewed and closed- procedure now includes GMP audits checklists to be used, internal audit procedure/SOP QA details corrective actions.
2. Amenities are only referenced as being separate to the storage area- section 9.8- 17.02.2021- discussed with site, missing reference to production (process and packing areas)in this statement. 12.04.2021- NC reviewed and closed- no covers amenities for storage, production and process area staff.
3. Unclear where production and packing staff lockers are.16.02.2021-CLOSED procedures refers to staff kitchen, area was sighted at audit and reflect the procedure.
4. Section 9.11 does not include if damaged product is isolated or held or if CAPA process is followed. 12.04.2021- NC reviewed and closed- now refers to relevant area SOPS for corrective actions.
5. Dropped product procedure is not clearly described and if product goes on hold- states 'will be disposed transferred to designated area for review by QA, prior to disposal immediately. 12.04.2021- NC reviewed and closed- procedure now refers to dropped product SOPS for further corrective actions, product will be isolated, reject notice raised and inspected before being rejected.
6. Is there a record kept to show the line or equipment has been cleared after a maintenance intervention. 18.02.2020- CLOSED- QAF037- Maintenance form is in place, referenced in FSM 3.8 Maintenance procedures.
7. 17.02.2021- discussed Hygiene zoning table with site, it is used to classify the hygiene and cleaning requirements at site, the table currently doesn't capture the definition of what constitutes the high, medium or low risk zones. 12.04.2021- NC reviewed and closed- now includes definitions for each zone.

   FSM 3.4 Storage Procedure findings.
8. Procedure does not clearly explain storage requirements; Section 9.1 paragraph 3 details how some products require temperature control, paragraph 5 then states no products or ingredients require temperature control, section 9.2 details different temperature requirements as well. 16.02.2021- sighted a chiller and chest freezers storing ingredients at site, monitoring controls are in place, FSM 3.4 requires amendment under paragraph 5 where it states no products or ingredients require temperature control
9. Storage requirements of export product have not been included.

   3.11 Allergen Control Procedure findings;

10. Scope does not include production and packing areas.
11. Under storage and handling (dot point 2) it refers to a pink label for allergens, but in the table it states orange.
12. Provide allergen validation data for each product line/area. 15.03.2021- allergen swab reports provided (report FM2103287 and FM2100921) from January 2021, but no support validation study report has been provided.

FSM 3.3 Findings:

13. Scope only refers to the warehouse, not production and packing areas.
14. Doesn't reference FSM 3.1 or reflect PPE requirements per hygiene zone, or personal effects as per FSM 3.1 or SOPPRO013 17.02.2021- discussed with site, reference to FSM 3.1 and SOPPRO013 to be added.
15. Procedure states an informal assessment is completed on uniform and PPE fitness for use- need a formal assessment as evidence it has been carried out. 17.02.2021- establishment confirmed that no formal assessment is in place, site to complete and provide.
16. Lacking detail on footwear requirements, only states they are provided and to be stored, or covers are provided. 17.02.2021- CLOSED- discussed with site, footwear requirements are captured under FSM 3.1 and SOPPRO013.

SOPPRO013 Gowning Procedure findings:

17. Procedures in this SOP do not align with zones or clothing requirements in FSM 3.1 or 3.3. For example the SOP refers to 2 zones, while FSM 3.1 refers to 3 zones. 17.02.2021- CLOSED- further discussion with site on zoning, FSM 3.1 zones are risk rated for hygiene and cleaning, zones in FSM 3.3. are specific to clothing & PPE requirements for each area, the site walk through verified compliance to the FSM 3.3 requirements for clothing and PPE.
18. Unclear if the SOP applies to the warehouse staff and packing area as only refers to production. 17.02.2021- discussed with site, applies to all staff and areas at site, clothing and PPE requirements for warehouse and packing staff has not been included. 12.04.2021- NC reviewed and closed- scope updated to cover manufacturing and warehousing areas.
19. Section 6.6 requires review to detail exact requirements for entering and exiting all zones listed. 17.02.2021- after review of procedures at site, procedure does not clearly capture PPE/clothing requirements for milk repack, freeze dry production and packing areas. 12.04.2021- NC reviewed and closed- procedure now clearly details enter/exit requirements for each area.
20. Further details on when/where PPE, boots are changed, stored, and cleaned is required. 17.02.2021- the documented procedure does not currently reflect requirements for each area and how they are stored/changed. 12.04.2021- NC reviewed and closed- procedure now clearly details footwear requirements for each area.
21. Section 6.7 States uniforms are to be placed in the storage unit if leaving area temporarily, but then states if unform is clean to place in locker. 17.02.2021- at audit confirmed that uniforms are stored on hooks if provided or in bin for cleaning. 12.04.2021- NC reviewed and closed- procedure now clearly details current storage/ disposal requirements for uniforms/PPE.

9. HACCP	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

The establishment has the following HACCP supporting documents in place;
FSM 2.02- HACCP Team – details persons at site who are part of the team, roles, experience and training are detailed. s. 22(1)(a)(ii) is the HACCP Team Leader.
FSM 2.03- HACCP Supporting Information – provides an overview of products produced at site and summary of hazards. New products are to be reviewed by the HACCP team and approved by the NSWFA or DAWE. Information details how hazard significance is determined via a risk matrix and a CCP decision tree is documented to be used.
FSM 2.04- Food Ingredient and Packaging Hazard Analysis – details hazards for ingredients and packaging used at site.
FSM 2.05- HACCP Verification Schedule- details HACCP verification activities at site, covering elements such as review of records, HACCP review, testing of product and environmental sources and more.

The establishment stores and processes blended dairy powder products, as well as transfers/receives products from their second site (Girraween). All dairy and eggs ingredients supplied and used at site are pasteurised and dried by approved suppliers.

4 HACCP plans in place for export related products are:
FSM 2.1.1-2.1.4- Dairy Products- covers receivals, storage and dispatch of packed dairy products

FSM 2.2.1- 2.2.4- Repacked Dairy products- covers repacking of dairy product powders into bottles/ sachets
FSM 2.3.1-2.3.4- Milk Dice Freeze Dried Products- covers processing of freeze-dried milk-based products with additional ingredients
FSM 2.4.1-2.4.4- Freeze dried yoghurt-based products- covers processing of freeze-dried milk yoghurt powders, with or without fruit/flavours.

As part of this desk audit the HACCP plan 2.3.1-2.3.4- Milk Dice Freeze Dried Products was reviewed.

- 2.3.1 Product Description and intended use- Milk Dice Freeze Dried Products – details cooking a blend of products with milk powder, anhydrous milk fat, egg, colours and flavours, product is aerated and freeze dried. Both milk and egg products used are pasteurised, the water activity of finished product is no more than 0.83. Product is packed into sachets and deemed ready to eat for general population, notes not for persons who are allergic to dairy and eggs.
- 2.3.2 Process Flow Chart - Milk Dice Freeze Dried Products- captures steps from receivals to dispatch/delivery, CCPS and RCPS detailed. Some inputs and output points are noted.
- 2.3.3.3.3 Milk Dice Freeze Dried Products- Hazard analysis- general hazards and hazards specific to the processing of milk dice freeze dried products has been documented, hazards identified into biological, physical, chemical, regulatory, traceability, hazards are risk rated, control measures listed and if a CCP or not has been described.
- 2.3.4- Milk Dice Freeze Dried Products- HACCP audit table- CCPs and RCPs identified and reflect the flow chart and hazard tables- hazard, control, critical limit, monitoring, records, corrective actions detailed.

- RCPs/CCPS across flow chart, hazard and HACCP audit tables align.

A site audit walk through occurred on 16.02.2021 to verify production processes, both FSM 2.4.2 Freeze Dried Yoghurt Bases Products and 2.2.2 Repacked Dairy Products Flow chart were reviewed, and findings have been noted. As only one room was in operation (freeze dry yoghurt sachets were being packed into retail packs and cartons), FSM 2.4.2 steps 24 to 27 were only able to be verified at audit against the process being undertaken. Another site audit is required to verify the remainder of the production process for FSM 2.4.2.

This element is non-compliant due to the following findings.

Findings:

FSM 2.01- Food Safety and Quality (HACCP) Scope and Purpose 17.02.2021 reviewed;

1. Does not capture the scope of the intended markets of products made at site.
2. Does not detail that the establishment is a contract manufacturer.

FSM 2.02 HACCP Team- 17.02.2021- discussed with site, still in process of update.

3. s. 22(1)(a)(ii) is listed as the QA Team Leader whereas the Organisation Chart lists s. 22(1)(a)(ii)
4. Qualifications of staff are not consistently listed in the HACCP team table. For example: s. 22(1)(a)(ii) has an engineering degree as mentioned in the procedure but is not included in the table.

FSM 2.03- HACCP Supporting Information

5. Does not capture if products produced at site are all GMP Pharmaceutical products or if contract packaging is also conducted at site- further details on scope and purpose required. 17.02.2021- CLOSED- to be captured under FSM 2.01, FSM 2.01 was not provided as part of the original desk audit,
6. Does not clearly detail that site is handling/processing product for domestic and export markets. 17.02.2021- CLOSED- to be captured under FSM 2.01, FSM 2.01 was not provided as part of the original
7. Processing hazard section doesn't include repack product section.

FSM 2.04- Food Ingredient and Packaging Hazard Analysis

8. Hazard significance has not been determined for each hazard identified.

FSM 2.3.1 Product Description and intended use- Milk Dice Freeze Dried Products – site to review findings against all HACCP plans.

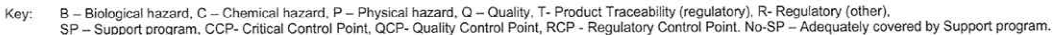
9. Shelf life of product states 24 months, whereas FSM 1.13 states products have a 12 month best before from DOM- 16.02.2021- CLOSED- site confirmed that shelf life is 24 months, FSM 1.13 is an example only, noted as e.g. 12months
10. Doesn't state the destination markets/ countries-17.02.2021- on review of 2.4.1 Freeze Dried Yoghurt based products the shipping section does not reflect the current process of the customer storing domestic product at site and they organise shipping.
11. Microbiological testing section does not reflect testing conducted under FSM 1.20a.
12. Final preparation and use states product is ready to eat- 16.02.2021- CLOSED- sighted freeze dry yoghurt product at audit, product is ready to eat, no reconstitution required.

FSM 2.3.2- Process Flow Chart - Milk Dice Freeze Dried Products-– site to review findings against other HACCP plans as well.

13. Inputs and outputs are not included at all relevant steps or linked to relevant steps. For example; no reject output has been noted at xray steps, not all inputs included (labels) step 5), waste output at step 14 (when product is held at correct temps the hazard table states is rejected).
14. Flow chart verification date is 2019, FSM procedures required an annual review. 17.02.2021-no review occurred in 2020, additionally FSM 2.2.2 has no review in 2020.

FSM 2.3.3 Milk Dice Freeze Dried Products- Hazard analysis

15. No supporting document was reviewed that defines the key/legend code for types of hazards (with the exception of CCPs/CPs). 17.02.2021- CLOSED- FSM 2.01 reviewed and includes definition of hazard types.


Key: B – Biological hazard, C – Chemical hazard, P – Physical hazard, Q – Quality, T- Product Traceability (regulatory), R- Regulatory (other), SP – Support program, CCP- Critical Control Point, QCP- Quality Control Point, RCP - Regulatory Control Point. No-SP – Adequately covered by Support program.

16. Hazard analysis only contains 31 steps, flow chart has 32 steps (missing label sachets in hazard table)
17. Step 11 Cooking include a hold time 17.02.2021- CLOSED site confirmed that no hold time as is not a CCP, product work orders detail steps for making each product which includes times for cooking/mixing ingredients.
18. Not all control measures have been considered, for example: all steps- equipment/utensils hasn't considered maintenance activities, steps where temperature control is required haven't considered storage/calibration procedures, training not considered as a control for some hazards such as CCP points. 17.02.2021- discussed finding with site, confirmed not all control measures have been included.
19. CIP is referenced as a control measure for cleaning of the heat exchanger and buffer tanks, is there other equipment's/lines where CIP is used? No CIP information has been received- validation material is required for review.
20. Some control measures for hazards have been recorded as 'refer to earlier steps' but no relevant step is named- 17.02.2021- site confirmed this is to do with specific steps, hazard table does not clearly define the specific steps.
21. Step 8 in the hazard table is sanitise with wipes, whereas the flow chart is Sanitise UV tunnel. 17.02.2021- no UV is used at site, flow charts FSM 2.3.2 and 2.2.2 currently include UV for sanitising.
22. Receivals steps refer to the GIN code, whereas 1.13 refers to the GIN and item code- is just the GIN code used for traceability 17.02.2021- CLOSED- site confirmed both can be used to trace, but GIN is the main identifier, GIN book captures products received, GIN and item code etc.
23. Step 25 in the hazard table is listed as xray, whereas the flow chart calls step 25 metal detection 17.02.2021- confirmed via site walk that xray is in used at site.

FSM 2.3.4- Milk Dice Freeze Dried Products- HACCP audit table- 12.04.2021- product not being produced at site, if site commences production of product then HACCP plan for this product is to be resubmitted for review and approval, shelf life validation data will also be required.

24. Step 1- RCP 2 details product will be rejected if export documentation is not received, whereas FSM procedures (e.g 1.10) indicate product will be used for domestic product.
25. Justification of critical limits doesn't reference annual revalidation of CCPs

General HACCP and FSM findings:

26. It is unclear after review of the above HACCP plan and FSM procedures (1.20, 1.18, 1.13- go back and check these) if raw materials are placed on hold (quarantine label), labelled until inspection and testing is completed; HACCP plan states they are inspected and tested. 17.02.2021- HACCP plan does not clearly detail the product is placed on hold under sample & inspect.
27. Water activity testing of product is not included in FSM 1.20a. 17.02.2021- CLOSED- discussed with site, not included as is a CCP covered under HACCP verification table
28. Shelf life validation data to be provided for export products. 15.03.2021- establishment confirmed that no shelf life data is available for Freeze dried milk dice products. Shelf life data has been provided for 2 Vmores products, but data is complete as has only tested up until 1 months shelf life, products has 24 months shelf life 12.04.2021 – due to Freeze dried yoghurt product now being deemed non-presrcibed by new export legislation no further review of this product is to occur as part of the review process, if at any stage the establishment is to export to a country that deems this product prescribed than the establishment is to contact the department to have the freeze dried yoghurt product approved.. Repacked dairy products shelf life has not been provided.

16.02.2021- A review of FSM 2.2.2 Process Flow Chart and 2.2.3- Hazard table for Repacked Dairy Products at site, the line was not in use. A review of FSM 2.4.2 and FSM 2.4.3 Freeze Dried Yoghurt based products also occurred (note only steps 24-27 were in operation), the following findings were noted;

29. Not all steps have been included in the process flow chart and hazard table. For example; decant/debag step not covered for all inputs (seals and scoops), transfers from storage to process areas (and back) or between process areas, or interim storage of WIP product are not all included.
30. The documented process flow steps do not reflect current process. For example; step 13 code container is not conducted at the current point on flow chart, no coding machine was in place at this step.
31. Process steps do not clearly describe what is occur at the step. For example; assemble order steps do not explain what is occurring at the step

32. Process flow steps do not align with those in the hazard table. For example, Step 16 on FSM 2.2.2 is 'carton', whereas step 16 on FSM 2.2.3 hazard table has pack in cartons/shipper.
33. The process flow charts and hazard tables do not clearly detail the steps when the carton and pallet is labelled.
34. Not all steps in the process are required for all products. For example; blending step is not required for all products.

10. Sampling and Testing	Compliant? (Yes / No/ NA-Not Assessed)	**No**

Summary of Findings:
Sighted FSM 1.20 Product Assessment, Inspection and Testing Procedure sighted, raw material, finished product and water testing requirements. Form QAF28 to completed for out of specification product. QA Manager or Technical officer reviews records relating to food safety, production, product, water and environmental testing.
An overview of testing is referenced, then refers to SOPS in place for testing of products, water, environmental testing; SOP QA0021 Sampling and Testing of Export Products, SOP QA0014 Water Quality Monitoring Programme, SOP QA0018 Environmental Monitoring Programme. All testing to be completed a NATA approved lab, only trained persons are to sample product. Any out of specification product is to follow SOP QA 0023 Out of Specification Procedure. Raw materials and finished products are inspected before and during production. Finished product testing is done to meet domestic and importing country/ customer requirements. Corrective actions detailed and include notification to the Department.
Quarterly allergen swabbing to occur, determine no presence of eggs
Air quality testing procedure are detailed, an annual positive air pressure check is completed by an external contractor. Establishment also completed air quality testing as well.

SOP QA0021 Sampling and Testing of Export Products reviewed- details microbiological testing requirements for export product.

FSM 1.20a Product Testing reviewed, captures domestic and export testing requirements (China and Hong Kong).

This element is non-compliant due to the following findings.

Findings:
The following findings have been noted with relation to FSM 1.2;

1. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager or technical Officer.
2. Corrective action procedures are not clearly documented to reflect forms and processes followed when test results are out of specification.
3. The procedure does not reflect who reviews Sydney water quality reports and actions when issues are identified with the report.
4. Section 9.8 details environmental swabbing for salmonella and Enterobacteriaceae, but this is not documented in SOP QA0018 Environmental Monitoring Programme.
5. Allergens to be sampled as per SOPQA0018 Environmental Monitoring Programme, but this programme when reviewed did not include allergen swabbing.
6. Section 9.9 Air Quality testing doesn't refer to and reflect SOP QA0018 Environmental Monitoring Programme; different frequency, limits, sampling locations and corrective actions.

1. SOP QA0021 Sampling and Testing of Export Products does not reference contacting the Department for out of specification product. 12.04.2021- NC reviewed and updated- now includes reference to contacting the department for Out of specification product. Relevant GACC standards are referenced.

11. Training	Compliant? (Yes / No/ NA-Not Assessed)	**Yes**

Summary of Findings:
01-05.02.2021- FSM Training 3.2 reviewed, all staff to completed induction before commencing work, inductions covers workplace induction, food safety, employee responsibility, contamination. Further Sop training completed in; personal hygiene, GMP, gowning procedure. Staff to complete an attendance record at induction, once staff are competent the training matrix is updated. Further training is conducted per department area, this training is based on department SOPS. Each staff member will have a training plan in place, training plans incorporate, induction, GMP, HACCP, food safety and external/special training. A training matrix/ register is used to capture

staff and training plans completed/in process. Training records are in use and are to include staffs competency assessment which is based on discussion, observation, execution or achieving 85% pass mark in a test. Refresh training on SOPS is to occur every 3 years or when changes occur, GMP training annually, additional training can be carried out as needed if deemed required. Procedure details export signatories will have knowledge of export, import country requirements, persons who are using Exdoc will also be trained.
This element is non-compliant due to the following findings.

11/02/2021- additional evidence was provided by the establishment to support FSM 3.2, this element is now compliant.

Findings:

1. Under the SOP training states staff will be observed and then deemed competent - unclear if this is occurring at induction and how competency is determined? Further on in Section 9.6 clearly details how staff are assessed, is this section applicable to induction as well? 11/02/2021- CLOSED- training matrix provided and includes Induction modules, training method and level of competency required. Information in the SOP is now understood and supported by the training matrix.
2. Sample of training matrix and or records not provided- 11/02/2021- CLOSED- a sample of the training matrix was provided, details training modules, method of training required per work area and the level of competency required. Sample of training records supplied for induction, HACCP, export and CAPA training.
3. Training is completed by either; read only, read and understand, onserved, observed, testing/quiz- how is this determined for each SOP/training package? 11/02/2021- CLOSED- training matrix details the method and level of competency required for each training module at site.
4. No details about how export signatories attain their knowledge in export, import country requirements etc is detailed. 11/02/2021- CLOSED- training matrix includes Export Dairy Control section, covers all modules (SOPS) staff are to be trained in, the method of training and level of competency required.

12. Identification/Traceability & Recall	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM 1.14 Product Identification and traceability reviewed, all raw materials are assigned a traceable item code when received this is linked to the receival register, is a sequential number. The traceable item code is used for traceability via the companys stock system and for the production process. A GIN (goods inward Notebook) captures information on the product. Product is transferred once received to it's a designated area, colour coded labels are applied to signify product status. Details export and domestic product to be labelled and segregated. Non-export products have different names and codes. Stored and WIP products labelling requirements are captured. Batch numbers of raw materials are recorded on production and packing work orders (these are generated for each batch. Finished products are issued a manually generated batch number and best before date (12 months from date of manufacture), these are printed onto packaging, HW signifies Huntingwood site, work orders and packaging document confirm batch number/best before date, these are checked for each run. Rework is allocated a work order and rework form and checklist are to be used. Finished products are traceable via; best before date, batch number and production and packing work orders and documents. When products are dispatched, dispatch docket is generated, links to computer system and captures traceability of product.

FSM 1.19 Recall and Withdrawal procedure reviewed, covers process for all products to be recalled and withdrawn, includes notification to the department for export product.

A site audit occurred on 16-17.02.2021 where further review of procedures both documented and on floor operations occurred. Products (raw materials, WIP and finished goods) were found to be labelled and segregated as hold and release procedures required. An overview of the receivals process occurred, GIN book and the dairy transfer log books were sighted, one book capture non-dairy ingredients and the other captures dairy goods received at site (batch, item codes, GIN id, supplier, est) were recorded in this book. Once the GIN is allocated the products/pallets are labelled with a quarantine label, once tested/inspected a release label is applied. QA also capture goods received in the sampling register, they notify the warehouse once product has been released. Details of goods received are also entered in the computer stock system (Pronto). The Pronto system was reviewed, the system captures raw material and finished goods hold and release details, and work orders for production-packing. Planning department create productions and packing batch numbers from the planning database and are a sequential number, these are then entered into the Pronto system for relevant work orders, the warehouse then uses the work orders and GIN ID to pick product required. Production and packing work orders are issued for each new batch of a product, captures ingredients used as per the BOM, the process steps of producing/packing product detailed, staff are to check off each step is completed on the work order, CCP and QCP monitoring is also included. A packing work order was sighted for Freeze dried Berry Vmore yoghurt sachet product at audit, records had been completed as required for cleaning, hygiene and QCP monitoring. A review of a Mock Recall completed on 05.08.2020 occurred for a packaging complaint of product, wrong cap used on product MV powder, product affected was traced and root cause was determined and actions were taken.

This element is non-compliant due to the following findings.

Findings:

FSM 1.13 Product Identification and traceability findings:

1. Unclear if the GIN and the item code are the same and how are they are linked (section 9.1.1) (item code is the raw material code , product code) 17.02.2021- CLOSED- site confirmed GIN and item code (product code) are separate, when goods are received, GIN is issued in GIN book and item code is recorded with it as well. Can track GIN and item code in the computer stock system (Pronto)
2. Unclear how the traceable item code, GIN, manual batch number and receival register are linked to computer stock system? 05/02/2021- establishment confirmed all link to the computer stock system, further review of the trace process to occur at site visit. 17.02.2021- CLOSED- discussed with site details of the product are entered in the Pronto system using information from the GIN book, receival register and production-packing work orders. Sighted example of Finished goods in Pronto system- records batch code, item code, work orders and quarantine/release status.
3. Raw material batch details are recorded on production and packing work orders, but where does the GIN/ traceable item code come into it? 05/02/2021- establishment confirmed that both the GIN and traceable item code (product codes) are recorded. NC CLOSED.
4. Procedure does not define how export product is labelled. 12.04.2021- NC reviewed and closed- procedure now clearly describes how export product will be labelled.
5. Procedure doesn't capture scheduling requirements of export and domestic product? 05 & 16/02/2021- site confirmed that Sales receive orders, sales confirm if export or not then arrange ingredients as required, production then scheduled, export then domestic production to occur, and export products will have a different code to non-export product- FSM 1.13 currently does not clearly capture this process. 12.04.2021- NC reviewed and closed- procedure now clearly details production scheduling process for export vs non-export product.

13. Approved Supplier Program; Ingredients and Packaging	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

FSM 1.22 Approved Supplier Procedure sighted, is supported by SOP QA0026 and Approved Supplier List. Only products on the approved supplier list are to be purchased. Procedures defines requirements for approval of suppliers for ingredients (dairy, non-dairy), packaging, service suppliers for maintenance, labs and chemicals. Procedure details the requirements for Australian and imported dairy ingredients suppliers (reflects requirements as detailed in FSM 1.10- see section 15. If products do not have enough documentation to show that it meets export requirements, then it is not used for export product. Eu supplier and product information must be met in order for the ingredients to be used not EU finished product. Dairy suppliers must also provide documentation such as: CoAs, Department Export Registration (or similar for imported product), HACCP certificate or equivalent, Supplier questionnaire. An annual review of suppliers occurs.

At the site audit on 16.02.2021 the site confirmed that they are not intending to export to the EU and that export products will have a different product code to non-export product.

This element is non-compliant due to the following findings.

Findings:

1. Procedure doesn't capture process of routine monitoring of suppliers and goods at time of receivals, or non-conformance process for suppliers- 16.02.2021- procedure does not include monitoring of receivals or corrective action process for non-compliant suppliers.

2. Approved Supplier Register/list and SOP QA0026 is still in process of being developed.

3. 16.02.2021- FSM 1.22 includes EU requirements, site is not intending to export to the EU.

14. Receiving and Dispatching Milk & Milk Products	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

SOPWHS009- Dispatching Goods reviewed, covers steps when dispatch goods at site, see findings as below.

Sighted SOPWHS0002- Receiving Items covers steps when receiving goods at site, findings have been noted below.

See sections 13 15- Information on receiving and dispatching of product

This element is non-compliant due to the following findings.

Findings:

SOPWHS009- Dispatching Goods findings:

1. Section 7.9 details checking of truck for dairy goods, but doesn't elaborate on what the checks are or if these are recorded- 17.02.2021- no dispatch checklist is currently in place. 12.04.2021- WHF 009 Domestic Dairy preloading checklist provided but refers to domestic product.
2. Section 7.9 is the only part that references a transfer certificate, procedure does not include what checks are required for export product.
3. Unclear in the SOP if a dispatch checklist is completed. 17.02.2021- no dispatch checklist is currently in place. 12.04.2021- WHF 009 Domestic Dairy preloading checklist provided but refers to domestic product.

SOPWHS0002- Receiving Items:

4. No reference to checking dairy products for export compliance is noted in the SOP.
5. FSM 1.13 refers to a traceable item code being issue first then a GIN, but SOP just refers to the GIN- which is correct. 17.02.2021- CLOSED confirmed with establishment that the GIN is issued at receivals, is recorded in the GN book with item code.
6. HACCP plan reviewed refers to a receival checklist, but this SOP doesn't not reference such as checklist. 17.02.2021- CLOSED- site confirmed that the checklist is 'QAF034' and is completed by QA for products requiring temp control only.
7. Is part b undertaken for all products received? 17.02.2021- closed site confirmed that part b is completed via the sampling sheet for each product, sample of these were sighed at audit.

15. Transfer & Manufacturers Declarations of Compliance	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:
Reviewed FSM 1.10 Export Documentation Procedure covers roles and responsibilities in completing export documentation at site. Documentation and information is reviewed by eligible persons to ensure export documentation & importing country requirements are met, this includes; Completed & received Transfer certificates, decs of compliances, RFPs, Micor, CoAs, product testing results. Procedures define the requirements for export permit, health certificates and prohibited goods, and when these cannot be generated. Persons who can complete transfer certificates and declaration of compliance are detailed and are trained in the procedure. Procedure details the requirements for completing and checking transfer certificates and declarations of compliance by eligible staff, as well as when they are required (at receival and dispatch).
Procedure details Australian dairy ingredients received are for domestic and export use, export product is required to have a transfer certificate and come from an export registered establishment, export product is labelled and segregated from domestic product. Requirements for Imported dairy ingredients are defined and include; must be registered, meet importing country requirements, provide COAs or health certificates. Only product that has documentation stating that it meets Eu requirements can be used in EU product. Additionally, if documentation is not sufficient to indicate product meets a specific importing country or general export requirements it is deemed not suitable for export- computer system and labelling will capture this information.

This element is non-compliant due to the following findings.

Findings:

1. No template has provided for transfer certificate or declaration of compliance. 18.02.2021- QAF025 – Transfer certificate sighted and was compliant. QAF026 Manufacturers Declaration of Compliance to be provided for review. 15.03.2021- reviewed QAF026 Manufacturers Declaration, does not reflect current requirements for export of dairy products- refer to; https://www.agriculture.gov.au/export/controlled-goods/dairy/registered-establishment/declaration-compliance
2. Under section 9.3 if refers to checking the product has come from an export registered establishment, but not how it is done. 12.04.2021- NC reviewed and closed- details operator will conduct a visual inspection of product and paperwork received.
3. Section 9.4 is not clear when a transfer certificate is required or not; Girraween is referenced as not requiring a transfer certificate (dot point 1), but then requires one in dot point 2, dot point 2 is requires rephrasing (repeated wording) 17.02.2021-wording of this statement is unclear. 12.04.2021- NC reviewed and closed- now clearly details when a transfer cert/ dec is required or not required.
4. Retention period is stated as 7 years for export documentation, this differs from document control procedures. 12.04.2021- NC reviewed and closed- now details retention as 5 years.

16. Importing Country Requirements	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

Sighted FSM 1.11 Importing Country requirements and FSM 1.11a Importing Country Requirements schedule reviewed.
FSM 1.11 references export products will meet export and importing country requirements, including China and EU. All products will meet export requirements and are deemed export until they are labelled domestic- both on the label and in the computer system. Importing country requirements is obtained when order is received, by review of Micor, department emails, market advice notices, contacting importing country customer and regulatory authorities. Products are checked to ensure they meet importing country requirements at the time a transfer certificate or declaration is to be completed, QAF056 Product HACCP Verification Form and QAF057 Export Documentation Checklist are completed.

FSM 1.11a reviewed, specific importing country requirements for China and Hong Kong.

Verification table 1.14a captures review of importing country requirements prior to shipment and or when changes have occurred.

Site confirmed 16.02.2021 that they will not be exporting to the EU. Additionally, the site confirmed export product is bought in as required for export orders, product will be checked at receival to ensure if meets export requirements and then logged into system as export or domestic.

This element is non-compliant due to the following findings.

Findings:

1. Verification table 1.14 states importing country requirements are checked prior to shipment, but then states that it is completed as part of an internal audit in February. 05/02/2021- establishment confirmed that they do carry out both activities- NC closed.
2. 1.11 references EU exports and to review 1.11a for further on specific importing country requirements, on review of 1.11a no EU information is detailed. Only China and Hong Kong are detailed in 1.11a- please confirm importing countries, and if EU is one update procedures to include EU requirements. 16.02.2021- procedure includes EU requirements at present, site confirmed they will not export to EU**.** 12.04.2021- NC reviewed and closed- reference to EU requirements removed from procedure.
3. 1.11 states that EU production is not routine, but site will ensure EU requirements are met, Eu checklist to be completed- no EU checklist received. 16.02.2021- 16.02.2021- procedure includes EU requirements at present, site confirmed they will not export to EU. 12.04.2021- NC reviewed and closed- reference to EU requirements removed from procedure.
4. No reference to training in export or importing country requirements for staff is detailed in 1.11. 12.04.2021- NC reviewed and closed- training requirements and reference to training procedure added into procedure.
5. Unclear if all raw materials and finished product are all export grade, on interpretation of 1.11 section 9.4 all products meet export requirements, unless theres documentation issues, whereas 1.10 details products when received are classed as export or domestic (section 9.3), which depends on documentation received. 16.02.2021- export product codes are still to be set-up. 12.04.2021- NC reviewed and closed- products are export unless export documentation is not received and it will then be treated as domestic. FSM 1.1.3 details labelling requirements of export product.

17. Loading of Sea and Air Freight Containers	Compliant? (Yes / No/ NA- Not Assessed)	**No**

Summary of Findings:

This element is non-compliant due to the following finding.

Findings:
01-05.02.2021- Unclear from evidence received if establishment is loading containers.
16.02.2021- FSM Procedures reviewed have not captured if loading of containers is to occur at site.

18. Department of Agriculture Seals	Compliant? (Yes / No/ NA- Not Assessed)	**n/a**

Summary of Findings: Not required at this stage for the establishment, as documented in FSM 3.1

Findings:
- Not Applicable

19. Pasteurisation	Compliant? (Yes / No/ NA- Not Assessed)	**n/a**

Summary of Findings:

Sighted FSM 3.1 GMP it documents that all dairy and egg products received at site are pasteurised and HACCP plans also detail product is pasteurised by suppliers, CoA or CoC is to be received.

Findings:
Nil

20. Trade Descriptions	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM reviewed 1.12 Trade Descriptions is in place, roles and responsibilities for checking and approving labels before use, as well as ensuring all goods (raw materials, finished products) are labelled during storage and use/production is described. A transfer cert/ dec of compliance is only generated and signed once it is in the computer system. Labelling requirements are detailed for export and domestic products, foreign translations for export product when required (China labels product must be approved by Chinese authorities)- Labels to be reviewed when changes occur or at least annually. SOPS are in place for printing labels & packaging.

FSM 1.12a Labelling Requirements details labelling requirements for product for retail and non-retail sale.

Verification table incorporates an annual review or review when changes occur for trade descriptions.

FSM 1.10 Export Documentation details that foreign language translation for labels/artwork are kept on file, are completed by a translator, each delivery is checked and logged onto QAF027.

This element is non-compliant due to the following finding.

Findings:
01-05.2021- Goat milk powder artwork provided, but doesn't list the Est1405

16.02.2021- sighted sample of Full Cream Milk Powder 1kg Jar- BBD date, batch number, est number, manufature date are printed via ink jet on base of the Jar. Sighted label checks for freeze dry yoghurt sachets production at audit- done at start of run, this is checked against label sample and the production work order.

21. Maintenance and Calibration	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

Establishment has FSM 3.8 Maintenance Procedure in place, covers scheduled (preventative) and unscheduled maintenance activities at site. Staff to report any issues with the plant/ equipment to manger/supervisor so that it can be addressed. Both planned and unplanned maintenance activities are recorded on either Preventative Maintenance Form (FDPM) or QAF-037 Maintenance Form. Procedure captures ensuring work area is checked before use to ensure it is cleaned and sanitised, no debri. The plant and equipment (including tools) are to be fit for use, kept clean and sanitised. Tool hygiene and reconciliation is checked as part of daily GMP audits or QAF-037. Repairs to plant or equipment's are risk rated in terms on priority- low to critical. Any major changes to the plant are to be approved by the department. FSM 3.9 Maintenance schedule is in place. Maintenance staff and contractors are trained in GMP and Hygiene requirements.

FSM 3.7 Calibration procedure sighted, covers equipment that is required to be calibrated at site and persons responsible, calibration register is in place and further details equipment calibration requirements. Equipment is to be labelled with calibration details, procedures are in place for when calibration fails- label not to use, repair, cease production if it relates to CCP. Calibrations can be completed by internal staff or external service contractors, the establishment retains records of calibrations. Overview of scale and thermometers calibrations is detailed. Sighted Calibration register.

A site audit walk through occurred on 16.02.2021, the establishment was found to of a satisfactory standard for structures and equipment., no issues were noted.

This element is non-compliant due to the following findings.

Findings:

Findings to be addressed for FSM 3.8:

1. Section 7 does not include monitoring of the production & packing areas. 12.04.2021- NC reviewed and closed- scope now covers all of site.
2. Procedure doesn't capture how equipment/fixtures are addressed to ensure they are fit for use- is a risk assessment completed. 17.02.2021-CLOSED- site confirmed assessment process is in place, SOP VAL00001 Site Validation Master Plan is used and was sighted.

Findings to be addressed for FSM 3.7:

3. Scope does not cover production and packaging areas. 12.04.2021- NC reviewed and closed- scope now covers all of site.

22. Miscellaneous (Alterations & additions to premise & FSP since last visit, AA approval/conditions, Registration details, Exemptions, Outstanding Non-Conformances raised during the previous audit not previously closed out or required to be verified)	Compliant? (Yes / No/ NA- Not Assessed)	**N/a**

Summary of Findings: Not applicable this audit

Findings: Not applicable this audit

Additional items of Concern identified during the audit and not mentioned above:

- No additional items, all issues of concern have been documented above

Notes:

- Not all the elements identified in the scope of the audit determined prior to the visit were able to be looked at during this visit. Effective review of those elements that were audited during this visit took longer than anticipated and those elements not reviewed this visit will be included in the next bi-annual audit.
- It has been identified that the current day allocated to undertake verification of your approved arrangement is insufficient to effectively verify compliance with legislative and importing country requirements, as such future audits of your site will be undertaken over two consecutive days for each of the Bi-Annual audits undertaken over the year.

Observations:

- All observations (where applicable) have been included in the report above

Non Compliances:

- Where a non-compliance has been documented in the report above, the information provided in the findings "as evidenced by" are those items identified that support why the element has been found non-compliant. It is not necessarily exhaustive and is not an itemised "to do" list, rather examples to support why a program/element is not effective. The expectation is that the non-conformance will be thoroughly reviewed to determine the root cause and actions taken to address both the root cause to why it happened as well as rectifying the "finding" (where applicable) and verification to ensure the failure does not re-occur.
- If you require further clarification please contact myself or in my absence dairy@agriculture.gov.au

Australian Government
Department of Agriculture, Water and the Environment

Department of Agriculture, Water and the Environment: Food Program (Dairy)
New Establishment Approved Arrangement Audit

Company:	GMP Pharmaceuticals PTY LTD		
Audit Location:	60 Huntingwood Drive, Huntingwood, NSW, 2148		
Compliance standard:	• Export Control (Milk & Milk Products) Rules 2021 • Export Control Act 2020 • Establishments Approved Arrangement (currently approved Est's) • Importing Country Requirements		
Auditee Representatives: Entry Meeting	s. 22(1)(a)(ii) QA Team Leader , s. 22(1)(a)(ii) - Site Manager, s. 22(1)(a)(ii)- Senior QA Associate.		
Auditee Representatives: Exit Meeting	s. 22(1)(a)(ii)- QA Team Leader , s. 22(1)(a)(ii) - Site Manager, s. 22(1)(a)(ii)- Senior QA Associate.		
Establishment No:	1405	**Audit Dates:**	01-05, 16-17/02, 24//02, 15/03 , 12/04/2021, 22/04/2021, 23/04/2021
Lead auditor:	s. 22(1)(a)(ii) (DAWE)	Additional audit team members:	Nil

Total Audit Time: For charging purposes (if applicable) * Report writing time is also charged and will be included in the invoice issued	Audit Time: 16 hours Report Writing: 1.00hr	01.02.2021:4 hrs
		02.02.2021: 4hrs
		02.02.2021: 4hrs
		03.02.2021: 4hrs (includes 1hr reporting)
	Audit Time: 14 hours Report Writing: 2.00hr	16.02.2021: 5.45hrs (on and off-site)
		17.02.2021: 8.15hrs (on and off-site)
	Audit & Report Time: 2 hours	24.02.2021- 2hrs
	Audit time: 0.5 hiurs	15.03.2021- 30 mins
	Audit & report Time: 1.5 hours	12.04.2021- 1.5 hours
	Audit & report Time: 0.5 hours	22.04.2021- 30 minutes
	Audit & report Time: 3.0 hours	23.04.2021- 3 hours
	Audit & report Time: 1.0 hours	23.04.2021- 1 hour

Auditor Name: s. 22(1)(a)(ii)		**Signature:** s. 22(1)(a)(ii)	
Date Report Issued:	5th February 2021 24th February 2021 12th April 2021 30th April 2021	**No# of Non-Compliances Issued This Audit:**	**nil**
No# NC Closed out from Previous Audit:	**n/a**	**No# of Non-Compliances Re-Issued:**	**n/a**

Additional Information (where applicable) can be found at the end of the report

Audit Scope and Objectives:

The audit of Est1405 was carried out via a combination of desk audit and site audits, adhoc meetings, dates and scope covered are detailed as below.

The scope of the desk audit on 01-05/02/2021 included review of the following AA elements:

- Review all applicable 21 elements of the food safety program of GMP Pharmaceuticals for approval as an export registered establishment with the Department of Agriculture for dairy powder products.
- GMP Pharmaceuticals is seeking approval as an export registered establishment with the Department of Agriculture, Water and the Environment (DAWE) for the production of Dairy Powder Products- repacked dairy and goats powders, freeze dried dairy and yoghurt products.

16-17/02/2021- a site audit was conducted to confirm process, structure, equipment and hygiene. A review of the desk audit findings also occurred. The establishment was only packing freeze dried yoghurt

sachets at time of audit, freeze dry production and milk repack production-packing was not occurring, another site audit is required to further review the production and packing.

A second site visit was planned for 29.03.2021 but was postponed due to COVID19 lockdown in Brisbane. A final site visit occurred 23.04.2021 to verify production processes relating to the Milk Powder Repack line.

A review of additional evidence has occurred over adoc dates, dates of such reviews are noted in the summary of findings/ and findings as below.

Summary of findings:

As of 05.02.20201 the food safety program reviewed does not currently meet all the requirements of the Export Control Milk and Milk Products Orders 2005. Those items required to be further actioned, amended or strengthened are detailed below (as noted in red writing, blue highlight sections are for further questioning).

After the site audit conducted on 16-17/02/2021 the food safety program reviewed does not currently meet all the requirements of the Export Control Milk and Milk Products Orders 2005. Items required to be further actioned, amended or strengthened are detailed below in red-yellow highlight from this visit. Any findings that have been actioned and closed have been noted as so in green, previous desk audit findings noted in red are still to be addressed.

Further review of updated food safety programme documentation occurred on 24.02, 15.03 and 12.04, 22-23.04.2021, findings that are now compliant are highlighted in green, those still to be addressed are highlighted red/yellow.

A final site visit occurred 23.04.2021 to verify production processes relating to the Milk Powder Repack line and as of 30.04.2021 all elements were found to be acceptable and meeting export requirements.

Audit Outcome: Acceptable? Not Acceptable?	Acceptable

1. *Management Practices* **2.** *Internal Audits, Corrective Actions* **3.** *Plans & Specifications* **4.** *Cleaning* **5.** *Water*
6. *Pest Control* **7.** *Protection, Segregation & Waste* **8.** *Protective Clothing, Premise Construction, Hygiene and GMP/GHP*
9. *HACCP* **10.** *Testing* **11.** *Training* **12.** *Identification/Traceability & Recall* **13.** *Approved Supplier*
14. *Receiving & Dispatching* **15.** *Transfer & Declarations of Compliance* **16.** *Importing Country Requirements*
17. *Loading of Sea and Air* **18.** *Seals* **19.** *Pasteurisation* **20.** *Trade Descriptions* **21.** *Maintenance and Calibration*
22. *Miscellaneous*

Approved Arrangement Elements Audited

1. Management Practices, Commitment to Food Safety and Records	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
The Declaration of Occupiers Commitment (FSM 1.5) sighted and details meeting export, importing country requirements and domestic requirements, Group CEO is responsible for signing. FSM 1.4 Food Safety and Quality Policy further details that the establishment will meet export and domestic requirements, Group CEO signs. FSM 1.4 also details that an annual management review is to occur.

Organisational structure is documented in FSM 1.6 sighted, showing staff from Group CEO to floor staff. Position descriptions are documented in FSM 1.7 for both the Huntingwood and Girwaween sites.

Management review procedures FSM 1.16 reviewed, annual review to occur, attendees and agenda items detailed including export requirements, management review meeting minutes are taken and filed, actions are assigned to attendees where required.

Document control procedures sighted in FSM 1.9, details process for approving new documents and amending current in use documents, includes seeking approval from the Department (DAWE- Department of Agriculture, Water and The Environment) for changes relating to export, importing country requirements or may affect the products integrity or fitness for human consumption. Master document list, amendment register and version control used to track documents. Retention period and persons who can amend/create and approve documents are detailed.

This element was found to be non-compliant due to the following findings.

Findings:

1. FSM 1.5 Declaration of Occupiers Commitment and FSM 1.4 Food Safety and Quality Policy supplied are not signed and dated by the Group CEO. 12.04.2021- NC reviewed and closed- version of both documents provided showing Group CEO s. 22(1)(a)(ii) has signed them.
2. The QA Associate is held by a different person in the organisational structure FSM 1.6 issue date October 2020 versus the FSM 1.7 Position descriptions issue date October 2020 23.04.2021- NC reviewed and closed- FSM 1.6 has been updated Jan 2021, reflects current staff at site in the listed roles.
3. It is unclear who has the main role in overseeing and management of the AA (FSM) as multiple QA roles are in place at the Huntingwood site, for example there is QA Team Leader and Senior QA Associate at the same level in the organisational chart. 23.04.2021- NC reviewed and closed- FSM 1.7 updated Jan 2021 to reflect FSM 1.6, food safety roles managed by various QA roles- Senior QA Associate, QA Team Leader are the main two managing the system.
4. Positions description titles in FSM 1.7 do not consistently state which site the role is at, the Organisational structure 1.6 clearly shows two sites. 23.04.2021- NC reviewed and closed- FSM 1.7 updated to reflect position and locations for roles as per FSM 1.6.
5. Documentation retention period varies between procedures. For example in FSM 1.9 it states 3, 4 and 5 years, FSM 1.15, 3.12 details 4 years. 12.04.2021- NC reviewed and closed- procedures now corrected, retention period now 5 years.
6. FSM 1.9 states that the QA Manager or delegate manages this procedure, whereas the organisational chart for Est1405 doesn't have a QA Manager. 12.04.2021- NC reviewed and closed- procedure 1.9 updated, QA officer to make changes to documents.
7. 17.02.2021- further discussed management review procedures at site. Management review procedure FSM 1.16 does not clearly describe that management review is conducted done 6 monthly as per the verification schedule and the annual management review internal audit is conducted as per QAF045- Internal Audit Schedule. 12.04.2021- NC reviewed and closed- procedure now clearly details that management review is done twice a year.

2. Internal Audits and Corrective Actions	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

Internal audit procedure 1.15 reviewed, details process for external and internal audits (GMP and Non-GMP audits). GMP audits are conducted as per SOP QA 008 Internal GMP Audit. Non-GMP audits are done as per the internal audit schedule/ Verification schedule 1.14a. Compliance to the audit is to be recorded on the internal audit summary, objective evidence to be captured on documents being audited or on internal audit summary. Form49 Internal audit summary report is used to document the audits findings, corrective and preventative actions. Corrective actions procedures are detailed for when immediate action can be taken or not. A corrective action report and following the corrective and preventative action procedures are detailed. For external audits a person from management will accompany the auditor/s, a quality incident form QAF007 and corrective and preventative actions are to be taken.

Internal audit checklist QAF017 and QAF009 Internal GMP audit form templates sighted.

Internal audit schedule QAF045 reviewed details audits conducted over the calendar year.

1.14a Verification schedule sighted and details internal audits to be completed on activities such as; quality system documents, corrective action and non-conforming product procedures, HACCP, importing country requirements, trade description, approved suppliers.

SOP QA 008 Internal GMP Audit sighted and reviewed covers internal audit requirements and process of completing systems and spot audits.

FSM 1.17Corrective and Preventative Action (CAPA) Procedure reviewed, capture processes for internal and external non-compliances. External non-compliances have CAPA and QID (quality incident deviation) form completed. Internal non-conformances follow CAPAs as per HACCP, if action can be taken immediately it is done so and recorded on the relevant monitoring form, if not CAPA and QID completed. Notification to the Department of QIDs is documented. CAPA process includes logging of incident into QID register, completing QID from and investigations, determine products status, determining corrective and preventive actions, timeframe for completion, verifying actions are acceptable, QID can only be closed once actions have been deemed acceptable, QA Manager to close, monthly review of QID occurs, QID maybe extended if a plan is in place to address and no food safety risk is present. If there is a risk to food safety or quality then immediate action must be taken to correct the non-compliance, non-urgent issue have up to 1 month for actioning.

17.02.2021 sighted Internal Audit Summary Report QAF036 for 27.01.2021- GMP Area and Pest control monthly audits for Jan 2021- CAPA 21001 raised for pest control sightings in January, closed 05.02.2021. Sighted 22.12.2020- IA on SOPQA0019 Receiving, SOPQA0021- Sampling and Testing of Dairy Goods- FSM 1.11 Importing Country requirements, FSM 1.10 Export Docs, FSM 1.12 Trade Description - QAF036 and QAF0017

completed. Also conformed with site that they undertake systems audits which are scheduled, and monthly GMP audits and spot audits. Spot audits are adhoc, are conducted during process and use IPQC forms.

This element was found to be non-compliant due to the following findings.

Findings:

The below findings have been identified for;

FSM 1.15:

1. Does not consistently describe forms and reports used as part of the internal audit process. 17.02.2021- discussed with site, site is using QAF036 as the Internal audit summary and QAF017 for the Internal Audit checklist. 12.04.2021- NC reviewed and closed- procedure now details QA036 and QAF017 to be used for internal audits., SOP QA008 now details internal audit process as well.
2. Corrective and preventative procedures for external audits do not describe the CAPA process. 12.04.2021- NC reviewed and closed- procedure now details CAPA process for corrective actions.
3. 17.02.2021 – on review of the Internal audits on SOPQA0019 Receiving, SOPQA0021- Sampling and Testing of Dairy Goods- FSM 1.11 Importing Country requirements, FSM 1.10 Export Docs, FSM 1.12 Trade Description. Observation: no supporting evidence to show that procedures had been checked against process and or current requirements was documented in the internal audit records reviewed.

SOP QA 008 Internal GMP Audit:

4. Does not describe GMP audit frequency, process, and how non-compliances are determined and actioned. 17.02.2021- discussed audit process with site, systems audits done as per QAF045, GMP audits done monthly, and spot audits are adhoc. 14.04.2021- SOP QA 008 updated, refers to spot audits being done monthly and checks GMP and hygiene standards. 23.04.2021- NC reviewed and closed- site confirmed that it is a GMP audit but also incorporates Non-GMP procedures as well, IPQC audit checklist to be used.
5. Monthly GMP audit forms have been provided, these forms are not captured in this SOP (QAF062, QAF063, QAF064) 12.04.2021- NC reviewed and closed- GMP forms to be used are now referenced in FSM 1.15.

Internal audit schedule QAF045:

6. Doesn't capture all elements of the AA including; importing country requirements, trade descriptions, HACCP, approved suppliers, the schedule also doesn't reflect internal audits referenced in 1.14a. 17.02.2021- CLOSED- clarified with site, QAF045 lists audits as an overview, SOP QA008 further details what is covered under each audit.

7. Verification procedure 1.14 not provided for review. 17.02.2021- CLOSED.- verification procedure FSM 1.14 reviewed and captures verification activities at site including review of importing country requirements, trade description and those as per 1.14a.

3. Plans & Specifications	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

01-05.02.2021- This element non-compliant at present due to plans not being finalised.

16.02.2021- reviewed under SMF001- Section 3.2- includes overview of site layout of process, packing and warehouse areas. Plans then split per production/packing area for; freeze dry goods processing and packing (milk powder packing under this chart), powder and sachet line flow chart for processing and packing (still under construction), tablet lines, chem and micro labs, warehouse. Plans show entry/exit points, product flow, raw materials entry points, equipment locations.

Plans sighted for shows water lines; cooling return line, cooling supply line, cold water, compressed air dated 05.09.19, Drainage plan map: 12.09.18- shows drain lines, vents and air service lines, Sewer Service diagram- 06.11.19- shows all sewer lines at site.

This element is deemed non-compliant due to the below finding;

Findings:

1. Plans provided do not clearly identify water inlets points, drains inlets, HEPA air outlets/inlets for all of site. 14.04.2021- NC reviewed and addressed- site plans of water inlets, drains and air inlets provided.

4. Cleaning & Sanitising	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

Sighted Cleaning and sanitising procedure FSM 3.12, covers all of site, daily pre-operational inspection to be completed. Cleaning effectiveness verified by in- house ATP swabs, monthly environmental swabbing, quarterly allergen swabbing and finished product testing. Production and Warehouse Manager or delegate are responsible for monitoring the effectiveness of cleaning daily. General overview of cleaning procedure and chemicals detailed. Cleaning equipment is colour coded for work area/equipment's, storage and cleaning requirements for cleaning equipment is detailed. Covers an overview of cleaning required and frequency, as well as monitoring.

SOP PFD013 General Cleaning procedure reviewed- provides cleaning procedure for bulk production, staging, packing areas for Freeze dry product.

FSM 3.13 Cleaning Schedule reviewed- captures areas of site to be cleaned and sanitised, frequency, chemicals to be used, how to clean, persons responsible and recording form.

FSM 3.14 Cleaning and Approved Chemicals List sighted- details chemicals at site, usage, SDS on file, allergen status and where stored.

SOPQA0018- Environmental Monitoring Procedure reviewed- details air monitoring and environmental swabs to be taken, temperature monitoring, sampling maps are included. Air monitoring to be completed monthly, limits, how to sample and corrective action requirements detailed. Listeria swabbing to be done monthly from a direct and non-direct contact surfaces, sampling process documented, sent to external lab for analysis. Corrective actions for positive listeria detections documented, includes- intensive clean, testing product, raising CAPA, notify NSW Food Authority, customer, instigating clearance programme.

FSM 3.5 reviewed and details that chemical containers are not to be used for any other purpose and are checked at receival to ensure that they are not damaged, labelled and clean.

QAF040 reviewed.

Sighted SOPPFD019 Portable CIP Machine Procedure sighted and is in place and used for hard to clean equipment such as the heat exchanger.
This element was found to be non-compliant due to the following findings.

On 11/02/2021 The establishment provided SOPS (SOPFPD030, SOPPK001) and checklists(forms- PRF001, PRF002, PRF028, PKF018) for Line Startups and clearance, these are to used be before starting assembly of equipment and materials and before starting manufacturing. SOPS detail procedures such as checking areas/equipment are clean, documentation/tags completed, product-packaging is removed, forms are used to verify rooms are acceptable and ready for use. SOPQA0031 Operation of Hygiena Ensure Touch- documents procedures for use ATP swabs and the acceptable limit.

A site audit occurred on 16-17/02/2021, a walk through of the premises occurred within the warehousing, freeze dry production & packing, milk repack, staff amenities areas, the facility was found to be clean and tidy, no waste overflow or product buildup/spills noted, unused equipment, production/packing rooms, warehousing, amenities, change room areas were visibly clean. Signage of rooms was also in use to show that they had been cleaned. Further discussion on cleaning procedures and monitoring occurred, the establishment uses cleaning and room usage logs, signage, prestart clearance checklist and forms to capture cleaning conducted. Cleaning chemicals were stored away from product, and colour coded cleaning equipment and signage was noted with production and packing areas. The establishment has SOPS in place for equipment use and cleaning, a sample of SOPS reviewed included. SOPPFD003- Cooking Machine Standard, SOPPRFD014- Freezer and Freeze Dryer Cleaning and SOPPFD025- Powder Mixer Liquid. PRF009- Production Cleaning Validation sighted at 16.02.2021- done after cleaning and includes ATP swabs.

A second site audit was conducted on 23.04.2021 to verify the Milk Repack processing line, the milk repacking production and packing areas were found to of an acceptable level of hygiene for being within operations.

This element has been non-compliant due to the below findings;

Findings:

The following findings have been noted for each document reviewed:
FSM 3.12:

1. No frequency is documented in FSM 3.12 for ATP and finished product testing. 16.02.2021- site advised this occurs after cleaning or change of product. 23.04.2021- NC reviewed and closed- FSM 3.12 now refers to ATP weekly or when product change occurs, for finished product testing refers to SOP QA0018 and FSM 1.20 and FSM 3.11.

2. Section 9.5 of procedure 3.12 refers to a cleaning schedule at the end of the document, but no schedule is included in 3.12. 23.04.2021- NC reviewed and closed- updated FSM 3.12 and removed reference to a schedule in the document, refer to FSM 3.13 Cleaning Schedule.

SOP PFD013 General Cleaning procedure:

3. Chemicals to be used in the SOP do not align with FSM 3.13. For example Triple S is to be used in the bulk storage area within the SOP, whereas FSM 3.1.3 refers to Ultramax. 14.04.2021- NC reviewed and closed- refers to cleaning schedules and chemical lists instead of specific chemicals.
4. Unclear if SOP PFD013 General Cleaning procedure is the only SOP for cleaning. 17.02.2021- CLOSED- site confirmed SOPS are in place for equipment use and cleaning, sighted SOPPFD003- Cooking Machine Standard, SOPPRFD014- Freezer and Freeze Dryer Cleaning and SOPPFD025- Powder Mixer Liquid, SOPS either covered cleaning, or cleaning and use of the equipment.

FSM 3.14 Cleaning and Approved Chemicals List:

5. Does not include Triple S or 70% Alcohol 12.04.2021- NC reviewed and closed- Triple S removed from list, 70% alcohol added into the chemical list for use.
6. Does not show location of chemicals in dishwasher area 12.04.2021- NC reviewed and closed- now includes locations of chemicals in the dishwasher area.

SOPQA0018- Environmental Monitoring Procedure:

7. Under listeria swabbing it refers to QAF040 for when areas are to be swabbed, on review of QA040 it doesn't detail when areas are to be swabbed. 05/02/2021- CLOSED establishment confirmed that QAF040 is the correct form, location swabs are coded E,F -listeria swabs, A and B settle plates, the legend code is included in SOPQA0018.

8. Procedures provided have not captured what CIPS systems are used at site. 05/02/2021- clarified with site, the only CIP system is for the cooking tanks only. Moulds are cleaned via dishwashing system- site to send validation data through for both. 15.03.2021- establishment provided Qualification Protocol procedure for the CIP tank (FDIQ004 and FDOQ004), but both documents do not capture validaton, further references it will be subsequently done- refer to Appendix 7 – FDOQ004. Validation reports need to capture information such as; how the validation is carried out, results of CIPs cycles (flow rates, temperatures, times, chemical concentration), testing and inspection of the equipment needs to be documented. 14.04.2021- NC reviewed- reviewed FDCV001- Cooking tank validation- details process of validating the cleaning of the cook tank, visual and microbial swabbing completed and was found to be acceptable. However, details on the CIP cycles used has not been included. 23.04.2021- NC reviewed and closed- confirmed with site that this is a re-validation and the procedure refers to SOPPFD003 Cooking Machine SOP which details the requirements for the CIP cycle (times, temps, chemicals.)

SOPPFD019 Portable CIP Machine Procedure— not used anymore- CLOSED

9. validation data to be provided for this unit, must capture each piece of equipment or process line it is used on
10. SOP doesn't include any monitoring or verification checks on equipment/process lines after using the portable unit
11. FSM 3.13 Cleaning Schedule only refers to use of this on the cooking tank system- unclear if this includes the heat exchanger. No heat exchanger is noted in the HACCP plans.

FSM 3.13 Cleaning Schedule

12. Unclear if the air lock and ante room are the same area? Air lock is an areas where you pass between warehouse and packing/production, ante room= change rooms. 05.02.2021- NC closed- Site clarified that the ante room = change room. And cleaning is done daily and weekly.
13. Ante room and bins are to be cleaned monthly on the schedule- frequency may not reflect use of area.- Bag is changed daily, bin cleaned weekly. 05/02/2021- Site clarified that the bins have bags, these are changed daily or when full, cleaning of bin is weekly. NC closed.

14. Procedures provided do not capture how compliance is determined after cleaning via a preoperational inspection, does another procedure capture this? 05/02/2021- clarified with establishment via teams meeting, line startup and clearance procedure and checklists are in place, site to provide. 11/02/2021- establishment provided line startup and clearance SOPS and checklists- SOPS (SOPFPD030, SOPPK001) and checklists(forms- PRF001, PRF002, PRF028, PKF018) however these procedures have not been included in FSM 3.12 for use. 23.04.2021- NC reviewed and closed- FSM 3.12 updated to reference above SOPS and forms.

15. No reference to ATP swabs being undertaken after cleaning is documented in any procedure provided. 11/02/2021- SOPQA0031 Operation of Hygiena Ensure Touch provided for review does not detail when ATP swabs are to be done, where results are recorded, corrective actions only capture reclean and reswab- no further actions detailed if failure still occurs. 16.02.2021- site advised that they redo until result ok, procedure does not capture process for when multiple failures occur. 12.04.2021- SOPQA0031- Operation of Ensure Hgienia Unit- NC reviewed and closed- now details that QID to be raised for repeat failures.

5. Water Sampling	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
Sighted FSM 1.2 Product Assessment, Inspection and Testing Procedure- covers general overview of testing done at site, including water. Water at site is potable, supplied by Sydney water, Sydney water monitors chemical and physical testing against the ADWG. The quarterly Sydney Water Quality report will be reviewed, issues with chemical and physical parameters will be investigated. Monthly ecoli testing of water occurs at site.

SOP QA0014 Water Quality Monitoring Programme reviewed, one sample per calendar month is taken, tested for Ecoli at NATA lab, sampling process defined, water sampling map and sample location list is included, corrective action documented for out of specification results covers notification to the department and investigations. Site obtains the annual Sydney water quality report or completes the testing if the report is not available.

This element is non-compliant due to the following findings.

Findings:
The following findings have been noted with relation to:
FSM 1.2;

1. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager or technical Officer. 12.04.2021- NC reviewed and closed- procedure refers to QA Manager/Delegate, Technical Officer, or QA Officer throughout the procedure.
2. Persons who review the Sydney water quality report and the process for investigating issues with the report is not documented. 12.04.2021- NC Reviewed and closed- details QA Manager or Technical officer to review results.

SOP QA0014 Water Quality Monitoring Programme:

3. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager. 12.04.2021- NC reviewed and closed- procedure refers to QA Manager/Delegate, or QA Officer throughout the procedure.
4. Sampling states one sample per month, rotating through the location list table 2, however there are > 12 samples. 05/02/2021- establishment confirmed that they are completing all test points each month. 12.04.2021- procedure has not been changed. 23.04.2021- NC reviewed and closed- site updated SOP to reference they are completing all samples in the table each month.
5. SOP QA0014 details that the annual Sydney Water quality report is obtained, whereas FSM 1.2 states the report is reviewed quarterly. 05/02/2021- site confirmed that they are conducting both activities. NC CLOSED
6. Retention period of water quality records is 7 years, this differs to FSM 1.9. 05.02.2021- site confirmed it should be 3 years, procedure to be updated. 12.04.2021- NC reviewed and closed- retention period changed to 5 years and reflects FSM 1.9 requirements.

6. Pest Control	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM 3.6 Pest Control Procedure sighted, monthly external services by a pest control technician are carried out, additionally staff are to report pest sightings, these are entered into the pest control log and a monthly Warehouse GMP audit is conducted. Procedure details hygiene and maintenance requirements to ensure compliance to pest control. FSM 1.18 Control of Non-conforming product is to be instigated if product is affected with pests. Recommendations from the pest control technician are to be actioned by the site.
Pest control service requirements are defined, including target pests/vermin. The technician conducts routine services and treatments, including actioning any issues noted in the pest sighting log, a pest control manual is on place that contains SDS, licences, bait station map.

A site audit walk through occurred on 16.02.2021 within warehousing, amenities, production and processing areas, no pest and vermin issues were noted. Pest and vermin controls are located outside of the production and

processing areas. Sighted bait stations within the warehouse area and building perimeter. Doors into the facility were closed when not in use, air locks (rapid doors) and personal doors are in place and are sealed/closed after use.

This element is non-compliant due to the following finding.

Findings:

1. Section 7 does not include GMP audits for the production & packing areas. 12.04.2021- NC reviewed and closed- procedure now reference to internal audit schedule.

7. Protection, Segregation, Waste and Other Products	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

FSM 3.5 Waste procedures sighted, GMP audits and cleaning to be conducted to ensure compliance to waste procedures. Waste is to be identified and separated from food product. Procedure captures requirements for handling and hygiene requirements of solid (recyclable and non-recyclable waste) and liquid waste. Non-conforming product is to be clearly labelled as so.

See section 4 for information on chemicals.

Refer to sections 8 and section 12 on product handling and identifications.

FSM 1.18 Non-conforming product procedure reviewed, details process of identifying non-conforming product/equipment/material and process of determining disposition of them, notification to the department has been included. Process includes isolation, labelling of affected product and placing on hold in the computer system so that it cannot be used.

A site audit walk through occurred on 16.02.2021, product and packaging within the warehouse areas was sighted to be labelled and contained in packaging. Waste bins were noted within the sachet packing room, and were separated from product, external kin bins for waste were sighted outside the milk repack area, were labelled and no overflow was noted. Raw materials and finished products were labelled and stored in areas for quarantine and final release, labels were in place to reflect status of these products. WIP sachet product was sighted in the freeze dry production & packing areas in labelled and covered tubs. Chemicals storage was separated from the product in the warehouse and dishwashing room. Products (raw materials, finished products) and cleaned equipment were stored off the floor and covered.

A second visit and walk through of the production process relating to the milk repack line occurred on 23.04.2021, controls relating to product protection, segregation and waste were found to be compliant at the time of the audit.

This element is non-compliant due to the following findings

Findings:

Findings for FSM 3.5:

1. Section states no rework, however FSM 1.13 details rework is used at site. 12.04.2021- NC reviewed and closed- procedure now details rework procedure.

Findings for FSM 1.18 Non-conforming product;

2. Refers to the title of a QA Manager, but no role is listed in the organisational chart or position descriptions for Est1405. 12.04.2021- NC reviewed and closed- updated to reference QA Manager or delegate.
3. Procedures to be followed for product being processed or received is not clearly defined. 05/02/2021- site confirmed that it WIP and received product follow the same process, procedure to be amended to incorporate reference to WIP and received product. 12.04.2021- NC reviewed and closed- procedure scope now covers receivals through to dispatch.
4. Does not include procedures for handling non-conforming export products. 12.04.2021- NC reviewed and closed- procedure reviewed , same NC process applies but different colour code and labelled applied for export products.
5. Procedures provided no not include how and if export product will be processed differently to domestic product. 12.04.2021- procedure FSM 1.13 covers handling of export vs. domestic product.

   Note: 17.02.2021- no operations were occurring in the freeze dry production area and the milk repack production- packing area at audit, further review of these areas is required to further verify compliance to

this element. 23.04.2021- NC reviewed and closed- verified process of repack milk powders via site production walk through on 23.04.2021- handling of product, chemicals, waste and GMP controls were compliant at the time of the audit while a trial of Goat milk powder was being packed.

8. Protective Clothing, Premise Construction, Personnel Hygiene and GMP/GHP	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM 3.1 GMP procedures reviewed, covers production, packaging and warehouse areas as follows;
Monitoring of GMP occurs via daily GMP inspections and cleaning, and monthly GMP audits. Major changes to the premises are to be approved by the DAWE. Three hygiene zones are in place at site and details entry, equipment and basic overview of PPE requirements in each. Procedure captures where warehouse staff store personal items and lunch. Refers to FSM 3.3 for details on Personal hygiene and PPE.
Equipment is to be kept clean and maintained, refers to the cleaning procedure 3.12 and maintenance procedure 3.8 for equipment requirements.
Further controls of GMP are via procedures; 3.6 Pest Control, 3.5 Waste Management, 3.3 Personal Hygiene, 3.4 Storage Procedure, 3.11 Allergen Control Procedure and work area SOPs.
All raw materials and finished products are to be fully enclosed, any damaged product is to disposed of. Controls are in place for introducing packing or raw materials into staging- outer packaging on raw materials is removed or cleaned. Only human food product is produced at site.
Doors, positive air pressure and air locks in high and medium risk areas are in place to prevent air born contamination. No animals are permitted at site. Compressed filtered air is used, not for direct contact with product, maintenance manages air filters.
Tools are to be stored in designated containers
Procedure defines requirements for glass, soft and hard plastics, wood and metal.
Cleaning chemicals are to be approved for use, stored in designated area, staff are trained in chemical handling and are to follow cleaning procedures/SOPS/schedules.
Tools used daily are kept in the work areas in designated containers.
Maintenance / contractors also bring tools into these areas but are checked for condition and cleanliness before and after use, the work area is also checked for debri and cleanliness.
Products are to be stored off the floor- applies to raw materials and finished products.
Stock transfers are recorded for product moved between both GMP sites.
Export product us transferred using approved suppliers, department seals are currently not required at site.
Site uses FEFO for stock rotation, the computer warehouse system manages this via the batch number.
Sighted GMP templates; QAF064, QAF062 and QAF063.

FSM 3.3 Personal Hygiene requirements sighted; covers health, handwashing and hygiene requirements of staff and visitors. General overview of uniform and PPE requirements is included. Uniforms and PPE are checked before use to ensure they are fit for use. QID and CAPA to be followed for any breaches of personal hygiene requirements.

See training element for details on GMP training.

SOPPRO013 Gowning Procedure sighted, captures procedures for adorning uniforms/PPE when entering and existing production/packing areas.

FSM 3.4 Storage reviewed, details procedure relating to storage of raw materials and finished products at site, daily and monthly monitoring occurs to determine compliance to the procedures. Details storage requirements of raw materials and finished products from time of receival to dispatch, all dairy products are pasteurised and received from Department registered establishments with transfer certificates. Corrective actions for damaged or quarantined stock is detailed Storage requirements of packaging, chemicals for cleaning, maintenance and pest control are documented.

FSM 3.11 Allergen Management Procedure reviewed, procedures for control of allergens at site, various allergens at site, specific storage, labelling and handling controls are in place for allergens except dairy, as dairy is the main allergen in products at site it is not treated as an allergen product. Risk matrix of allergens is in place, processing and cleaning procedures are in place for allergen and non-allergen products, verification is via ATP & environmental swabbing and product testing.

A site audit walk through occurred on 16.02.2021, areas reviewed as part of this walk included the; milk repack and Freeze dry production and packing, warehousing, amenities and cold storage area. At the time of the site walk through only one room within the freeze dry production area was running, freeze dry yoghurt sachets were being packed and staff within this area were observed to be wearing the required PPE and uniforms. Change rooms and air lock rooms where staff and products are moved into/out of production/packing were sighted, air showers are in place for when staff enter the freeze dry production and packing areas. Both milk repack and freeze production change rooms had PPE and uniforms available, gowning procedures were in place. Areas reviewed were found to be maintained and clean, and waste was separated from edible product and identified. Cold storage units (chillers and chest freezers) were sighted with monitoring controls in place. No specific

allergen procedures were reviewed as part of the site walk. Raw materials, WIP and finished products were identified/labelled, were covered/packed and were stored off the floor. No maintenance issues were noted with equipment or structures at the time of the audit. Within the milk repack area on entering/exiting staff change and apply/remove PPE such as striped poncho, hair net, snood, shoe covers, wash and sanitise hands, once inside repack area staff cannot cross over the redline, same applies to warehouse staff bringing product into the area. On entering the freeze dry production and packing areas, similar PPE and uniforms are applied, with different boots and poncho for packing versus production, no cross over between areas, staff must enter and exit via change room protocols. Each production, packing and storage room has a cleaning log, and where required an air pressure and humidity log, these are completed am and pm when in use, sighted samples of these logs at audit. Further review of the freeze dry production process is required to verify GMP controls in these areas.

A second visit and walk through of the production process relating to the milk repack line occurred on 23.04.2021, GMP and hygiene controls were found to be compliant at the time of the audit.

This element is non-compliant due to the following findings

Findings:

FSM 3.1 areas that require addressing:

1. Corrective actions for GMP audits don't capture preventative actions or reference to SOP QA 008 Internal GMP Audit. 12.04.2021- NC reviewed and closed- procedure now includes GMP audits checklists to be used, internal audit procedure/SOP QA details corrective actions.
2. Amenities are only referenced as being separate to the storage area- section 9.8- 17.02.2021- discussed with site, missing reference to production (process and packing areas)in this statement. 12.04.2021- NC reviewed and closed- no covers amenities for storage, production and process area staff.
3. Unclear where production and packing staff lockers are.16.02.2021-CLOSED procedures refers to staff kitchen, area was sighted at audit and reflect the procedure.
4. Section 9.11 does not include if damaged product is isolated or held or if CAPA process is followed. 12.04.2021- NC reviewed and closed- now refers to relevant area SOPS for corrective actions.
5. Dropped product procedure is not clearly described and if product goes on hold- states 'will be disposed transferred to designated area for review by QA, prior to disposal immediately. 12.04.2021- NC reviewed and closed- procedure now refers to dropped product SOPS for further corrective actions, product will be isolated, reject notice raised and inspected before being rejected.
6. Is there a record kept to show the line or equipment has been cleared after a maintenance intervention. 18.02.2020- CLOSED- QAF037- Maintenance form is in place, referenced in FSM 3.8 Maintenance procedures.
7. 17.02.2021- discussed Hygiene zoning table with site, it is used to classify the hygiene and cleaning requirements at site, the table currently doesn't capture the definition of what constitutes the high, medium or low risk zones. 12.04.2021- NC reviewed and closed- now includes definitions for each zone.

FSM 3.4 Storage Procedure findings.

8. Procedure does not clearly explain storage requirements; Section 9.1 paragraph 3 details how some products require temperature control, paragraph 5 then states no products or ingredients require temperature control, section 9.2 details different temperature requirements as well. 16.02.2021- sighted a chiller and chest freezers storing ingredients at site, monitoring controls are in place, FSM 3.4 requires amendment under paragraph 5 where it states no products or ingredients require temperature control. 23.04.2021- NC reviewed and closed- section updated to reflect temp controls for chillers and freezers at site.
9. Storage requirements of export product have not been included. 23.04.2021- NC reviewed and closed- covered under FSM 1.14 Product Identification and traceability procedure.

3.11 Allergen Control Procedure findings;

10. Scope does not include production and packing areas. 23.04.2021- NC reviewed and closed- scope now covers all of site.
11. Under storage and handling (dot point 2) it refers to a pink label for allergens, but in the table it states orange. 23.04.2021- NC reviewed and closed- procedure updated to reflect pink label for allergens.
12. Provide allergen validation data for each product line/area. 15.03.2021- allergen swab reports provided (report FM2103287 and FM2100921) from January 2021, but no support validation study report has been provided. 23.04.2021- NC reviewed and closed- sighted validation report FDCV001 Cleaning Validation for cook tank which included allergen validation after cleans, completed 26.03.2021, no issues noted with validation study.

FSM 3.3 Findings:

13. Scope only refers to the warehouse, not production and packing areas. 23.04.2021- NC reviewed and closed- scope now covers all of site.

14. Doesn't reference FSM 3.1 or reflect PPE requirements per hygiene zone, or personal effects as per FSM 3.1 or SOPPRO013 17.02.2021- discussed with site, reference to FSM 3.1 and SOPPRO013 to be added. 23.04.2021- NC reviewed and closed- no refers to these additional support procedures.
15. Procedure states an informal assessment is completed on uniform and PPE fitness for use- need a formal assessment as evidence it has been carried out. 17.02.2021- establishment confirmed that no formal assessment is in place, site to complete and provide. 23.04.2021- NC reviewed and closed- procedure updated to include a risk assessment on uniforms and PPE at site.
16. Lacking detail on footwear requirements, only states they are provided and to be stored, or covers are provided. 17.02.2021- CLOSED- discussed with site, footwear requirements are captured under FSM 3.1 and SOPPRO013.

SOPPRO013 Gowning Procedure findings:

17. Procedures in this SOP do not align with zones or clothing requirements in FSM 3.1 or 3.3. For example the SOP refers to 2 zones, while FSM 3.1 refers to 3 zones. 17.02.2021- CLOSED- further discussion with site on zoning, FSM 3.1 zones are risk rated for hygiene and cleaning, zones in FSM 3.3. are specific to clothing & PPE requirements for each area, the site walk through verified compliance to the FSM 3.3 requirements for clothing and PPE.
18. Unclear if the SOP applies to the warehouse staff and packing area as only refers to production. 17.02.2021- discussed with site, applies to all staff and areas at site, clothing and PPE requirements for warehouse and packing staff has not been included. 12.04.2021- NC reviewed and closed- scope updated to cover manufacturing and warehousing areas.
19. Section 6.6 requires review to detail exact requirements for entering and exiting all zones listed. 17.02.2021- after review of procedures at site, procedure does not clearly capture PPE/clothing requirements for milk repack, freeze dry production and packing areas. 12.04.2021- NC reviewed and closed- procedure now clearly details enter/exit requirements for each area.
20. Further details on when/where PPE, boots are changed, stored, and cleaned is required. 17.02.2021- the documented procedure does not currently reflect requirements for each area and how they are stored/changed. 12.04.2021- NC reviewed and closed- procedure now clearly details footwear requirements for each area.
21. Section 6.7 States uniforms are to be placed in the storage unit if leaving area temporarily, but then states if unform is clean to place in locker. 17.02.2021- at audit confirmed that uniforms are stored on hooks if provided or in bin for cleaning. 12.04.2021- NC reviewed and closed- procedure now clearly details current storage/ disposal requirements for uniforms/PPE.

9. HACCP	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

The establishment has the following HACCP supporting documents in place;
FSM 2.02- HACCP Team – details persons at site who are part of the team, roles, experience and training are detailed. s. 22(1)(a)(ii) is the HACCP Team Leader.
FSM 2.03- HACCP Supporting Information – provides an overview of products produced at site and summary of hazards. New products are to be reviewed by the HACCP team and approved by the NSWFA or DAWE. Information details how hazard significance is determined via a risk matrix and a CCP decision tree is documented to be used.
FSM 2.04- Food Ingredient and Packaging Hazard Analysis – details hazards for ingredients and packaging used at site.
FSM 2.05- HACCP Verification Schedule- details HACCP verification activities at site, covering elements such as review of records, HACCP review, testing of product and environmental sources and more.

The establishment stores and processes blended dairy powder products, as well as transfers/receives products from their second site (Girraween). All dairy and eggs ingredients supplied and used at site are pasteurised and dried by approved suppliers.

4 HACCP plans in place for export related products are:
FSM 2.1.1-2.1.4- Dairy Products- covers receivals, storage and dispatch of packed dairy products
FSM 2.2.1- 2.2.4- Repacked Dairy products- covers repacking of dairy product powders into bottles/ sachets
FSM 2.3.1-2.3.4- Milk Dice Freeze Dried Products- covers processing of freeze-dried milk-based products with additional ingredients
FSM 2.4.1-2.4.4- Freeze dried yoghurt-based products- covers processing of freeze-dried milk yoghurt powders, with or without fruit/flavours.

As part of this desk audit the HACCP plan 2.3.1-2.3.4- Milk Dice Freeze Dried Products was reviewed.

- 2.3.1 Product Description and intended use- Milk Dice Freeze Dried Products – details cooking a blend of products with milk powder, anhydrous milk fat, egg, colours and flavours, product is aerated and

freeze dried. Both milk and egg products used are pasteurised, the water activity of finished product is no more than 0.83. Product is packed into sachets and deemed ready to eat for general population, notes not for persons who are allergic to dairy and eggs.
  - 2.3.2 Process Flow Chart - Milk Dice Freeze Dried Products- captures steps from receivals to dispatch/delivery, CCPS and RCPS detailed. Some inputs and output points are noted.
  - 2.3.3.3.3 Milk Dice Freeze Dried Products- Hazard analysis- general hazards and hazards specific to the processing of milk dice freeze dried products has been documented, hazards identified into biological, physical, chemical, regulatory, traceability, hazards are risk rated, control measures listed and if a CCP or not has been described.
  - 2.3.4- Milk Dice Freeze Dried Products- HACCP audit table- CCPs and RCPs identified and reflect the flow chart and hazard tables- hazard, control, critical limit, monitoring, records, corrective actions detailed.
- RCPs/CCPS across flow chart, hazard and HACCP audit tables align.

A site audit walk through occurred on 16.02.2021 to verify production processes, both FSM 2.4.2 Freeze Dried Yoghurt Bases Products and 2.2.2 Repacked Dairy Products Flow chart were reviewed, and findings have been noted. As only one room was in operation (freeze dry yoghurt sachets were being packed into retail packs and cartons), FSM 2.4.2 steps 24 to 27 were only able to be verified at audit against the process being undertaken. Another site audit is required to verify the remainder of the production process for FSM 2.4.2.

A second site audit occurred on 23.04.2021 to verify the HACCP plan for Repacked dairy products which involves ~ 25 kg bags of milk powders being repacked into smaller retail sized packages. A trial of goat milk powder was being re- packed at the time of audit for the domestic market, the process flow chart was found to reflect documented flow with the exception of container gas flushing and rejection at the x ray step missing. Updated Hazard and HACCP plans were reviewed and verified as part of the process walk through, with hazards and control measures being adequately identified. The establishment reconfirmed that the Repacked dairy products line that includes milk powders (whole and skim dairy powders, goat milk powder), whey protein powders and concentrates have been identified as for export, additional export products may be introduced in the future including nutritional dairy powders.

This element is non-compliant due to the following findings.

Findings:

FSM 2.01- Food Safety and Quality (HACCP) Scope and Purpose 17.02.2021 reviewed;

1. Does not capture the scope of the intended markets of products made at site. 22.04.2021- NC reviewed and closed- FSM 1.11a details export markets and their importing country requirements, FSM 2.01 also details export markets.
2. Does not detail that the establishment is a contract manufacturer. 22.04.2021- NC reviewed and closed- FSM 2.01 now details the establishment is a contract manufacturer.

FSM 2.02 HACCP Team- 17.02.2021- discussed with site, still in process of update.

3. s. 22(1)(a)(ii) is listed as the QA Team Leader whereas the Organisation Chart lists s. 22(1)(a)(ii) 23.04.2021- NC reviewed and closed- sighted FSM 1.6 which now reflects the HACCP team names and roles.
4. Qualifications of staff are not consistently listed in the HACCP team table. For example: s. 22(1)(a)(ii) has an engineering degree as mentioned in the procedure but is not included in the table. 22.04.2021- NC reviewed and closed- s. 22(1)(a)(ii) qualifications, skills and experience have been added.

FSM 2.03- HACCP Supporting Information

5. Does not capture if products produced at site are all GMP Pharmaceutical products or if contract packaging is also conducted at site- further details on scope and purpose required. 17.02.2021- CLOSED- now detailed under FSM 2.01.
6. Does not clearly detail that site is handling/processing product for domestic and export markets. 17.02.2021- CLOSED- now captured under FSM 2.01.
7. Processing hazard section doesn't include repack product section. 22.04.2021- NC closed- FSM 2.03 now includes repack dairy product hazards.

FSM 2.04- Food Ingredient and Packaging Hazard Analysis

8. Hazard significance has not been determined for each hazard identified. 23.04.2021- NC reviewed and closed- hazard significance added into the table.

FSM 2.3.1 Product Description and intended use- Milk Dice Freeze Dried Products (23.04.2021- note milk dice product is not being produced at site at present and site confirmed dairy content is not at required level to be classed as prescribed, thus reviewed below findings for Repacked dairy products HACCP))

9. Shelf life of product states 24 months, whereas FSM 1.13 states products have a 12 month best before from DOM- 16.02.2021- CLOSED- site confirmed that shelf life is 24 months, FSM 1.13 is an example only, noted as e.g. 12months
10. Doesn't state the destination markets/ countries-17.02.2021- on review of 2.4.1 Freeze Dried Yoghurt based products the shipping section does not reflect the current process of the customer storing domestic product at site and they organise shipping. 23.04.2021- NC reviewed and closed- 2.6.1 Product Description and Intended Use- Milk powders refers to import country requirements table FSM 1.11a, products is either palletised or loaded into a container at site.
11. Microbiological testing section does not reflect testing conducted under FSM 1.20a. NC reviewed and closed- 2.6.1 Product Description and Intended Use- Repacked dairy powders which reflects 1.20a for milk powder testing.
12. Final preparation and use states product is ready to eat- 16.02.2021- CLOSED- sighted freeze dry yoghurt product at audit, product is ready to eat, no reconstitution required.

FSM 2.3.2- Process Flow Chart - Milk Dice Freeze Dried Products-– (23.04.2021- note milk dice product is not being produced at site at present and site confirmed dairy content is not at required level to be classed as prescribed, thus reviewed below findings for Repacked dairy products HACCP))
(23.04.2021- note milk dice product is not being produced at site at present, thus reviewed below findings for Repacked dairy products HACCP)

13. Inputs and outputs are not included at all relevant steps or linked to relevant steps. For example; no reject output has been noted at xray steps, not all inputs included (labels) step 5), waste output at step 14 (when product is held at correct temps the hazard table states is rejected). 23.04.2021- Reviewed updated FSM 2.2.2 Repacked Dairy products and now includes waste outputs at several steps, no rework of product occurs, all to waste. A site walk verified the process flow chart for Repacked Dairy products and identified missing steps relating to xray rejection and air flush of containers. 29.04.2021- NC closed- FSM 2.2.2 updated to include rejection of product at xray and flushing of containers.

14. Flow chart verification date is 2019, FSM procedures required an annual review. 17.02.2021- NC reviewed and closed - no review occurred in 2020, as product is not being produced at site.

FSM 2.3.3 Milk Dice Freeze Dried Products- Hazard analysis (23.04.2021- note milk dice product is not being produced at site at present and site confirmed dairy content is not at required level to be classed as prescribed, thus reviewed below findings for Repacked dairy products HACCP))

15. No supporting document was reviewed that defines the key/legend code for types of hazards (with the exception of CCPs/CPs). 17.02.2021- CLOSED- FSM 2.01 reviewed and includes definition of hazard types.

Key: B – Biological hazard, C – Chemical hazard, P – Physical hazard, Q – Quality, T- Product Traceability (regulatory), R- Regulatory (other).
SP – Support program, CCP- Critical Control Point, QCP- Quality Control Point, RCP - Regulatory Control Point. No-SP – Adequately covered by Support program.

16. Hazard analysis only contains 31 steps, flow chart has 32 steps (missing label sachets in hazard table)
17. Step 11 Cooking include a hold time 17.02.2021- CLOSED site confirmed that no hold time as is not a CCP, product work orders detail steps for making each product which includes times for cooking/mixing ingredients.
18. Not all control measures have been considered, for example: all steps- equipment/utensils hasn't considered maintenance activities, steps where temperature control is required haven't considered storage/calibration procedures, training not considered as a control for some hazards such as CCP points. 17.02.2021- discussed finding with site, confirmed not all control measures have been included. 23.04.2021- NC reviewed and closed after review of the process flow and observation of the Milk powder repacking and the updated hazard table (2.2.3) control measure were found to be adequately documented.
19. CIP is referenced as a control measure for cleaning of the heat exchanger and buffer tanks, is there other equipment's/lines where CIP is used? No CIP information has been received 23.04.2021- NC reviewed and closed- cleaning validation for cook tank reviewed under element 4.
20. Some control measures for hazards have been recorded as 'refer to earlier steps' but no relevant step is named- 17.02.2021- site confirmed this is to do with specific steps, hazard table does not clearly define the specific steps. 23.04.2021- NC reviewed and closed- Hazard tables 2.2.3, 2.4.3 and 2.6.3 updated to reflect 'all steps' which is the generic hazard analysis for like steps and hazards in each HACCP plan.
21. Step 8 in the hazard table is sanitise with wipes, whereas the flow chart is Sanitise UV tunnel. 17.02.2021- no UV is used at site, flow charts FSM 2.3.2 and 2.2.2 currently include UV for sanitising. 23.04.2021- NC reviewed and closed- reviewed FSM 2.4.2 – Process Flow chart for Freeze dry yogurt and FSM 2.2.2 Process flow chart updated to reflect the use of a sanitise wipe not UV, also reflects the Hazard tables FSM 2.4.3 and FSM 2.2.3, 2.6.3.
22. Receivals steps refer to the GIN code, whereas 1.13 refers to the GIN and item code- is just the GIN code used for traceability 17.02.2021- CLOSED- site confirmed both can be used to trace, but GIN is the main identifier, GIN book captures products received, GIN and item code etc.
23. Step 25 in the hazard table is listed as xray, whereas the flow chart calls step 25 metal detection 17.02.2021- confirmed via site walk that xray is in used at site. 23.04.2021- NC reviewed and closed- reviewed FSM 2.4.2 – Process Flow chart for Freeze dry yogurt and FSM 2.2.2 Process flow chart for Repacked dairy products which now refers to Xray.

FSM 2.3.4- Milk Dice Freeze Dried Products- HACCP audit table- 12.04.2021- product not being produced at site, if site commences production of product then HACCP plan for this product is to be resubmitted for review and approval, shelf-life validation data will also be required.

24. Step 1- RCP 2 details product will be rejected if export documentation is not received, whereas FSM procedures (e.g 1.10) indicate product will be used for domestic product.

25. Justification of critical limits doesn't reference annual revalidation of CCPs

General HACCP and FSM findings:

26. It is unclear after review of the above HACCP plan and FSM procedures (1.20, 1.18, 1.13- go back and check these) if raw materials are placed on hold (quarantine label), labelled until inspection and testing is completed; HACCP plan states they are inspected and tested. 17.02.2021- HACCP plan does not clearly detail the product is placed on hold under sample & inspect. 23.04.2021- NC reviewed and closed- now refers to product being labelled for status, then held until testing done and product released in FSM 2.2.2 and FSM 2.2.3
27. Water activity testing of product is not included in FSM 1.20a. 17.02.2021- CLOSED- discussed with site, not included as is a CCP covered under HACCP verification table
28. Shelf life validation data to be provided for export products. 15.03.2021- establishment confirmed that no shelf life data is available for Freeze dried milk dice products. Shelf life data has been provided for 2 Vmores products, but data is complete as has only tested up until 1 months shelf life, products has 24 months shelf life 12.04.2021 – due to Freeze dried yoghurt product now being deemed non-prescribed by new export legislation no further review of this product is to occur as part of the new registration process, if at any stage the establishment is to export to a country that deems this product prescribed than the establishment is to contact the department to have the freeze dried yoghurt product approved. NC closed- 29.04.2021- shelf life validation report dated 23.04.2021 provided by establishment for equivalent milk powder product packed at the sister site and confirmed that the shelf life of 24 months is valid.

16.02.2021- A review of FSM 2.2.2 Process Flow Chart and 2.2.3- Hazard table for Repacked Dairy Products at site, the line was not in use. A review of FSM 2.4.2 and FSM 2.4.3 Freeze Dried Yoghurt based products also occurred (note only steps 24-27 were in operation), the following findings were noted;

29. Not all steps have been included in the process flow chart and hazard table. For example; decant/debag step not covered for all inputs (seals and scoops), transfers from storage to process areas (and back) or between process areas, or interim storage of WIP product are not all included. 23.04.2021- Reviewed updated FSM 2.2.2 Repacked Dairy products and now includes waste outputs at several steps, no rework of product occurs, all to waste. A site walk verified the process flow chart for Repacked Dairy products and identified missing steps relating to xray rejection and air flush of containers. 29.04.2021- NC closed- FSM 2.2.2 updated to include rejection of product at xray and flushing of containers.
30. The documented process flow steps do not reflect current process. For example; step 13 code container is not conducted at the current point on flow chart, no coding machine was in place at this step. 23.04.2021- NC reviewed and closed- coding has been corrected on the flow chart to being done before it enters the fill side.
31. Process steps do not clearly describe what is occur at the step. For example; assemble order steps do not explain what is occurring at the step – 17.02.2021- Clarified with site what process involves and reflects information in the HACCP plan.
32. Process flow steps do not align with those in the hazard table. For example, Step 16 on FSM 2.2.2 is 'carton', whereas step 16 on FSM 2.2.3 hazard table has pack in cartons/shipper. 23.04.2021- NC reviewed and closed- FSM 2.2.2 and FSM 2.2.3 updated to reflect correct naming of steps between each document, including step 16.
33. The process flow charts and hazard tables do not clearly detail the steps when the carton and pallet is labelled. 23.04.2021- NC reviewed and closed- FSM 2.2.2 and FSM 2.2.3 updated to reflect labelling of the carton and pallet at steps 16 and 17.
34. Not all steps in the process are required for all products. For example; blending step is not required for all products. 23.04.2021 NC reviewed and closed- not included on the process flow chart moved to the formulated milk powders HACCP plan (2.6.1 – 2.6.4), product and process area still being set-up.

10. Sampling and Testing	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

Sighted FSM 1.20 Product Assessment, Inspection and Testing Procedure sighted, raw material, finished product and water testing requirements. Form QAF28 to completed for out of specification product. QA Manager or Technical officer reviews records relating to food safety, production, product, water and environmental testing.

An overview of testing is referenced, then refers to SOPS in place for testing of products, water, environmental testing; SOP QA0021 Sampling and Testing of Export Products, SOP QA0014 Water Quality Monitoring Programme, SOP QA0018 Environmental Monitoring Programme. All testing to be completed a NATA approved lab, only trained persons are to sample product. Any out of specification product is to follow SOP QA 0023 Out of Specification Procedure. Raw materials and finished products are inspected before and during production. Finished product testing is done to meet domestic and importing country/ customer requirements. Corrective actions detailed and include notification to the Department.

Quarterly allergen swabbing to occur, determine no presence of eggs

Air quality testing procedure are detailed, an annual positive air pressure check is completed by an external contractor. Establishment also completed air quality testing as well.

SOP QA0021 Sampling and Testing of Export Products reviewed- details microbiological testing requirements for export product.

FSM 1.20a Product Testing reviewed, captures domestic and export testing requirements (China and Hong Kong).

This element is non-compliant due to the following findings.

Findings:

The following findings have been noted with relation to FSM 1.20;

1. Naming convention of roles is not consistent with the Organisational chart and position description for Huntingwood, refers to the Quality Manager or technical Officer. 23.04.2021- NC reviewed and closed- now refers to QA Manager or QA Officer which reflects FSM 1.6.
2. Corrective action procedures are not clearly documented to reflect forms and processes followed when test results are out of specification. 14.04.2021- NC reviewed and closed- corrective action procedures updated and clearly detail actions for food safety and quality issues, refers to CAPA process as well.
3. The procedure does not reflect who reviews Sydney water quality reports and actions when issues are identified with the report. 14.04.2021- NC reviewed and closed- now details QA officer to review.
4. Section 9.8 details environmental swabbing for salmonella and Enterobacteriaceae, but this is not documented in SOP QA0018 Environmental Monitoring Programme. 14.04.2021 NC reviewed and closed- SOP QA 0018 updated and includes details on Enterobacteriaceae testing.
5. Allergens to be sampled as per SOPQA0018 Environmental Monitoring Programme, but this programme when reviewed did not include allergen swabbing. 14.04.2021- NC reviewed and closed- FSM 1.2 updated to include further details on allergen validation, now refers to SOP QA 0018 for further information.
6. Section 9.9 Air Quality testing doesn't refer to and reflect SOP QA0018 Environmental Monitoring Programme; different frequency, limits, sampling locations and corrective actions. 14.04.2021- NC reviewed and closed- now refers to SOP QA 0018, testing process is covered under the SOP, corrective actions and sampling locations are now detailed in FSM 1.2.

1. SOP QA0021 Sampling and Testing of Export Products does not reference contacting the Department for out of specification product. 12.04.2021- NC reviewed and updated- now includes reference to contacting the department for Out of specification product. Relevant GACC standards are referenced.

11. Training	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

01-05.02.2021- FSM Training 3.2 reviewed, all staff to completed induction before commencing work, inductions covers workplace induction, food safety, employee responsibility, contamination. Further Sop training completed in; personal hygiene, GMP, gowning procedure. Staff to complete an attendance record at induction, once staff are competent the training matrix is updated. Further training is conducted per department area, this training is based on department SOPS. Each staff member will have a training plan in place, training plans incorporate, induction, GMP, HACCP, food safety and external/special training. A training matrix/ register is used to capture staff and training plans completed/in process. Training records are in use and are to include staffs competency assessment which is based on discussion, observation, execution or achieving 85% pass mark in a test. Refresh training on SOPS is to occur every 3 years or when changes occur, GMP training annually, additional training can be carried out as needed if deemed required. Procedure details export signatories will have knowledge of export, import country requirements, persons who are using Exdoc will also be trained.
This element is non-compliant due to the following findings.

11/02/2021- additional evidence was provided by the establishment to support FSM 3.2, this element is now compliant.

Findings:

1. Under the SOP training states staff will be observed and then deemed competent - unclear if this is occurring at induction and how competency is determined? Further on in Section 9.6 clearly details how staff are assessed, is this section applicable to induction as well? 11/02/2021- CLOSED- training matrix provided and includes Induction modules, training method and level of competency required. Information in the SOP is now understood and supported by the training matrix.
2. Sample of training matrix and or records not provided- 11/02/2021- CLOSED- a sample of the training matrix was provided, details training modules, method of training required per work area and the level of competency required. Sample of training records supplied for induction, HACCP, export and CAPA training.
3. Training is completed by either; read only, read and understand, onserved, observed, testing/quiz- how is this determined for each SOP/training package? 11/02/2021- CLOSED- training matrix details the method and level of competency required for each training module at site.

4. No details about how export signatories attain their knowledge in export, import country requirements etc is detailed. 11/02/2021- CLOSED- training matrix includes Export Dairy Control section, covers all modules (SOPS) staff are to be trained in, the method of training and level of competency required.

12. Identification/Traceability & Recall	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM 1.14 Product Identification and traceability reviewed, all raw materials are assigned a traceable item code when received this is linked to the receival register, is a sequential number. The traceable item code is used for traceability via the companys stock system and for the production process. A GIN (goods inward Notebook) captures information on the product. Product is transferred once received to it's a designated area, colour coded labels are applied to signify product status. Details export and domestic product to be labelled and segregated. Non-export products have different names and codes. Stored and WIP products labelling requirements are captured. Batch numbers of raw materials are recorded on production and packing work orders (these are generated for each batch. Finished products are issued a manually generated batch number and best before date (12 months from date of manufacture), these are printed onto packaging, HW signifies Huntingwood site, work orders and packaging document confirm batch number/best before date, these are checked for each run. Rework is allocated a work order and rework form and checklist are to be used. Finished products are traceable via; best before date, batch number and production and packing work orders and documents. When products are dispatched, dispatch docket is generated, links to computer system and captures traceability of product.

FSM 1.19 Recall and Withdrawal procedure reviewed, covers process for all products to be recalled and withdrawn, includes notification to the department for export product.

A site audit occurred on 16-17.02.2021 where further review of procedures both documented and on floor operations occurred. Products (raw materials, WIP and finished goods) were found to be labelled and segregated as hold and release procedures required. An overview of the receivals process occurred, GIN book and the dairy transfer log books were sighted, one book capture non-dairy ingredients and the other captures dairy goods received at site (batch, item codes, GIN id, supplier, est) were recorded in this book. Once the GIN is allocated the products/pallets are labelled with a quarantine label, once tested/inspected a release label is applied. QA also capture goods received in the sampling register, they notify the warehouse once product has been released. Details of goods received are also entered in the computer stock system (Pronto). The Pronto system was reviewed, the system captures raw material and finished goods hold and release details, and work orders for production-packing. Planning department create productions and packing batch numbers from the planning database and are a sequential number, these are then entered into the Pronto system for relevant work orders, the warehouse then uses the work orders and GIN ID to pick product required. Production and packing work orders are issued for each new batch of a product, captures ingredients used as per the BOM, the process steps of producing/packing product detailed, staff are to check off each step is completed on the work order, CCP and QCP monitoring is also included. A packing work order was sighted for Freeze dried Berry Vmore yoghurt sachet product at audit, records had been completed as required for cleaning, hygiene and QCP monitoring. A review of a Mock Recall completed on 05.08.2020 occurred for a packaging complaint of product, wrong cap used on product MV powder, product affected was traced and root cause was determined and actions were taken.

This element is non-compliant due to the following findings.

Findings:
FSM 1.13 Product Identification and traceability findings:

1. Unclear if the GIN and the item code are the same and how are they are linked (section 9.1.1) (item code is the raw material code , product code) 17.02.2021- CLOSED- site confirmed GIN and item code (product code) are separate, when goods are received, GIN is issued in GIN book and item code is recorded with it as well. Can track GIN and item code in the computer stock system (Pronto)
2. Unclear how the traceable item code, GIN, manual batch number and receival register are linked to computer stock system? 05/02/2021- establishment confirmed all link to the computer stock system, further review of the trace process to occur at site visit. 17.02.2021- CLOSED- discussed with site details of the product are entered in the Pronto system using information from the GIN book, receival register and production-packing work orders. Sighted example of Finished goods in Pronto system- records batch code, item code, work orders and quarantine/release status.
3. Raw material batch details are recorded on production and packing work orders, but where does the GIN/ traceable item code come into it? 05/02/2021- establishment confirmed that both the GIN and traceable item code (product codes) are recorded. NC CLOSED.
4. Procedure does not define how export product is labelled. 12.04.2021- NC reviewed and closed- procedure now clearly describes how export product will be labelled.
5. Procedure doesn't capture scheduling requirements of export and domestic product? 05 & 16/02/2021- site confirmed that Sales receive orders, sales confirm if export or not then arrange ingredients as required, production then scheduled, export then domestic production to occur, and export products will have a different code to non-export product- FSM 1.13 currently does not clearly capture this process.

12.04.2021- NC reviewed and closed- procedure now clearly details production scheduling process for export vs non-export product.

13. Approved Supplier Program; Ingredients and Packaging	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM 1.22 Approved Supplier Procedure sighted, is supported by SOP QA0026 and Approved Supplier List. Only products on the approved supplier list are to be purchased. Procedures defines requirements for approval of suppliers for ingredients (dairy, non-dairy), packaging, service suppliers for maintenance, labs and chemicals. Procedure details the requirements for Australian and imported dairy ingredients suppliers (reflects requirements as detailed in FSM 1.10- see section 15. If products do not have enough documentation to show that it meets export requirements, then it is not used for export product. Eu supplier and product information must be met in order for the ingredients to be used not EU finished product. Dairy suppliers must also provide documentation such as: CoAs, Department Export Registration (or similar for imported product), HACCP certificate or equivalent, Supplier questionnaire. An annual review of suppliers occurs.

At the site audit on 16.02.2021 the site confirmed that they are not intending to export to the EU and that export products will have a different product code to non-export product.

This element is non-compliant due to the following findings.

Findings:

1. Procedure doesn't capture process of routine monitoring of suppliers and goods at time of receivals, or non-conformance process for suppliers- 16.02.2021- procedure does not include monitoring of receivals or corrective action process for non-compliant suppliers. 22.04.2021- NC reviewed and closed- FSM 1.22 details corrective action processes for NC suppliers and SOPWHS0002- Receiving Items details process for monitoring.
2. Approved Supplier Register/list and SOP QA0026 is still in process of being developed. 14.04.2021- NC reviewed- approved supplier list provided, still in development, no export registered suppliers listed at present. 23.04.2021- NC reviewed and closed. establishment confirmed that export supplier questionnaires and certificates are still to be returned, site is aware that dairy ingredients for export must be from export registered suppliers and the documented systems detail this.
3. 16.02.2021- FSM 1.22 includes EU requirements, site is not intending to export to the EU. 22.04.2021- NC reviewed and closed- EU references removed from FSM 1.22.

14. Receiving and Dispatching Milk & Milk Products	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
SOPWHS009- Dispatching Goods reviewed, covers steps when dispatch goods at site, see findings as below.

Sighted SOPWHS0002- Receiving Items covers steps when receiving goods at site, findings have been noted below.

See sections 13 15- Information on receiving and dispatching of product

This element is non-compliant due to the following findings.

Findings:

SOPWHS009- Dispatching Goods findings:

1. Section 7.9 details checking of truck for dairy goods, but doesn't elaborate on what the checks are or if these are recorded- 17.02.2021- no dispatch checklist is currently in place. 23.04.2021- NC reviewed and closed- sighted WHF 003 Export Dairy preloading checklist which is to be used for each export loadout/dispatch.
2. Section 7.9 is the only part that references a transfer certificate, procedure does not include what checks are required for export product. 23.04.2021- NC reviewed and closed- SOPWHS009 updated to include checking that a transfer cert/dec is completed and sent with the product.
3. Unclear in the SOP if a dispatch checklist is completed. 17.02.2021- no dispatch checklist is currently in place. 23.04.2021- NC reviewed and closed- sighted WHF 003 Export Dairy preloading checklist which is to be used for each export loadout/dispatch.

SOPWHS0002- Receiving Items:

4. No reference to checking dairy products for export compliance is noted in the SOP.

5. FSM 1.13 refers to a traceable item code being issue first then a GIN, but SOP just refers to the GIN- which is correct. 17.02.2021- CLOSED confirmed with establishment that the GIN is issued at receivals, is recorded in the GN book with item code.
6. HACCP plan reviewed refers to a receival checklist, but this SOP doesn't not reference such as checklist. 17.02.2021- CLOSED- site confirmed that the checklist is 'QAF034' and is completed by QA for products requiring temp control only.
7. Is part b undertaken for all products received? 17.02.2021- closed site confirmed that part b is completed via the sampling sheet for each product, sample of these were sighed at audit.

15. Transfer & Manufacturers Declarations of Compliance	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
Reviewed FSM 1.10 Export Documentation Procedure covers roles and responsibilities in completing export documentation at site. Documentation and information is reviewed by eligible persons to ensure export documentation & importing country requirements are met, this includes; Completed & received Transfer certificates, decs of compliances, RFPs, Micor, CoAs, product testing results. Procedures define the requirements for export permit, health certificates and prohibited goods, and when these cannot be generated. Persons who can complete transfer certificates and declaration of compliance are detailed and are trained in the procedure. Procedure details the requirements for completing and checking transfer certificates and declarations of compliance by eligible staff, as well as when they are required (at receival and dispatch).
Procedure details Australian dairy ingredients received are for domestic and export use, export product is required to have a transfer certificate and come from an export registered establishment, export product is labelled and segregated from domestic product. Requirements for Imported dairy ingredients are defined and include; must be registered, meet importing country requirements, provide COAs or health certificates. Only product that has documentation stating that it meets Eu requirements can be used in EU product. Additionally, if documentation is not sufficient to indicate product meets a specific importing country or general export requirements it is deemed not suitable for export- computer system and labelling will capture this information.

This element is non-compliant due to the following findings.

Findings:
1. No template has provided for transfer certificate or declaration of compliance. 18.02.2021- QAF025 – Transfer certificate sighted and was compliant. QAF026 Manufacturers Declaration of Compliance to be provided for review. 15.03.2021- reviewed QAF026 Manufacturers Declaration, does not reflect current requirements for export of dairy products- refer to; https://www.agriculture.gov.au/export/controlled-goods/dairy/registered-establishment/declaration-compliance. 14.04.2021- NC reviewed and closed- QAF026 updated to reflect new export legislation.
2. Under section 9.3 if refers to checking the product has come from an export registered establishment, but not how it is done. 12.04.2021- NC reviewed and closed- details operator will conduct a visual inspection of product and paperwork received.
3. Section 9.4 is not clear when a transfer certificate is required or not; Girraween is referenced as not requiring a transfer certificate (dot point 1), but then requires one in dot point 2, dot point 2 is requires rephrasing (repeated wording) 17.02.2021-wording of this statement is unclear. 12.04.2021- NC reviewed and closed- now clearly details when a transfer cert/ dec is required or not required.
4. Retention period is stated as 7 years for export documentation, this differs from document control procedures. 12.04.2021- NC reviewed and closed- now details retention as 5 years.

16. Importing Country Requirements	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

Sighted FSM 1.11 Importing Country requirements and FSM 1.11a Importing Country Requirements schedule reviewed.
FSM 1.11 references export products will meet export and importing country requirements, including China and EU. All products will meet export requirements and are deemed export until they are labelled domestic- both on the label and in the computer system. Importing country requirements is obtained when order is received, by review of Micor, department emails, market advice notices, contacting importing country customer and regulatory authorities. Products are checked to ensure they meet importing country requirements at the time a transfer certificate or declaration is to be completed, QAF056 Product HACCP Verification Form and QAF057 Export Documentation Checklist are completed.

FSM 1.11a reviewed, specific importing country requirements for China and Hong Kong.

Verification table 1.14a captures review of importing country requirements prior to shipment and or when changes have occurred.

Site confirmed 16.02.2021 that they will not be exporting to the EU. Additionally, the site confirmed export product is bought in as required for export orders, product will be checked at receival to ensure if meets export requirements and then logged into system as export or domestic.

This element is non-compliant due to the following findings.

Findings:

1. Verification table 1.14 states importing country requirements are checked prior to shipment, but then states that it is completed as part of an internal audit in February. 05/02/2021- establishment confirmed that they do carry out both activities- NC closed.
2. 1.11 references EU exports and to review 1.11a for further on specific importing country requirements, on review of 1.11a no EU information is detailed. Only China and Hong Kong are detailed in 1.11a- please confirm importing countries, and if EU is one update procedures to include EU requirements. 16.02.2021- procedure includes EU requirements at present, site confirmed they will not export to EU**.** 12.04.2021- NC reviewed and closed- reference to EU requirements removed from procedure.
3. 1.11 states that EU production is not routine, but site will ensure EU requirements are met, Eu checklist to be completed- no EU checklist received. 16.02.2021- 16.02.2021- procedure includes EU requirements at present, site confirmed they will not export to EU. 12.04.2021- NC reviewed and closed- reference to EU requirements removed from procedure.
4. No reference to training in export or importing country requirements for staff is detailed in 1.11. 12.04.2021- NC reviewed and closed- training requirements and reference to training procedure added into procedure.
5. Unclear if all raw materials and finished product are all export grade, on interpretation of 1.11 section 9.4 all products meet export requirements, unless theres documentation issues, whereas 1.10 details products when received are classed as export or domestic (section 9.3), which depends on documentation received. 16.02.2021- export product codes are still to be set-up. 12.04.2021- NC reviewed and closed- products are export unless export documentation is not received and it will then be treated as domestic. FSM 1.1.3 details labelling requirements of export product.

17. Loading of Sea and Air Freight Containers	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

This element is non-compliant due to the following finding.

Findings:
01-05.02.2021- Unclear from evidence received if establishment is loading containers.
16.02.2021- FSM Procedures reviewed have not captured if loading of containers is to occur at site.
22.04.2021- NC reviewed and closed- FSM 2.01 updated and details no container loading at site at present.

18. Department of Agriculture Seals	Compliant? (Yes / No/ NA- Not Assessed)	**n/a**

Summary of Findings: Not required at this stage for the establishment, as documented in FSM 3.1

Findings:

- Not Applicable

19. Pasteurisation	Compliant? (Yes / No/ NA- Not Assessed)	**n/a**

Summary of Findings:

Sighted FSM 3.1 GMP it documents that all dairy and egg products received at site are pasteurised and HACCP plans also detail product is pasteurised by suppliers, CoA or CoC is to be received.

Findings:
Nil

20. Trade Descriptions	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:
FSM reviewed 1.12 Trade Descriptions is in place, roles and responsibilities for checking and approving labels before use, as well as ensuring all goods (raw materials, finished products) are labelled during storage and use/production is described. A transfer cert/ dec of compliance is only generated and signed once it is in the computer system. Labelling requirements are detailed for export and domestic products, foreign translations for export product when required (China labels product must be approved by Chinese authorities)- Labels to be reviewed when changes occur or at least annually. SOPS are in place for printing labels & packaging.

FSM 1.12a Labelling Requirements details labelling requirements for product for retail and non-retail sale.

Verification table incorporates an annual review or review when changes occur for trade descriptions.

FSM 1.10 Export Documentation details that foreign language translation for labels/artwork are kept on file, are completed by a translator, each delivery is checked and logged onto QAF027.

This element is non-compliant due to the following finding.

Findings:
01-05.2021- Goat milk powder artwork provided, but doesn't list the Est1405

16.02.2021- sighted sample of Full Cream Milk Powder 1kg Jar- BBD date, batch number, est number, manufature date are printed via ink jet on base of the Jar. Sighted label checks for freeze dry yoghurt sachets production at audit- done at start of run, this is checked against label sample and the production work order.

21. Maintenance and Calibration	Compliant? (Yes / No/ NA- Not Assessed)	**Yes**

Summary of Findings:

Establishment has FSM 3.8 Maintenance Procedure in place, covers scheduled (preventative) and unscheduled maintenance activities at site. Staff to report any issues with the plant/ equipment to manger/supervisor so that it can be addressed. Both planned and unplanned maintenance activities are recorded on either Preventative Maintenance Form (FDPM) or QAF-037 Maintenance Form. Procedure captures ensuring work area is checked before use to ensure it is cleaned and sanitised, no debri. The plant and equipment (including tools) are to be fit for use, kept clean and sanitised. Tool hygiene and reconciliation is checked as part of daily GMP audits or QAF-037. Repairs to plant or equipment's are risk rated in terms on priority- low to critical. Any major changes to the plant are to be approved by the department. FSM 3.9 Maintenance schedule is in place. Maintenance staff and contractors are trained in GMP and Hygiene requirements.

FSM 3.7 Calibration procedure sighted, covers equipment that is required to be calibrated at site and persons responsible, calibration register is in place and further details equipment calibration requirements. Equipment is to be labelled with calibration details, procedures are in place for when calibration fails- label not to use, repair, cease production if it relates to CCP. Calibrations can be completed by internal staff or external service contractors, the establishment retains records of calibrations. Overview of scale and thermometers calibrations is detailed. Sighted Calibration register.

A site audit walk through occurred on 16.02.2021, the establishment was found to of a satisfactory standard for structures and equipment., no issues were noted.

This element is non-compliant due to the following findings.

Findings:
Findings to be addressed for FSM 3.8:
1. Section 7 does not include monitoring of the production & packing areas. 12.04.2021- NC reviewed and closed- scope now covers all of site.
2. Procedure doesn't capture how equipment/fixtures are addressed to ensure they are fit for use- is a risk assessment completed. 17.02.2021-CLOSED- site confirmed assessment process is in place, SOP VAL00001 Site Validation Master Plan is used and was sighted.

Findings to be addressed for FSM 3.7:
3. Scope does not cover production and packaging areas. 12.04.2021- NC reviewed and closed- scope now covers all of site.

22. Miscellaneous (Alterations & additions to premise & FSP since last visit, AA approval/conditions, Registration details, Exemptions, Outstanding Non-Conformances raised during the previous audit not previously closed out or required to be verified)	Compliant? (Yes / No/ NA- Not Assessed)	**N/a**

Summary of Findings: Not applicable this audit

Findings: Not applicable this audit

Additional items of Concern identified during the audit and not mentioned above:

- No additional items, all issues of concern have been documented above

Notes:

- Not all the elements identified in the scope of the audit determined prior to the visit were able to be looked at during this visit. Effective review of those elements that were audited during this visit took longer than anticipated and those elements not reviewed this visit will be included in the next bi-annual audit.
- It has been identified that the current day allocated to undertake verification of your approved arrangement is insufficient to effectively verify compliance with legislative and importing country requirements, as such future audits of your site will be undertaken over two consecutive days for each of the Bi-Annual audits undertaken over the year.

Observations:

- All observations (where applicable) have been included in the report above

Non Compliances:

- Where a non-compliance has been documented in the report above, the information provided in the findings "as evidenced by" are those items identified that support why the element has been found non-compliant. It is not necessarily exhaustive and is not an itemised "to do" list, rather examples to support why a program/element is not effective. The expectation is that the non-conformance will be thoroughly reviewed to determine the root cause and actions taken to address both the root cause to why it happened as well as rectifying the "finding" (where applicable) and verification to ensure the failure does not re-occur.
- If you require further clarification please contact myself or in my absence dairy@agriculture.gov.au

Department of Primary Industries Food Authority

Audit

Print date: 09-04-2020

Audit Details			
License number	25372	**Audit reference Number**	124266
License permission	Dairy Processing		
Approved activities	Process pasteurised dairy products		
Processes	Other dairy desserts, Milk Powder		
FTE	40	**Update FTE Count**	40
Audit date	09-04-2020	**Audit type**	Licensing
Audit category	License	**Audit status**	COMPLETE
Lead Auditor	s. 22(1)(a)(ii)	**Duration (Hours)**	2.25
Outcome	Acceptable	**Audit Level**	A
Audit Score	0	**No. of Corrective Actions**	0

Facility			
Reference number	203797	**Trading name**	
Registration number		**LFB number**	
Facility LGA	Blacktown	**Facility type**	Fixed Premise
Facility address	60 Huntingwood Drive Huntingwood2148		

Company Details			
Company name	GMP Pharmaceuticals Pty Ltd	**ABN**	80 063 353 006
Food Notify Notification Number		**ACN**	063 353 006
Business type		**Business type other**	
Company address	14 Amax Avenue GIRRAWEEN2145		

Notes

2nd licensing audit of a newly fitted out facility that is producing a range of freeze dried dairy snacks with flavour added such as apple, cranberry and orange. The entire process takes 2-4 days. Product being manufactured has a low water activity (tested at each batch) with microbiological testing to be conducted. Facility is also doing a similar product referred to as yogurt buttons with yogurt received from approved supplier stored on site. Since previous audit, cool room has been built and in use.

Facility will also be processing milk powders on site (which is currently undertaken at Girraween site) for domestic sale only (at this stage). Auditor is to seek advice from Science & Policy to determine correct category and testing frequency based on NSW Food Safety Schemes Manual.

Facility will be applying for export certification with DoAWR but has already received DoAWR storage approval with export establishment number 1405.

As advised by Team Leader (s. 22(1)(a)(ii)) over the phone on 08/04/2020, documentation audit to be conducted only as facility has not produced any products since January 2020.

Results Summary	
Food safety program	Acceptable
Construction and maintenance	Acceptable
Hygiene and sanitation	Acceptable
Process control	Acceptable
Product ID and traceability	Acceptable
Analytical and testing	Acceptable
Pre-requisite programs	Acceptable
Corrective action	Acceptable

Results			
Food safety program	Acceptable		
Audit Item	**Compliant**	**Findings**	**Timeframe**
Is the businesses licence on display and correct for activities undertaken?	Yes		
Is the Food Safety Program documented and available for audit?	Yes		
Does the Food Safety Program reflect all the procedures and practices of the business?	Yes		
Does the Food Safety Program outline appropriate corrective actions to be taken when the identified hazards are found not to be under control?	Yes		
	Comments	Licence on display with expiry date 21 June 2020. Reviewed HACCP Plan for Milk Dice Freeze Dried Products, Freeze Dried Yogurt Based Products, Freeze Dried Fruit.	
Construction and maintenance	Acceptable		
Audit Item	**Compliant**	**Findings**	**Timeframe**
Do the equipment, fixtures, fittings and utensils comply with maintenance and construction requirements?	Yes		
Do the walls, floors and ceilings of the facility comply with the construction and maintenance requirements?	Yes		
Does the construction and maintenance program and procedures ensure that the facility complies with requirements?	Yes		
Hygiene and sanitation	Acceptable		
Audit Item	**Compliant**	**Findings**	**Timeframe**
Do equipment, fixtures, fittings and utensils comply with hygiene requirements?	Yes		
Do walls, floors and ceilings comply with hygiene requirements?	Yes		
Does the hygiene program and procedures ensure the facility complies with hygiene requirements?	Yes		

Results			
Process control	Acceptable		
Audit Item	**Compliant**	**Findings**	**Timeframe**
Has the business correctly completed monitoring records?	N/A		
Does the business have all monitoring records completed since last audit available?	N/A		
Is the facility complying with temperature control requirements?	Yes		
Is all food and ingredients fit for intended use?	Yes		
Is the facility ensuring that food is protected from contamination?	Yes		
Has the business taken sufficient corrective action against issues identified in CCP/CP monitoring?	Yes		
Is the business correctly receiving raw milk?	N/A		
Is the business correctly conducting heat treatment of milk or cream (continuous flow pasteurisers)?	N/A		
Is the business correctly conducting continuous flow pasteurisation?	N/A		
Has the business correctly conducted annual pressure checks? (conventional plates only)	N/A		
Has the business correctly conducted heat exchanger checks? (duo plate / double skinned heat exchangers only)	N/A		
Is the business correctly conducting batch pasteurisation? (raw milk & cream only)	N/A		
Is the business correctly conducting batch heat treatment correctly?	N/A		
Is the pH of cultured products below pH 4.5?	N/A		
	Comments	Sighted Receiving Checklist QAF034 for yogurt receival, Sighted Warehouse Temperature Record Log Book Cool Room 1 & Warehouse Cleaning Record Log Book Cool Room 1 which are being completed twice per day. Also sighted updated Material Dispensary SOP PFD002.	
Product ID and traceability	Acceptable		
Audit Item	**Compliant**	**Findings**	**Timeframe**
Do product labelling policies and procedures comply with requirements?	Yes		
Are products and ingredients labelled correctly?	Yes		
Does the business have a system to trace all inputs and products within their business?	Yes		
Has business complied with traceability requirements?	Yes		
Does the business have a documented recall program?	Yes		
Is the recall program effective and accurate?	Yes		

Results			
	Comments	FSM 1.13 Product Identification & Traceability Procedure refers to GIN for yogurt. FSM 1.19 Recall Procedure	
Analytical and testing	Acceptable		
Audit Item	**Compliant**	**Findings**	**Timeframe**
Is the testing program adequately documented?	Yes		
Has the business carried out testing as outlined in their Food Safety Program? (shelf life testing/hygiene swabbing)	N/A		
Has the business carried out testing as required by the Food Safety Schemes Manual?	N/A		
Has the facility carried out appropriate corrective action in the case of a failed test?	N/A		
Has the business notified the NSW Food Authority in the case of a failed product test?	N/A		
Has the business carried out verification testing as outlined in their Food Safety Program? (shelf life testing/hygiene swabbing)	N/A		
	Comments	No testing has been conducted since previous audit as no products have been produced.	
Pre-requisite programs	Acceptable		
Audit Item	**Compliant**	**Findings**	**Timeframe**
Does the calibration program and procedures ensure all equipment used to monitor temperatures of potentially hazardous food is accurate?	Yes		
Is the calibration program adequately documented /implemented and all measuring devices and equipment are accurate?	Yes		
Has the business conducted an annual review of their food safety systems?	N/A		
Has the internal audit been effective in identifying deficiencies in the system?	N/A		
Does the pest control program and procedures adequately control pests at the facility?	Yes		
Is the pest control program adequately documented, implemented and monitored?	Yes		
Does the GMP program and procedures ensure all GMP hazards are identified and controlled?	Yes		
Does the business have a training program to ensure staff have sufficient skills and knowledge for their work activities?	Yes		
Is the staff training program effective?	Yes		
Does the business have a system to identify and approve suppliers?	Yes		
Does the business have a program to identify/ prevent/ control allergen contamination?	Yes		
Does the allergen management program effectively control allergens within the facility?	Yes		

Results			
Are all chemicals suitable for use in a food processing environment?	Yes		
Does the calibration program and procedures ensure all measuring devices and equipment are accurate?	Yes		
	Comments	Sighted pest control reports dated 05/03/2020, 06/02/2020, 02/01/2020 & SOP QA0011 with chemical approval listed in procedure.	
Corrective action	Acceptable		
Audit Item	**Compliant**	**Findings**	**Timeframe**
Has the business sufficiently addressed all CARs from previous audits within the rectified dates?	Yes		

Images

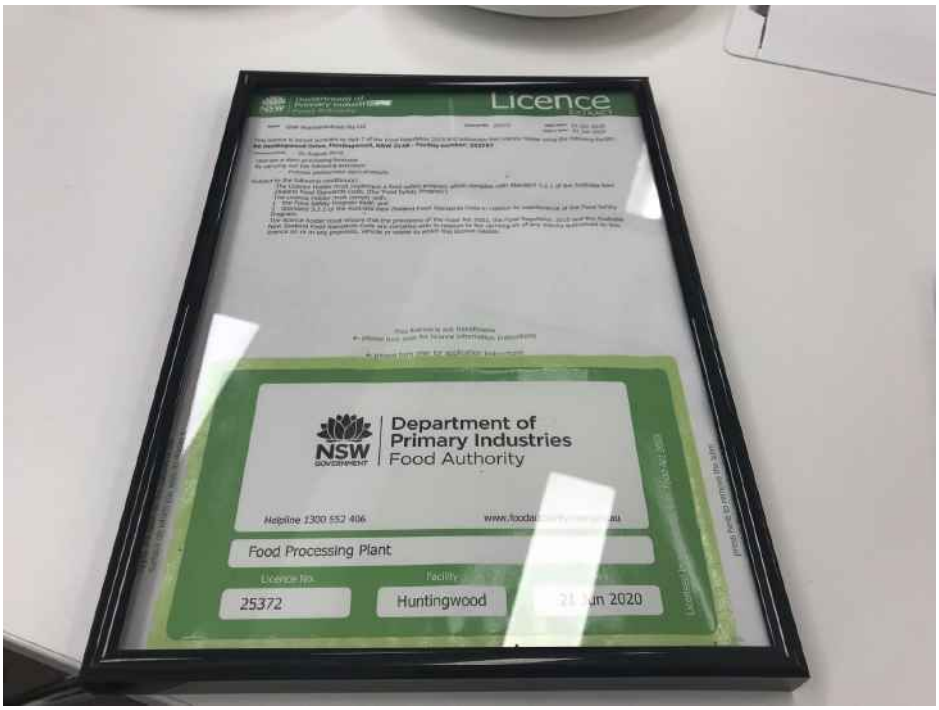
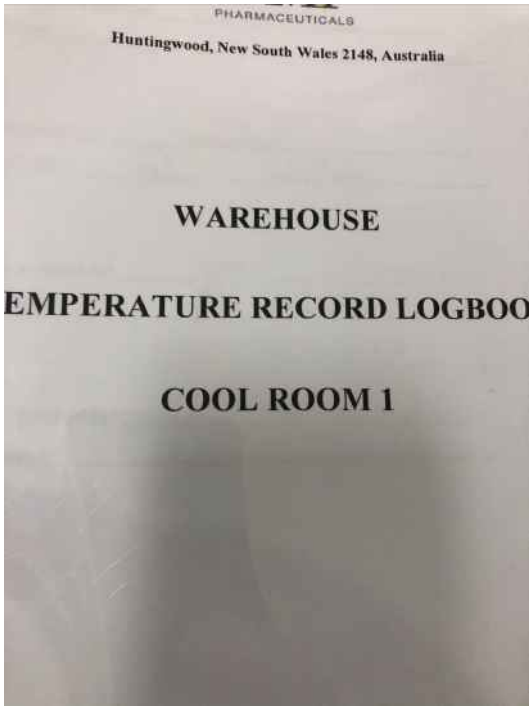


Photo of licence.

Images



Temperature Record Book for cool room 1.

I am of the opinion that the food business is being operated in compliance with the regulations relating to food safety programs and in compliance with the food safety standards.	I have read and understood the above findings of this report and acknowledge that any issues of noncompliance with the requirements need to be rectified.
Officer Name: s. 22(1)(a)(ii)	**Facility Representative:** s. 22(1)(a)(ii)
s. 22(1)(a)(ii) **Signature:**	s. 22(1)(a)(ii) **Signature:**