AsureQuality

A world-class provider of food safety and biosecurity services

www.asurequality.com

Presentation Outline - Dairy Recognised Agency

Overview - AsureQuality

Requirements on Recognised Agencies and Recognised Persons

Regulatory Model

Structure and Recognised Agency Duties

Reporting to MPI, Definitions, Exceptions and Product Dispositions

RMP Verifications - general

Questions for everything else I forgot to include…

Assurance Services

We can meet our customers' needs wherever they operate in the food supply chain.

ON-FARM	IN-PROCESS	PRODUCT & ENVIRONMENT TESTING	MARKET ACCESS
Dairy	Dairy Plants	All Dairy Products	Regulatory Compliance
Meat, Poultry and Seafood	Processing Plants	Beef, Lamb, Venison, Poultry and Seafood	USDA/EU Compliance
Horticulture and Wine	Packing Houses	Fruit, Vegetables and Wine	GLOBALG.A.P Certification
Food	Food Processing Plants	Dairy, Meat, Horticulture and Grain-based Products	BRC & SQF Certification
Arable	Storage, Sorting and Processing Facilities	Seeds and Grains	Organic Certification
Forestry	Mills	Logs, Timber and other Wood Products	Farm Assurance Schemes
Live Animal Export	Isolation Facilities		CARB Certification
Biosecurity	Farms, Forests, Orchards, Apiaries and Natural Environments	Food, Plant, Animal and Environment, Pest and Disease Identification	ISTA, OECD and AOSCA Certification
			Phytosanitary and Zoosanitary Certification
			Forest Stewardship Certification

International Accreditations

ACCREDITATION AUTHORITIES

TESTING

LABORATORY PROFICIENCY

- LAS Proficiency
- Seed and Plant Pest & Disease

LABORATORIES
OECD, ISO/IEC 17025

- Chemistry
  - General
  - Inorganic
  - Organic
  - Nutritional
- Microbiology
  - Serology
  - Pathogens
- GMO
- Medsafe GMP
- OECD GLP

INSPECTION

INSPECTION BODY
ISO/IEC 17020

- MPI Recognised Agency
  - Dairy
  - Organics
  - Bee Products
- MPI HACCP Based Food Safety Programmes
- MPI Risk Management Programmes
- Live Animal & Animal Germplasm Official Assurances
- MPI Independent Verification Agency for Import and Plant Export Certification

AUDITING

RABQSA

- Certified Personnel
  - Competency Based Food Safety Auditor Scheme

MANAGEMENT SYSTEMS CERTIFICATION
ISO/IEC 17021

- ISO 9001 Quality Management Systems
- ISO 22000 Food Safety Management Programmes
- ISO 14001 Environmental Management Systems
- FSSC 22000 Food Safety System Certification

PRODUCT CERTIFICATION
ISO/IEC GUIDE 65

- Organics
- GLOBALG.A.P
- BRC
- Timber Preservation
- New Zealand GAP
- Australian Wood Packaging Certification Scheme
- SQF 1000
- SQF 2000
- Farm Assurance Schemes
- PINENZ - Pine Manufacturers Association Programme
- Verification of Timber Properties
- California Air Resource Board ATCM 93120

GOOD MANUFACTURING PRACTICE (GMP)

- MPI - Agricultural Compounds and Veterinary Medicines
- USDA
- Australian Pesticides and Veterinary Medicines Authority

IFOAM

- AsureQuality Organic Standard

Auditing & Inspection Accreditations

JAS-ANZ is the government-appointed accreditation body for Australia and New Zealand responsible for providing accreditation of conformity assessment bodies (CABs) in the fields of certification and inspection. AsureQuality's accreditation by JAS-ANZ demonstrates our competence and independence as a CAB.

ISO/IEC 17020 Inspection Body – [Recognised Agency]

MPI plays an integral part in the accreditation process.

- MPI Recognised Agency - dairy, organics, bee products
- MPI HACCP based Food Safety Programmes
- MPI Risk Management Programmes
- MPI Individual Recognised Persons

Auditing & Inspection Accreditations

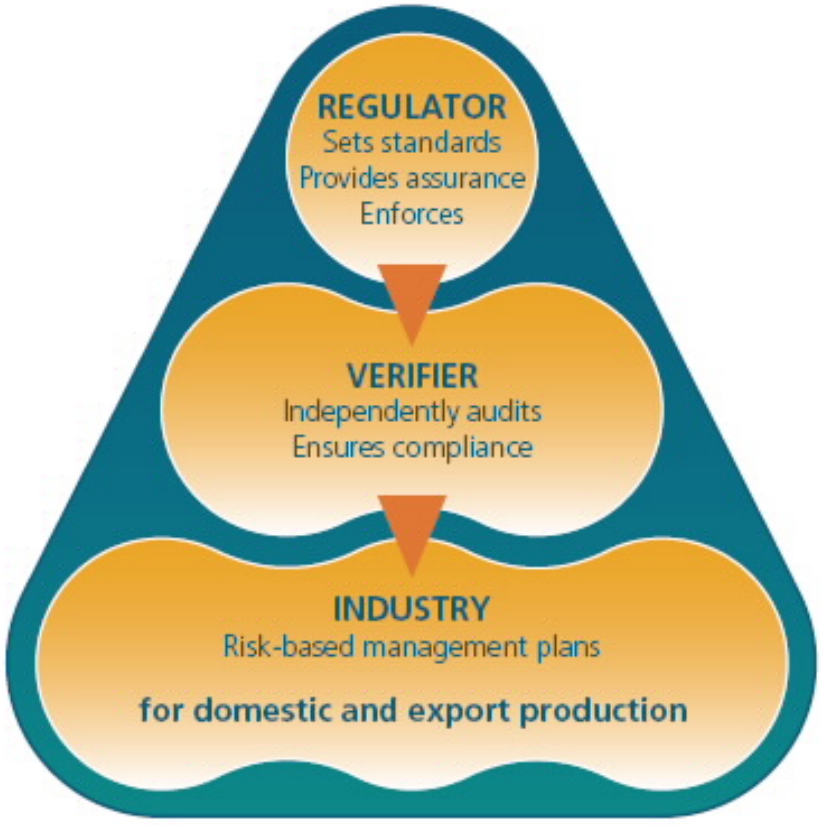
ISO/IEC 17021 Conformity Assessment

- ISO 9001 Quality Management Systems
- ISO 14001 Environmental Management Systems
- FSSC 22000 Food Safety Management Systems

ISO/IEC Guide 65 Product Certification

- Organics
- GLOBALGAP
- BRC - Food Safety and Storage and Distribution

Regulatory Model – Dairy



THE NEW ZEALAND FOOD SAFETY REGULATORY MODEL

MPI's Expectations:

RAs operate on their behalf in accordance with accepted standards. MPI wants confirmation that regulatory requirements are being met.

Recognised Agencies:

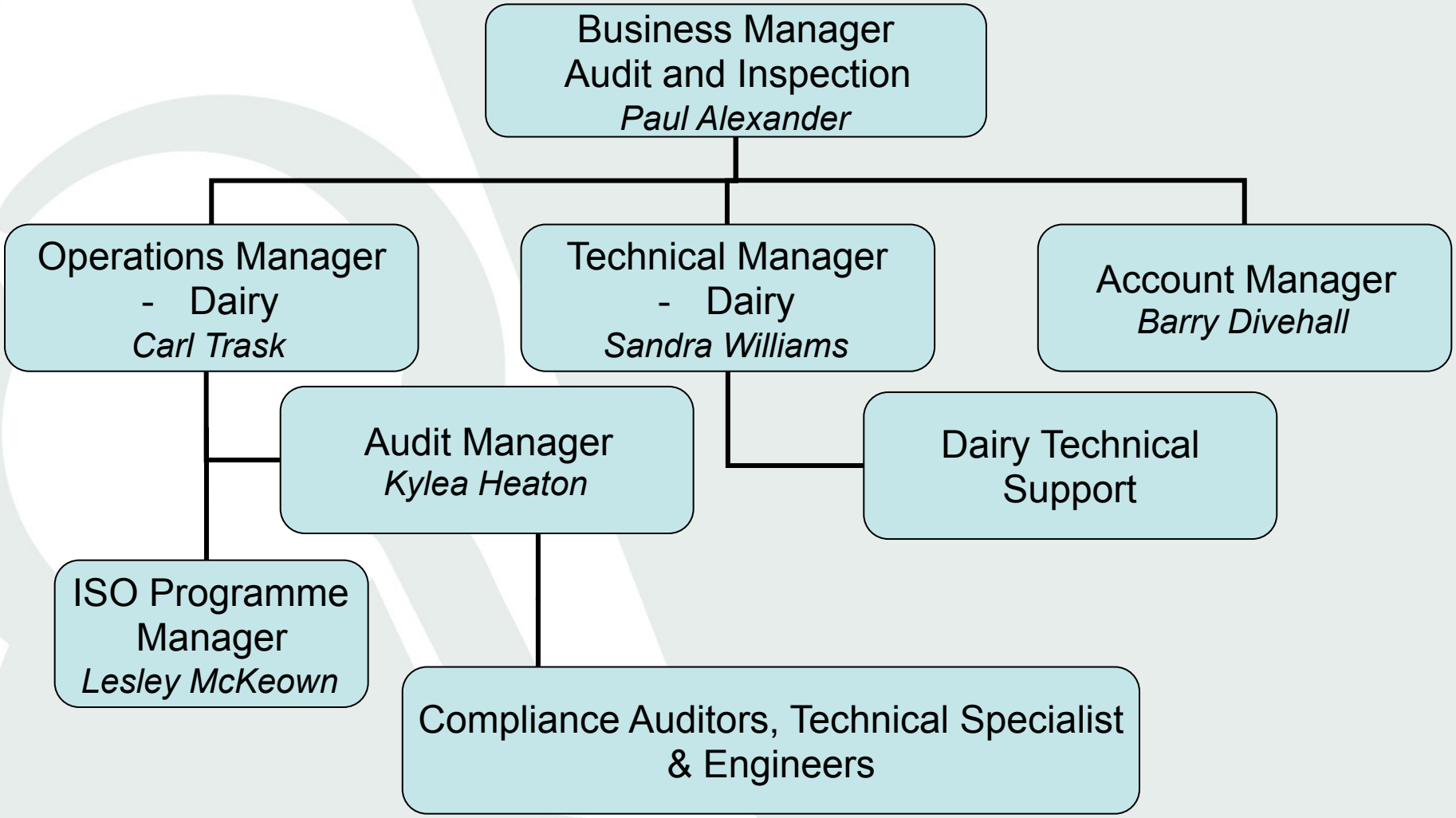
Independent, meets recognised agency standards [corporate and individual], operates with integrity, is responsive, maintains a high level of technical expertise and considers the needs of all stakeholders.

Industry Expectations:

Wants the audit process to add value,

is credible, technically sound, with integrity, empathetic, impartial, respects confidentiality and consistent.

Dairy & ISO Team



Duties of Recognised Agencies & Persons

Animal Products Act 1999 – Clause 107

Undertake only those functions and activities they are recognised for

(eg Verification and Evaluation, Specific Product Groups)

Comply with any relevant Notices or Specifications

Maintain an appropriate degree of impartiality and independence

Maintain appropriate confidentiality

Report to the appropriate MPI Official, in accordance with the requirements of the APA

- *Any failure to comply with, or any inadequacy in, a risk management programme.*
- *Any other matter which is required by or under this Act to be reported by Recognised Persons*

Recognised Agencies and Persons Criteria

Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Persons

Requirements to advise MPI

- *Critical non-compliances relating to non-conforming dairy material or product, where product is deemed affected, and as such will require written disposal instruction prior to release, within 24 hours…*
- *Exception reports with all information required provided to MPI; get any missing information*
- *Reviews corrective actions and reports to MPI on resolutions*

Critical Situations

- *Reported to MPI as soon as practicable but within 24 hours*

Monthly Report to MPI

- *Details of all exceptions received, including those not forwarded to MPI (where no product deemed affected.*
- *Status of all non-conformances identified*
- *All verification reports (provided as issued)*

Critical Non-Compliance – MPI Definition

Animal Products (Dairy Processing Specifications) Notice 2011

critical non-compliance *means an action, event or omission which may result in—*

(i) failure to follow the lawful direction of an Animal Products Officer;

(ii) an alleged offence against the Animal Products Act 1999;

(iii) a critical situation;

(iv) failure of a critical control point within a risk management programme or approved plan;

(v) failure to identify when dairy material or dairy product is non-conforming;

(vi) failure to stop a non-compliance;

(vii) failure to keep accurate and complete records;

(viii) failure to provide accurate, complete, and timely reports;

(ix) failure to dispose of non-conforming dairy material or dairy product in compliance with regulatory requirements;

(x) failure to prevent recurrence of a non-compliance; or

(xi) failure to rectify a non-compliance within the specified timeframe.

Critical Situation – MPI Definition

Animal Products (Dairy Processing Specifications) Notice 2011

Critical Situation *means any situation which, in the professional judgment of an Animal Products Officer, places public health, animal welfare, market access, official assurances, national good, or the credibility of MPI or the Director-General at risk, or where an offence is suspected.*

AsureQuality Procedures – Communications to MPI

Unacceptable Audit Outcomes

Defined review process involving the Lead Auditor, a Peer Reviewer and the Technical Manager (ultimate sign-off)

Critical Situations

Notified to MPI typically through the Technical Manager

Technical Queries - support

Through the Technical Manager or Technical Specialist

Exceptions and Product Dispositions

Verifiers interaction between operator and MPI

Exception Reports

Animal Products (Dairy Processing Specifications) Notice 2011, Section 5
DPC1: Animal Products (Dairy): Approved Criteria for General Dairy Processing, Section 7

Exceptions are to be reported for

- *Identification of non-conforming dairy material or product; or*
- *Occurrence of a Critical Non-Compliance*

Content of an exception report is detailed in DPC1

If a company has dispensation to notify by email rather than verbally but a response from the Accountable Person is still required within the 24 hour notification period, or they need to be contacted verbally.

Product Disposal Requests (PDs)

Animal Products (Dairy) Regulations 2005, Section 5
DPC1: Animal Products (Dairy): Approved Criteria for General Dairy Processing, Section 7
Animal Products (Disposal of Non-conforming Dairy Material or Dairy Product) Notice 2012

PDs outline what the RMP Operator wants to do with non-conforming product

May be approved by the RA if the criteria in the Animal Products (Disposal of Non-conforming Dairy Material or Dairy Product) Notice 2012 are met

Alternately need to be submitted to MPI with a recommendation from the RA supporting or not supporting the request.

Procedures for PDs

AsureQuality Procedures
Animal Products (Disposal of Non-conforming Dairy Material or Dairy Product) Notice 2012

Recognised Agency reviews the PD on receipt for accuracy and alignment with the exception report details (eg affected product)

A determination is made if it can be approved under the Animal Products (Disposal of Non-conforming Dairy Material or Dairy Product) Notice 2012. Due to the serious nature of the decision this is signed off by 2 Senior Verifiers

If it cannot be approved under the Notice, the PD and recommendation are sent to MPI

If the RA does not support the request this is required to be communicated to the RMP Operator before submitting the PD so that they have opportunity to address any concerns raised.

Follow-Up of Exporter Non-Conformances

Exporter Non-Conformances (ENCs) are reported to MPI directly from the Exporter

Where MPI consider that there has been a failure at the Premises of Manufacture or the Premises of Final Control they forward these to the Verifier for follow-up at verification audits.

MPI normally ask that we review the traceback and ensure the corrective actions are effective.

Monthly Reporting

Recognised Agencies are required to submit monthly reports to MPI

Details of all exceptions & PDs managed (including those not reported to MPI)

Status of all non-conformances

Management System activities

Reporting on demand…

Like RMP Operators, Recognised Agencies and Persons are also required to report on demand

i.e. provide requested information within a reasonable timeframe.

RMP Verifications – Export Premises

Animal Products (Export Verification Requirements) Notice 2011

Animal Products Export Verification Programme

Defined Frequencies

- *Performance Based Verification (PBV)*
- *Performance Steps assigned to each Site, defined audit intervals (verification period)*

Verification step	Verification interval
Step 00	To be determined by the Director (Compliance and Investigation)
Step 1	2 weeks
Step 2	1 month
Step 3	6 weeks
Step 4	2 months
Step 5	3 months
Step 6	6 months
Step 7	1 year
Step 8	5 years (20% of businesses within the business category each year)

Initial and Ceiling Frequencies

Animal Products Businesses have defined initial (starting) and ceiling frequencies

Animal product business	Initial Step	Ceiling Step
Primary processors of mammals and birds for human consumption	Step 2	Step 5
Secondary processors of mammals and birds for human consumption	Step 2	Step 5
Primary and secondary processors of seafood for human and animal consumption, including fishing vessels	Step 2	Step 6
Dairy material – farm dairy RMP and raw milk transport	Step 5	Step 7
Dairy transport RMP – processed product	Step 6	Step 7
All other processors of dairy product and dairy material for human consumption	Step 2	Step 5
All other processors of animal product for human consumption	Step 2	Step 5
Export stores	Step 2	Step 6

Audit Outcomes

At the conclusion of each verification an outcome needs to be assigned. This determines the next verification interval.

Acceptable

> ***An acceptable outcome**, where the verifier is satisfied that—*
>
> *(i) the operator is substantially complying with regulatory requirements; and*
>
> *(ii) where there have been any departures from requirements, the operator's corrective actions are appropriate and being applied effectively.*

Unacceptable

> ***An unacceptable outcome,** where the verifier has determined that the operator is not in substantial compliance with regulatory requirements.*

Changes in Verification Frequencies

One Unacceptable Audit = Down, More than One Acceptable Audit = Up (to ceiling)

Verification Step	Number of consecutive acceptable outcomes required to move to a higher step when no full-time verification agency supervision is present	Number of unacceptable outcomes to move to a lower step
1	3 (move to step 2)	1 (Move to step 00)
2	3 (move to step 3)	1 (move to step 1)
3	2 (move to step 4)	1 (move to step 2)
4	2 (move to step 5)	1 (move to step 3)
5	2 (move to step 6)	1 (move to step 4)
6	2 (move to step 7)	1 (move to step 5)
7	2 (move to step 8)	1 (move to step 6)
8	—	1 (move to step 7)

Verification Audits

There are different types of audits to introduce 'randomness' into the verification process

Scheduled Audits

Audits that are notified and occur at or near the end of the verification period

Unscheduled Audits

Audits that are notified but occur at an earlier time in the verification period

Don't change the date for the next scheduled audit

1 in 5 audits is Unscheduled

Unannounced Audits

Audits that are notified not more than 48 hours prior to the audit

Type of Unscheduled Audit, 1 in 2 Unscheduled Audits are Unannounced

Effectively 1 in 10 Audits are Unannounced

Scope of Verification Audits - Manufacturing

Each Audit Elements; completed each Verification

- *Operator Verification, RMP Scope, Management of Corrective Actions, Records and Documents*
- *Management of Processing Environment*
- *Control of Critical Control Points*
- *Management of Reporting and Non-Conforming Product (includes Exceptions, PDs, Complaints…)*
- *Management of Product Eligibility (includes OMARs, SORs, ROMEs…)*

Annual Elements; completed once each Season

- *Pest Management & External Environment*
- *Pathogen Management*
- *Water Management*
- *Product Labelling and Traceability*
- *Manufacturing Systems*
- *Heat Treatment*
- *On Site Services & Utilities*
- *RORP*
- *Training*
- *Specification Development and Implementation and Product Testing*

Scope of Verification Audits - Stores

Each Audit Elements; completed each Verification

- *Operator Verification, RMP Scope, Management of Corrective Actions, Records and Documents*
- *Management of Processing Environment*
- *Management of Reporting and Non-Conforming Product (includes Exceptions, PDs, Complaints…)*
- *Management of Product Eligibility (includes OMARs, SORs, ROMEs…)*

Annual Elements; completed once each year - typically

- *Pest Management & External Environment*
- *Product Traceability, Acceptance and Dispatch Systems*
- *Premises and Equipment Hygiene, Maintenance and Calibration*
- *Container Loadouts and Control of Security Devices *unless sending to EU = each audit*
- *Risk Organism Response Programme*
- *Training*

AsureQuality Procedures

Timetable and Audit Scope [entry and exit meetings]

Site Report with NCs, Observations

Audit outcome

Unacceptable outcomes need to be approved by the Technical Manager

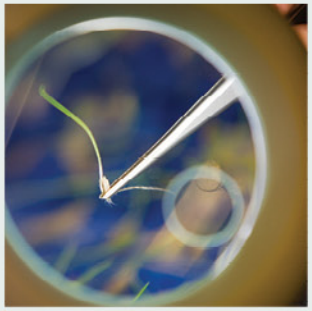
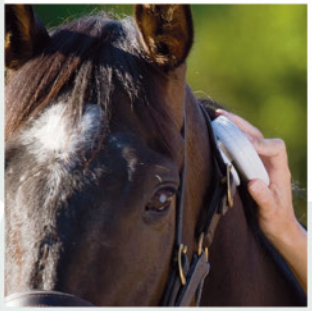
Full report is provided

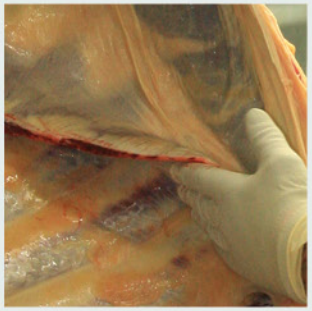
10 working days of the conclusion of the audit

Management of non-conformances

Escalation Processes

Complaints and Appeals Processes



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