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Dairy Manufacturing

A Review of the Food Safety Regulatory System for Large Dairy Manufacturers

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Disclaimer

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1 Foreword

Given the significance of New Zealand's dairy export industry, and the risk to human health and trade in the event of a regulatory failure, in late 2019 I selected dairy manufacturing as the focus for my first regulatory review. With the agreement of the Director-General, I chose to narrow this review to the regulation of large manufacturers who are responsible for producing the bulk of New Zealand's dairy product exports.

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The role of Inspector General Regulatory Systems – Kaitirotiro Matua Pūnaha Waeture, Ministry for Primary Industries – Manatū Ahu Matua was established in June 2019 as part of the Strengthening Accountabilities change within MPI. I was appointed by the Director-General of MPI late in 2019, with a mandate to establish the Office and commence a programme of regulatory review work over MPI's regulatory systems.

Covid-19 caused some delay in finalising the review and consequently this report. I especially thank those who gave time and shared considerable expertise to explain the evolution and operation of the regulatory system for dairy manufacturing. Overall, I found engagement constructive and helpful, and the significant contributions aided immensely in characterising the operation of this system.

I am pleased to now present this report on the *Food Safety Regulatory System for Large Dairy Manufacturers in New Zealand*.

This report is intended to provide a high-level overview of the key themes which emerged over the course of my review. It reflects a point-in-time review into how MPI undertakes its regulatory obligations in respect of dairy manufacturing, in particular for large operators.

2 Executive summary

Dairy manufacturing is one of New Zealand's largest volume and value areas for primary sector exports. Dairy exports for the year to June 2019 were worth over $18 billion. As at 2019, there were approximately 50 large export focused dairy processing plants operating in New Zealand. Fonterra own more than 30, with the remainder owned by 12 other companies.

2.1 Background

In large part, the export success of the dairy sector is attributed to the reputation for quality of New Zealand dairy products, and the recognition by trading partners that New Zealand has credible regulatory systems that deliver safe food and can meet import requirements. New Zealand's management of food safety and suitability risks is dependent on effective regulation by MPI and its verifiers, and strong quality and risk management by operators.

Alongside consistent delivery of safe and suitable food products, New Zealand's export success is dependent on satisfying trading partner import requirements. New Zealand has experienced success in achieving market access as favourable, or better than, competitor countries through advancement and adherence to international risk management principles, standards and guidelines. This is supported by efforts to nurture trusted technical relationships across borders, and recognition of MPI's technical competency as a world leader in systems innovation and standards development.

The animal products regulatory system is designed, and operates, to ensure food safety outcomes are achieved in a way that best facilitates trade, including meeting New Zealand's international (treaty) obligations.

When these regulation and quality management practices are challenged, as happened in August 2013, with a false detection of *Clostridium botulinum* in whey protein concentrate (the WPC 80 incident), the trade, economic and reputation impacts can be significant and long lasting.

In November 2019, the Inspector General Regulatory Systems commenced a proactive review on the performance of aspects of the regulatory system for dairy manufacturing food safety. The review was not prompted by any significant or specific concerns about the way in which the system was working but recognised the significance of the dairy export trade for New Zealand. This report sets out the findings of the review.

The Inspector General interviewed key people responsible for managing the regulatory system, including MPI staff, third parties like AsureQuality and Eurofins, and dairy plant operators and other industry representatives including key people from Fonterra Co-Operative Group (Fonterra), Tatua Dairy Company (Tatua), Dairy Companies Association of New Zealand (DCANZ) and others, to gain an understanding of how the system and its components operate. Our thanks go to these people for generously providing their time and expertise. We appreciated the candour and support during our enquiries.

This review considered MPI's approach to the regulatory design, monitoring, oversight and reporting of the dairy manufacturing food safety system. It looked at how the system manages existing and emerging risks, and how the Director-General, Senior Leadership Team, and Deputy Director-Generals responsible for system components, like the operational activity, compliance and policy development, gain confidence that regulatory risks are being recognised and effectively managed.

The scope of this regulatory review focused on the manufacture of dairy products by New Zealand's largest dairy manufacturers. This scope was selected on the basis that these companies are responsible for the majority of dairy production and related export revenue. Their products are consumed by millions of consumers globally, and New Zealand's export success depends on the confidence trading partners have in the ability of New Zealand's regulatory systems to consistently meet import requirements, in addition to ensuring the safety and suitability of those products.

Consideration was given to what contributes to an effective regulatory system. The review considered the dairy manufacturing system against nine key components[1] which we used as a framework to assess this effectiveness:

- **Effective regulatory strategy** – having a strategy that sets out the key elements of how the agency/regulator will undertake its regulatory role, what its operating model consists of, its approach to regulatory decision making, compliance and enforcement, service delivery, and continual improvement. Critically, it should also consider environmental and global change, and be able to be adapted to meet changing requirements and expectations.
- **Effective governance and accountability** – having well defined system leadership, governance arrangements and systems supported by clear objectives and outcomes. Governance should consider strategy, risks and operational performance, as well as determining shifts in expectations and guiding changes in government policy.
- **Fitting culture and leadership** – an effectively promoted and maintained culture, driven by people who are motivated, engaged and invested in the system's purpose and outcomes, committed to sharing learnings, making changes and exploring emerging strategic issues and risks.

1 These components are loosely based on the Martin Jenkins review of NZTA regulatory systems for vehicle registration and warranting checks.

- **Effective supporting structure which clearly designates roles and responsibilities** – having a structure that best allows the application of transparent, consistent and risk-based approaches to regulatory decision making, and effective delivery of front-line services.
- **People and resources with the right capability and capacity** – people working in and on the system who have the right capabilities, skills and diversity to achieve the system's enduring purpose and the effective functioning of the system, as well as to identify and manage risk.
- **Operational practices and processes for effective regulatory delivery activities** – practices that deliver value to stakeholders and New Zealanders, make use of effective system design, allow continuous improvement and innovation, and allow ease of business for regulated parties.
- **Effective technology** – technology systems that allow the agency to deliver its services optimally and effectively, that provide accessible and timely information for decision making, and that make regulated parties' experience as simple and straightforward as possible.
- **Processes for analysis and insights over regulatory systems design and operation** – using insights, information and knowledge to inform system improvement strategies, identify emerging risks and opportunities, and anticipate change.
- **Assurance over how regulatory systems operate** – having regular and systematic monitoring and evaluation routines that help assess the ongoing performance and condition of the regulatory system and the environment within which it operates.

The review of the dairy manufacturing food safety regulatory system sought to consider:

1. how the system is meeting the object of relevant legislation (Section 5);
2. the effectiveness of monitoring, oversight and reporting (Section 6); and
3. how system improvement is achieved (Section 8).

The report comments further on these three elements below.

The review also considered how the responsibilities of the Minister and the Director-General are defined in relation to the Animal Products Act 1999 (Animal Products Act) and Food Act 2014 (Food Act) and how these are delegated to MPI staff.

2.2 Statement of limitations

Our description and assessment of MPI's dairy manufacturing regulatory system is based on information obtained through a desktop literature review and interviews with relevant staff, and various stakeholders and industry. The insights gained through this work are referenced to regulatory good practice.

This review addresses a variety of significant system operating issues and concerns, drawing on the information available to the Inspector General. While the review has attempted to cover key system elements, it does not, and was not designed to, capture all issues and concerns. Accordingly, the review is a snapshot in time of the high-level operation of MPI's operation of the food safety regulatory system for large scale dairy manufacturing.

2.3 Findings of review

Overall, the food safety regulatory system for dairy manufacturing remains effective and fit for purpose. The system continues to achieve the object of the Animal Products Act. It is internationally well regarded and is generally well placed to maintain and grow New Zealand's dairy export sector.

MPI has the core components of an effective food safety regulatory system for dairy manufacturing in place. To support continuous improvement, there are elements of the system that MPI could nonetheless consider enhancing. These include:

- **Regulatory design**: regulatory design practices that reduce complexity, cope with change in a timely and effective manner, and meet the needs of operators;
- **Governance and accountability**: governance structures that drive cross-system coordination in the absence of a single system owner, encourage effective risk management, and provide oversight of effectiveness, efficiency, and continuous improvement;
- **Verification**: a robust verification model that reinforces the independence and quality of verification of operator Risk Management Programmes (RMPs);
- **Assurance**: enhanced visibility of system performance to support system-wide improvement;
- **Resources**: maintain the required expertise and technology to optimise the operation of the system; and
- **Data, information and analysis**: better management and use of data, information and analysis to inform system operation and improvement.

Insightful and well informed governance drives good regulatory performance. Given the size and importance to New Zealand of the dairy industry, there is an opportunity to establish stronger governance mechanisms that have end to end oversight of the dairy regulatory system.

Appropriate internal, independent and sector governance expertise that supports consideration of sector specific risks, assurance mechanisms, regulatory outcomes, and service delivery is critical to an effective regulatory system.

This would also work to augment connections across the dispersed regulatory system components, and encourage an improved collective forward facing strategy for food safety in dairy manufacturing in New Zealand.

2.4 How the object of legislation is being met

Dealing with challenges and change

New Zealand's largest dairy manufacturers predominantly focus on producing for the export market. The key legislation setting out the requirements that they need to meet for export of their products is the Animal Products Act. The focus of this review has been on how the object of the Animal Products Act is being met.

The review considered how the Food Act applies to the export dairy manufacturing sector.

The interaction of the Food Act and Animal Products Act adds a layer of complexity to the regulation that applies to dairy manufacturing. Section 6 of the Food Act sets out the relationship between the Food Act and Animal Products Act. Broadly it recognises the general equivalence of their respective food safety regimes. The Food Act still applies to animal products processed under the Animal Products Act, which are foods. To address the overlapping requirements, a number of exemptions to Food Act requirements apply where the Animal Product Act prevails.

The legislative outcomes of the Animal Products Act and the associated regulations and notices that underpin the regulatory approach are still largely meeting the desired objects articulated by Cabinet in the 1990s when the legislation was passed. These were:

- managing risks to human health;
- ensuring food is fit for purpose; and
- facilitating entry of products into overseas markets.

Continuing to achieve these aims into the future comes with challenges. Regulators must actively and continuously consider whether the design of a regulatory system remains effective and capable of delivering the intended outcomes under ever changing circumstances. There are challenges in making significant change in the regulatory system for dairy manufacturing due to the need to maintain existing recognition by trading partners of MPI's official assurances for dairy product exports. The current system has evolved to provide the assurances overseas markets require and therefore, fundamental change could undermine these arrangements, which are the foundation on which New Zealand's market access and trade relations depend. For this reason, among others, there is a natural hesitancy to fundamentally alter the systems.

Some regulatory change has occurred since the Animal Products Act was enacted in 1999. Most recently, on March 2018 the Food Safety Law Reform Act 2018 (Food Safety Law Reform Act) was passed into law. This introduced significant changes to the regulatory environment for safe and suitable food. Amongst the aims of this Act are the desire to strengthen RMP requirements, traceability and recalls requirements, and enhancing compliance and enforcement tools for animal and other food products. An important element in this process is the development of the regulations and notices required to implement these changes. Currently the Regulatory Redesign project to complete this is on track to do this by the statutory deadline of March 2022. Meeting this deadline is important because after this date the current legal instruments will no longer be valid.

Concerns over the complexity of regulations and requirements

MPI's regulatory strategy aims to put "customers at the centre". However, operators and wider industry stakeholders report that some of the regulations and rules are complex and difficult to follow. Industry also reports that various technical requirements demanded by importing countries and captured in overseas market access requirements (OMARs) are difficult to interpret. MPI does, however, consult with industry on regulatory design, through projects like the Regulatory Redesign programme for animal products manufacture.

MPI's regulatory system has a dispersed set of accountabilities

MPI, as regulator, faces challenges because of the way in which the regulatory functional structure has evolved over the last eight years. MPI uses a matrix system for regulatory system management: while the Deputy Director-General of New Zealand Food Safety holds responsibility and accountability for regulatory implementation of the Animal Products Act, other components of the regulatory system, such as policy development and legislative design, compliance and enforcement, intelligence and planning, market access and trade, and response and readiness sit within other parts of MPI's wider business structure and serve multiple systems.

The dispersed structure can have advantages, however it can mean that the business units and agency functions that hold responsibility for system components (Policy and Trade for legislative design and review, New Zealand Food Safety for regulatory implementation and performance oversight, Compliance and Governance for compliance enforcement action, and Biosecurity New Zealand for Intelligence and Planning, and Readiness and Response), must collaborate effectively to ensure the effective functioning of the entire primary sector regulatory system. This collaboration is essential to effectively deliver the object of the Animal Products Act which requires MPI to "minimise and manage risks to human or animal health arising from the production and processing of animal material and products by instituting measures that ensure so far as is practicable that all traded animal products are fit for their intended purpose, [and at the same time,] facilitate the entry of animal material and products into overseas markets by providing the controls and mechanisms needed to give and to safeguard official assurances for entry into those markets."[2]

Beyond the Director-General, overall single accountability for the system is challenging due to components of the dairy manufacturing regulatory system being dispersed. Effective and continuous feedback between MPI's dispersed regulatory system components is, therefore, not only essential for day to day operations, but critical to ensuring continuous improvement and that the whole of system is meeting the requirements of the changing wider environment. The responsiveness of the overall regulatory system relies upon clear accountabilities and agreed levels of service between those responsible for the dispersed system components. This is an area deserving of strengthening.

How the third party verification model operates

Verification of RMPs for dairy manufacturing processing plants is an important element in ensuring that the intentions of the relevant legislation are being met by operators. The model in place since the legislation was passed in 1999 provides for verification services to be offered by third party verifiers, like AsureQuality and Eurofins, directly to operators under a user pays model. MPI monitors and oversees these verifiers. An internal review of the third party verification model was undertaken in 2017-18 to consider the

2 Animal Products Act 1999, http://www.legislation.govt.nz/act/public/1999/0093/latest/whole.html#DLM33510

policy settings of the verification model for dairy manufacturing. This provided a preliminary view to a group of MPI Food Directors, however, did not result in substantive changes to the way the model operated.

Questions have been raised over the years about the third party verifier model. Key challenges include:

- **Operator pays for the verifier**: there is potential for verifier conflicts of interest and capture due to verifiers (recognised agencies) being contracted and paid directly by the dairy manufacturer to verify RMP requirements are being met. Trading partner competent authorities accept the use of third party service providers on the grounds that MPI has strong oversight and verifiers are accredited to internationally recognised standards. However, the model is unique to New Zealand and would be undermined if inappropriate verifier behaviour was identified. To mitigate this risk while maintaining the principle of third party verification, MPI could contract third party verifiers and then on-charge operators for the cost of services provided. However, such a centralised approach would come with additional costs.
- **Contestability**: there is limited competition amongst recognised agency verifiers of dairy manufacturing operations, which is often attributed to the relatively small size of the New Zealand market and the size of our largest dairy company. There are two main providers of these services for dairy manufacturing in New Zealand – AsureQuality and Eurofins – with MPI Verification Services acting as verifier of last resort. AsureQuality undertakes the majority of verification services, including for New Zealand's largest dairy processing company. This has the potential to increase the cost of services, while increasing the need for MPI to exercise greater oversight of registered agencies and persons providing verification services to ensure the quality of those services.
- **Frequency of verifier visits and checks**: MPI sets the rules for the frequency of verifier visits based upon a well established, stepped performance-based verification (PBV) process. For dairy manufacturing, the PBV process works in such a way that processing plants that pass their checks and are considered well run may only be subject to a verification once every month to three months. This risk management framework sees the level of oversight adjusted according to compliance risk.
- **Scope of verifier visits**: the scope of verifier visits can be constrained by the time available during a check. Not every element of processing plant activity can be covered in a single visit. Further, only one in four visits are required to be unannounced. Operators could ensure that on the day(s) of announced visits, site staff are prepared for verifier checks. Operators can also employ independent consultants to check processes and practices, and resolve potential issues, prior to verifier visits.

MPI needs to monitor the integrity of the model in terms of independence, capability and capacity of third party verifiers, and the frequency and effectiveness of verifier visits.

2.5 Monitoring oversight and reporting

There are benefits to be derived from greater monitoring and oversight of the dairy regulatory system

Monitoring, oversight, and reporting are central to ensuring that the food safety system, including within it, the dairy manufacturing system, is operationally robust and effective, and meeting the object of the Acts. Monitoring and reporting on the effectiveness of regulatory interventions, including risk management programmes, chemical and microbiological controls and practices for food safety to ensure regulatory thresholds are not breached, helps maintain the confidence that New Zealand's trading partners have in New Zealand's food safety system and export assurances it can generate.

MPI's framework for monitoring and oversight of the regulatory system for dairy manufacturing has some key components that, when working well, can provide real value. Part of governance responsibility is to regularly stress-test performance to ensure that it has the right resources (people, processes, technology) to achieve the outcomes required of the regulatory system. Development of measures to assess the performance of the regulatory system could be introduced, and end to end evaluation undertaken from time to time.

Governance of the food safety regulatory system (including for dairy manufacturing) could be enhanced

The Senior Leadership Team as the senior governance body responsible for high-level strategic direction and performance and risk monitoring across all of MPI's regulatory systems, has a role in governance oversight of food safety and, therefore, of dairy manufacturing. However, given the size of MPI's regulatory mandate (approximately 60 primary acts of legislation, and numerous regulations and notices to support), the Senior Leadership Team must necessarily prioritise and delegate aspects of its oversight activity.

In order to support Senior Leadership Team's oversight of the food safety system, the Food Safety Steering Group (FSSG) was established to replace the Food Safety Systems Board in June 2019 and met quarterly up until December 2019. While meetings have not occurred since then due to Covid-19, the New Zealand Food Safety Leadership Team has, in the interim been across governance or management issues.

The FSSG had incorporated some good governance principles by including membership from MPI's regulatory system component representatives (e.g. from New Zealand Food Safety, Compliance, Internal Audit, Policy and Trade, Business Technology Information Systems) as members of this Group. However, the FSSG receives limited reporting on the performance of specific regulatory systems, and emerging sector risks or issues, other than the wider emerging food safety risks or specific issues as they arise.

Processes could be introduced to provide enhanced reporting and feedback on the operation of the food system, including dairy, to senior management within FSSG, and upwards to Senior Leadership Team.

Within the food safety system, risks and issues judged by managers to be "business as usual" are not generally escalated to Deputy Director-Generals or, therefore, to Senior Leadership Team. This

is generally appropriate if good judgement is exercised about what and when risks and issues should be escalated. This is the intention of delegating responsibilities and authorities to Deputy Director-Generals and managers. However, this means that Senior Leadership Team and the Steering Group are generally only informed of significant food safety issues, where escalation may be unavoidable. Responsibilities for risk oversight would operate well in a governance forum, which had oversight of the food safety regulatory system.

External groups like the Dairy Products Safety Advisory Council and Food Safety Assurance Advisory Council could play more of a role in oversight of the system

The Food Safety Assurance Advisory Council (FSAAC) was set up in late 2014, in response to the WPC incident. It meets quarterly. FSAAC is tasked with providing MPI with "high quality, independent, strategic advice on how to ensure New Zealand's world-class food safety and assurance system is maintained and enhanced." While these FSAAC advisory functions remain relevant, the FSAAC members did acknowledge at the 30 August 2019 meeting that the "terms of reference may not be representative of the current purpose of the Council".

Since August 2019, due to the impact of Covid-19, FSAAC has met twice (December 2019 and June 2020). Only meeting quarterly does make it challenging for members to fully undertake their duties in any meaningful way and to gain the knowledge to be best placed to provide the advice that MPI requires on food and assurance systems.

The FSAAC noted at the December 2019 meeting that it needs to build its knowledge and understanding of specific topics and develop a work plan that added real value.

The Dairy Products Safety Advisory Council was established in 1999 to promote communication between MPI and industry and assist in developing standards and policies. The council plays a useful role in promoting engagement, and supports continuous improvement, including through establishment of working groups to address specific regulatory issues.

Greater use could be made of information to deliver effective insights for managing performance and supporting continuous improvement

Processes for providing analysis and insights are fundamental tools for managing regulatory systems. The use of data, information, and knowledge helps to inform system improvement strategies, identify emerging risks and opportunities, and to anticipate change. Having effective information and intelligence gathering mechanisms to identify regulatory risks and issues helps to signpost when regulation settings may need revision.

To support this, MPI has an opportunity to develop a formal approach to collecting, collating and sharing insights and information across the dispersed accountabilities. While privacy issues always require careful consideration and management, the use of data and information driven insights is a key pathway to regulatory flexibility and improvement, and supports operational decision making as well as stakeholder engagement.

Front line staff involved in compliance, monitoring, assurance and oversight activity continuously receive data and information that could provide insights on issues and concerns of the day, through their interactions with operators and other stakeholders. This data and information is captured for various purposes, and housed across multiple independent data systems (from Excel to legacy databases). Verification Services, Compliance, Food and Live Animal Assurance, Border Control staff and Systems Audit teams all receive rich information on the performance of aspects of the regulatory system. The development of standardised MPI-wide data and information capture, grooming and use protocols, plus interoperable storage systems could support better risk and issue trend mapping, and highlight regulatory matters requiring attention. However, careful consideration of return on investment would be necessary.

The Food Safety Strategy Action Plan 2020-23 has initiated a data insights team that will focus on integrating data and identifying key trends and findings to drive improvement. It also proposes developing an emerging food safety risks (or early warning system) function to provide stronger direction and coordination over new hazards. These are sound actions that can be expected to support regulatory improvement through data and information driven insights.

Food safety compliance activity requires a range of parties from within MPI and across industry to play a role

Compliance and enforcement activity is a key element of any regulatory system. MPI has long applied the Voluntary, Assisted, Directed and Enforced (VADE) model to compliance and enforcement activities, a variation of the Braithwaite model. The VADE approach supports MPI to take a scalable approach to the enforcement of regulatory compliance issues and recognises that a risk-based system can assist with prioritisation of precious resource.

Accountability for compliance rests with various MPI business units, directorates and teams. Day-to-day compliance with regulation falls to teams in the Assurance, Food Regulation, and Science and Risk Assessment directorates within New Zealand Food Safety. Other compliance and enforcement activities are undertaken by different teams within, but not limited to, the Compliance Services Directorate in Compliance and Governance.

The regulatory system for dairy manufacturing requires a range of internal and external parties to play a role in compliance activity, including:

- granting approvals and recognition of verifiers, laboratories, operator risk management programmes and export assurances (compliance through licensing and registration functions);
- monitoring and auditing the performance of verifiers and operators (compliance through verification, audit and inspection assurance oversight functions);
- undertaking compliance, surveillance and enforcement activities, including investigation and prosecution, to identify and remedy non-compliance issues.

The Food Act and Animal Products Act place responsibility on dairy operators to comply with relevant regulation, recognised verifiers provide oversight of operator compliance, including the resolution of non-compliances. All export non-compliances are reported to

MPI's Food and Live Animal Assurance Team in New Zealand Food Safety for review.

MPI has a Food Compliance Team, in Compliance and Governance, which becomes involved when product recalls are required, or potential serious offending is identified. At present the approach of the Food Compliance Team is generally reactive, however, with the additional resourcing provided for food compliance in the 2019 Budget, increased proactive work is expected in the future.

A more proactive food safety compliance strategy

Currently, the Food Compliance Team uses a risk-based, graduated and proportionate approach to compliance and enforcement, whether Food Act or Animal Product Act related. This approach supports a food safety culture that encourages operator compliance and effectively intervenes to address non-compliance where it occurs. The approach also provides for resources to be prioritised according to risk. Priority is given to serious issues where there is an imminent risk to public health or actual or potential threat to New Zealand's trade reputation, or an incident that would violate the fundamental basis of the regulatory regime or situations of intense public interest.

MPI has acknowledged that it would benefit from a compliance strategy to guide the range of activities that fall within the broad understanding of the concept of food safety compliance. This will provide a useful mechanism from which to assess compliance and enforcement performance.

The Compliance Oversight Group (COG) noted at its 17 March 2020 meeting that the "development of a MPI Compliance Strategy will need to be clear about what type of compliance is desired and what this looks like including which sectors, standards, foods etc. should be the focus, as well as which are the appropriate tools to fix the 'problem'."

Regulatory stewardship activity could be further enhanced

A regulatory system is a set of formal and informal rules, norms and sanctions, given effect through the actions and practices of designated actors, that work together to shape people's behaviour or interactions in pursuit of a broad goal or outcome.[3]

"Regulatory stewardship is a responsibility of government regulatory agencies. It involves them adopting a whole-of-system, lifecycle view of regulation, and taking a proactive, collaborative approach, to the monitoring and care of the regulatory system(s) within which they have policy or operational responsibilities."[4]

Regulatory system stewardship requirements are designed to ensure that New Zealand has a durable and effective system of high quality regulation. It is incumbent on agencies to proactively identify and manage any risks to administration of regulatory systems. Regulatory stewardship activities like regulatory system reviews play an important role in this.

In MPI, there are a range of parties that have a specific interest and involvement in elements of regulatory stewardship type activity, most prominently the Policy and Trade Regulatory Stewardship Team, Inspector General Regulatory Systems and Legal Services. Opportunity exists for these groups and other teams within MPI to collaborate to further the regulatory expertise and focus within MPI.

The Regulatory Stewardship Team was instituted to undertake the government-required regulatory health assessments of the regulatory systems under MPI administration.

Regulatory thought leadership, research on good regulatory practices, and deeper proactive regulatory audits or reviews have traditionally been the responsibility of the Deputy Director-Generals responsible for system components. More recently, reviews of third parties have started to be undertaken by the Legal Services Team.

MPI and its predecessor agencies have had some form of systems audit function since the early 1990s. This function was set up with the desire to stimulate improvement in the organisation's regulatory oversight and verification practices. The current Systems Audit Team in New Zealand Food Safety has a complement of 13 FTE and a manager, and reports to the Director Assurance, with the ability to autonomously report to the head of New Zealand Food Safety for independence purposes.

Through its work across these core functions, the Systems Audit Team can provide vital insights into dairy manufacturing processes. However, because the team works across all food production systems, the resources devoted specifically to dairy manufacturing is limited.

It is important to note that Systems Audit Team is not tasked with providing an holistic, end-to-end view of the performance of the food safety regulatory system.

An end-to-end view is, however, required to stimulate effective continuous improvement and to this end, MPI has recently commissioned an internal review of the food safety regulatory system.

2.6 Tracing, and readiness and response

Tracing, recall and contingency planning activities are important

In spite of best efforts, food safety problems are inevitable. The first step in putting things right is the identification and removal of all affected items from the food chain. Simple and straightforward food recalls are something that MPI deals with on a regular basis. Food recalls are normally managed by New Zealand Food Safety and the Food Compliance Team. However, more complex and significant events which could entail the removal of a whole production line from a processing plant, or an entire product range from the supply chain, require more sophisticated and organised systems of tracing, recall and contingency planning.

Dairy manufacturing food safety readiness and response activity could be increased

Many of the activities that support food safety readiness and response, including decisions on when to stand up a formal food

3 Government Expectations for Good Regulatory Practice, The Treasury, April 2017, https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf

4 Treasury, https://www.treasury.govt.nz/information-and-services/regulation/regulatory-stewardship#:~:text=Regulatory%20stewardship%20is%20a%20responsibility,have%20policy%20or%20operational%20responsibilities

safety response are the responsibility of New Zealand Food Safety. New Zealand Food Safety handles day to day food safety issues and incidents, including food recalls, although it does not have a dedicated readiness and response team. Activities that form part of a typical response are managed by the Food and Live Animal Assurance Team, Food Compliance Team, Market Access and other relevant parts of MPI. New Zealand Food Safety has recognised the need to undertake response preparedness, and that there is an absence of set criteria for identifying when to move to formal response.

To undertake these formal responses, MPI has a centralised readiness and response capability in Biosecurity New Zealand. This capability sits in the Readiness and Response Directorate, and brings together critical expertise to effectively prepare for and manage responses, and to coordinate recovery and long-term management activities across MPI including New Zealand Food Safety.

Much of Readiness and Response Services' focus and time has been on Biosecurity related response and readiness activity. However, this directorate is intended to provide services across MPI, including biosecurity, trade, food safety and primary production. There are trade-offs that this shared portfolio must make in prioritising the focus of its work and resources.

An important element of preparedness and readiness is simulation and practice exercises. There has been a limited focus on food safety response simulation exercises in recent years, which has been acknowledged. Exercise Ariadne was run with Fonterra in 2016 and focused on traceability in the event of food contamination. This was prompted from recommendations from the WPC80 incident. There have been no food related exercises since, although a food safety scenario (Simulation Wight) was piloted in May 2018 and is subject to review in 2020.

In December 2019 the Food Safety Steering Group discussed the need for a renewed focus on food safety related readiness and response. Therefore prior to the Covid-19 outbreak, the MPI Readiness and Response Directorate and New Zealand Food Safety began work to enhance food safety readiness activity.

There is more that could be done, which has been recognised in the recent work of the Director Food Safety Regulatory System Review who has helped to identify areas for increased funding.

Dairy product tracing is constrained by technology limitations

Rapid and effective product tracing is well understood to be a core component of a robust and credible food safety system. While responsibility for product tracing sits with operators, MPI as the regulator needs to be able to compile product tracing information in any significant export related response situation. The system that MPI uses for dairy product tracing, animal product electronic certification system (AP E-cert), is limited to products for export to markets that require official assurances, and largely depends on manual collation and analysis.

A key element of any food safety response is the ability to quickly trace and recall product. Responsibility for product traceability, as with food safety generally, sits with manufacturers and operators of risk management programmes. Under the Animal Products Act, MPI through New Zealand Food Safety is responsible for checking that manufacturers have the required ability to recall animal material and products for export or domestic sale, where a product may not be fit for intended purpose or in accordance with its labelling.

Operators mostly take a one up, one down approach to meeting their tracing and recall responsibilities. This means they can identify where a product was received from (one up) and where any of that product is then sent (one down). This is a reasonable approach. However, in the event of a response, it means that some dairy manufacturers will likely only be able to provide MPI with incomplete information on ingredient origin, or final product destination due to the complexity of supply chains.

During the 2013 WPC incident, the recall of the potentially affected product was a manual process with data gathered by the tracing team and then mapped by the National Intelligence Team. Since WPC80, this process has remained largely manual, although tracing data for exported product is able to be extracted from MPI's AP E-cert for all infant formula and formulated supplementary food for young children exports[5], to markets other than Australia, as well as other dairy products that require an official assurance.

2.7 How systems improvement is achieved

Continuous system improvement is dependent upon a number of factors

With any regulatory system, the ability to continuously improve the system is dependent on a number of factors; it requires the regulator and service delivery agencies involved to have the right structures, mechanisms, processes and capabilities in place to stimulate and facilitate change.

Importantly it also needs the right mix of monitoring, oversight and reporting around system quality assurance, system performance and system review activity to ensure system decision makers are provided with timely feedback, information on emerging risks and changes in policy to prompt change and improvement. The structures, mechanisms, processes and capabilities required for continuous systems improvement include:

- Effective regulatory design
- Effective governance and management
- Resourcing – capacity and capability
- Data, information, analysis and insights to improve systems design and operation
- Performance management
- Assurance over how regulatory systems operate.

Tools and end-to-end dairy manufacturing expertise in New Zealand Food Safety

We had reports from plant operators, verifiers, and industry-good bodies that technical expertise in dairy manufacturing is constrained in New Zealand. For MPI, there is a balance between administering efficient regulatory systems, and providing responsive guidance and advice to operators where new products and innovations are being developed. The Animal Products Dairy Team provides critical technical expertise to support the operation of the system. They are strong contributors to stakeholder engagement and are heavily invested in the regulatory redesign

5 Animal Products (Export Requirements for Infant Formula Products and Formulated Supplementary Food for Young Children) Notice 01 Feb 2016

currently underway. Funding for these roles is cost recovered from industry, and fees and levies are required to be reviewed every three years. Costs recovered are tied directly to the delivery of government services that support the industry.

While a constant challenge, recruiting and retaining people with technical dairy experience and expertise is integral to system improvement and performance.

The food safety regulatory system for dairy production supports New Zealand's highest value primary products exports sector. Proactive improvement of the regulatory system can always be achieved faster and more efficiently with more qualified staff, however critical to the regulatory outcomes will be obtaining access to more dedicated information, data and analysis. Investment in technology tools to facilitate this, along with the expertise to analyse, interpret and present insights would inform a more responsive regulatory environment.

Performance management and measurement could have a focus on systems improvement

Management and measurement of the performance of the food safety regulatory system for dairy manufacturing plays an important part in helping to deliver continuous improvement.

Greater insights could be gained from performance measurement of the food safety system regulatory practices in dairy manufacturing. There are pockets of performance management across food safety activities, including:

- Food Safety related performance measures – this includes a suite of measures designed to cover both external reporting requirements and the requirements of the business to measure its own performance in delivering both strategic and operational outcomes and outputs (a wide food safety view).
- Reports on elements of dairy sector performance for the Dairy Products Safety Advisory Council (DPSAC). This is a series of quarterly reports which provide an overview of performance-based verification, critical exceptions and dairy non-export conformances.

While these contribute to measuring the performance of the wider food safety system, there could be specific focus placed on the performance of system elements and associated practices.

MPI's ongoing performance management of the dairy manufacturing regulatory system tends toward being responsive, rather than proactive. MPI would benefit from setting some performance indicators (lead and lag) to help to discern the health of the regulatory system.

3 Introduction

Dairy manufacturing is New Zealand's largest value primary sector export. Dairy exports for the year to June 2019 were worth in excess of $18 billion.

The success of this export sector is attributed to the continued reputation that New Zealand has for being a trusted provider of safe and suitable food products. This reputation for world class management of food safety and suitability risks has been hard won and is dependent on effective regulation by MPI and strong quality management by operators.

When these regulation and quality management practices are challenged, as happened in August 2013 with a false detection of *Clostridium botulinum* in whey protein concentrate, the trade, economic reputation and impacts for New Zealand can be significant.

In November 2019, the Inspector General Regulatory Systems initiated a proactive review on the performance of aspects of the regulatory system for dairy manufacturing food safety. The request was not prompted by any specific concerns about the way in which the system was working. This report sets out the findings of the Inspector General Regulatory Systems work.

3.1 Objectives

The agreed objectives of the review of the dairy manufacturing food safety regulatory system were to:

- understand the system components;
- consider whether the system is meeting the intended outcomes of relevant legislation;
- consider the effectiveness of oversight, monitoring and reporting;
- consider how clearly defined are the responsibilities of the Director-General, and how these are delegated; and
- consider how system improvement is achieved.

3.2 Scope

The scope of the work included MPI's approach to regulatory design, monitoring, oversight and reporting of the dairy manufacturing food safety system. It also looked at how existing and emerging risks related to this system are managed and escalated, and how the Director-General, and the Senior Leadership Team gains confidence about the management of these regulatory risks.

This review looked at the regulated activities for the processing of milk and ingredients into market-ready manufactured products by the largest dairy manufacturing operations for New Zealand, as these provide the greatest contribution to the export value of dairy products for New Zealand.

3.3 Approach

In order to understand the complexities and risks of the regulatory model for food safety in dairy manufacturing and its relevant assurance mechanisms we:

- undertook a desktop review of relevant information, including legislation, regulation, rules and guidance; and
- interviewed a wide range of relevant staff, and key external stakeholders to understand their insights and perspectives.

As far as practically possible, the views obtained from staff and stakeholders were confirmed through review of current and historic documentation, and observation of practices through field visits to processing plants.

As part of this review, the findings and recommendations of the December 2013 and November 2014 reports of the government inquiry into the August 2013 Whey Protein Concentrate Contamination (WPC80) incident (the WPC inquiry reports) were considered, and progress against the actions associated with those recommendations assessed. The WPC80 review considered an incident where it was feared botulinum toxin-producing *Clostridium botulinum* had been detected in whey protein concentrate at one of Fonterra's dairy manufacturing plants. While this fear was later confirmed not to be the case, the resulting reports highlighted a number of areas where practices could be improved.

In the process of completing our review, a variety of other historic independent and internal reviews conducted on the food safety regulatory system were also considered, including:

- the 2008 Slorach Review of the New Zealand Food Safety Risk Management Framework;
- the 2019 high-level assessment of the Food Safety System undertaken by MPI's Skills and Regulatory Stewardship Team; and
- the internal reviews of the food safety verification model commissioned over the last three years.

4 Context

A regulatory system is a set of formal and informal rules, norms and sanctions, given effect through the actions and practices of designated actors, that work together to shape people's behaviour or interactions in pursuit of a broad goal or outcome.

4.1 Regulatory systems management

4.1.1 Importance of regulatory systems

Regulation impacts the everyday lives of New Zealanders. It provides a common set of enforceable rules informed by societal values, which enshrine in law certain principles, expectations, rights and interests. The quality of regulatory design and practice is therefore fundamental to ensuring that regulation achieves its intended objectives.[6]

4.1.2 Challenges of managing regulatory systems

The administration and operation of any regulatory system is informed by a range of considerations. These often include social and cultural values, political structure, economic conditions, market orientation, technology, and government policy and regulatory objectives.

The operation of regulatory systems may be further complicated through the involvement of multiple agencies or organisations with overlapping responsibilities for parts of a system. Multiple agencies sharing responsibility for administration of a regulatory system may have differing agency objectives and accountabilities.

To remain fit for purpose, regulation and regulatory practice requires regular review, and where necessary, updating to address issues and circumstances unforeseen at the time of development.

Good regulatory practice therefore holds that regulatory agencies regularly and systematically review the effectiveness of the administration and operation of regulatory systems, including that the objectives of its regulations are fit for purpose in the current context.

4.2 Good practice regulatory systems

4.2.1 Government expectations of good regulatory systems

In 2013 the Productivity Commission was asked by the government of the day to carry out a review of Regulatory Institutions and their practices. When the Commission's report was published in June 2014 it highlighted a number of weaknesses in New Zealand's regulatory systems which it considered could be addressed by more effective regulatory practices, culture and leadership, governance and accountability, monitoring and oversight, regulatory stewardship review, better information and insights to run and improve systems.[7]

Following the publication of the Commission's report, the Government (through Treasury New Zealand) set out a series of baseline expectations that regulatory agencies like MPI needed to follow in the design of regulatory systems and in relation to regulatory stewardship[8], including:

- regular monitoring, review and reporting on regulatory systems;
- robust analysis and implementation support for changes to regulatory systems; and
- good regulatory practice (including engagement and communications with regulated parties, frontline regulatory services, compliance and enforcement activity).

Regulatory systems need to deliver, over time, positive benefits and outcomes which outweigh cost or negative outcomes. In this regard, they need to deliver the desired change in behaviour.

Government expectations are also driven by the lessons that can be learned from regulatory failures. Recent examples include NZTA's management of the vehicle warranting regulatory system. Some of the key lessons from that failure included:

- self-regulation had been encouraged in an attempt to ensure the operator owns their own compliance responsibilities;
- regulation was highly operator centric and adjusted in response to strong customer resistance to high levels of oversight, and compliance burden. This had the effect of allowing operators to determine how much or how little regulatory oversight occurred;
- limitations due to insufficiently detailed or unclear secondary and tertiary regulation, guidance, standards and notices;
- a lack of focus on key areas of concern or risk in the system (can be the result of desensitisation due to lack of failure occurrences);
- poor oversight of regulated parties, such as warrant of fitness providers;
- a lack of information sharing between co-regulating parties can hamper efforts to ensure a healthy, continuously learning, and holistic regulatory system;
- poor governance over regulatory systems – unclear about risk, insufficient regulatory reporting, and lack of regulatory experience on governance bodies;
- poor specialty expertise and lack of training or development opportunities in sectors and industries; and
- poor monitoring and reporting of key regulatory indicators.

We considered these themes as we reviewed the regulation of food safety in dairy manufacturing.

6 Government Expectations for Good Regulatory Practice, The Treasury, April 2017, https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf

7 Regulatory Institutions and Practices, New Zealand Productivity Commission, June 2014, https://www.productivity.govt.nz/assets/Documents/d1d7d3ce31/Final-report-Regulatory-institutions-and-practices-v2.pdf

8 Government Expectations for Good Regulatory Practice, The Treasury, April 2017, https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf

4.2.2 Key components of regulatory systems

Any regulatory system needs to be built on firm foundations and to have clear objectives, flexibility to evolve, be consistent (as far as practicable) with international practices, allow fair and equitable treatment, and be easy for users to navigate and understand. The key components of any system[9] that contribute to achieving these expectations include having:

- **Effective regulatory strategy** – a strategy that sets out the key elements of how the agency/regulator will undertake its regulatory role, what its operating model consists of, its approach to regulatory decision making, compliance and enforcement, service delivery, and continual improvement. Critically, it should also consider environmental and global change, and be able to be adapted to meet changing requirements and expectations.
- **Effective governance and accountability** – well defined system leadership, governance arrangements and systems supported by clear objectives and outcomes. Governance should consider strategy, risks and operational performance, as well as determining shifts in expectations and guiding changes in government policy.
- **Fitting culture and leadership** – an effectively promoted and maintained culture, driven by people who are motivated, engaged and invested in the system's purpose and outcomes, committed to sharing learnings, making changes and exploring emerging strategic issues and risks.
- **Effective supporting structure which clearly designates roles and responsibilities** – a structure that best allows the application of transparent, consistent and risk-based approaches to regulatory decision making and delivery of front-line regulatory services.
- **People and resources with the right capability and capacity** – people working in and on the system who have the right capabilities, skills and diversity to achieve the system's enduring purpose and the effective functioning of the system, as well as to identify and manage risk.
- **Operational practices and processes for effective delivery** – practices that deliver value to stakeholders and New Zealanders, make use of effective system design, allow continuous improvement and innovation, and allow ease of business for regulated parties.
- **Effective technology** – technology systems that allow the agency to deliver its services optimally and effectively, that provide accessible and timely information for decision making, and that make regulated parties' experience as simple and straightforward as possible.
- **Processes for analysis and insights over regulatory systems design and operation** – using insights, information and knowledge to inform system improvement strategies, identify emerging risks and opportunities, and anticipate change.
- **Assurance over how regulatory systems operate** – regular and systematic monitoring and evaluation routines that help assess the ongoing performance and condition of the regulatory system and the environment within which it operates.

4.3 Regulatory context for food safety

4.3.1 MPI's strategic plan

MPI revised its overarching strategy in 2019, setting out its four outcomes (prosperity, sustainability, protection, and visible leadership) and new vision, that "New Zealand will be the most sustainable provider of high-value food and primary products." The first three outcomes in particular, capture well the object of the legislation that MPI administers and supports through regulation. Achieving the legislated object (i.e. for the Animal Products Act 1999: managing risk to human health, ensuring food is fit for purpose, and facilitating the entry of animal products into overseas markets) is central to maintaining Government, trading partner, stakeholder and consumer confidence, and the social licence to operate. This means that MPI must regularly check that its settings align with, and support, the legislated object.

4.3.2 MPI's regulatory stewardship strategy

While it is no longer a requirement of the Treasury that departments have a regulatory strategy, MPI did develop a strategy in October 2016 which remains current and relevant. The MPI regulatory strategy is based on a series of nine principles[10]:

1. regulate only where necessary, on the basis of scientific evidence and risk.
2. regulate for outcomes, rather than process (what we are trying to achieve, rather than how it is to be achieved).
3. user pays – those who create risks and/or use MPI services cover the costs of those services.
4. regulation should be practical and enabling.
5. regulation should take a "whole of system" focus.
6. recognise that customers are subject to multiple regulatory systems.
7. recognise that regulatory burden should be in proportional to its benefits.
8. regulation should be as simple to understand as possible.
9. regulation should incentivise the "right" behaviour and reduce compliance action.

These principles are applied to the management of the food safety regulatory system and the sectors it covers, such as dairy manufacturing and meat processing.

9 These components are loosely based on research done by Martin Jenkins as part of their review of NZTA regulatory systems for vehicle registration and warranting checks.

10 MPI Regulatory Stewardship Strategy, October 2016, https://www.mpi.govt.nz/dmsdocument/14848/

4.3.3 New Zealand Food Safety Strategy and Action Plan

New Zealand Food Safety's strategic direction and core objectives for food safety and suitability are articulated in their strategy and action plan. These were released in December 2019 and set the direction and priorities for New Zealand Food Safety through to 2024. The strategy sets out five key priorities for the business unit:

- ensure New Zealand's world-class food safety system remains robust;
- proactively support consumers to make informed food choices;
- actively contribute to new thinking in international forums;
- work in genuine partnership with Māori; and
- is innovative and forward-looking in meeting new challenges.

The strategy reiterates the objectives of maintaining and growing global trust in New Zealand's food safety system, as well as New Zealand's reputation for producing safe and suitable food.

The key priority 'ensuring the food safety system remains robust' is particularly relevant because New Zealand Food Safety's Action Plan highlights that this requires change to better target regulatory activities to ensure that the food safety system is fit for purpose, resilient, and proactively encompasses the need to work with food businesses and stakeholders to ensure that regulatory controls are understood. These high-level priorities and actions provide a good basis for further enhancing New Zealand's already world class food safety system.

5 How the object of the legislation is being met

The legislative outcomes of the Animal Products Act and the associated regulations and notices that underpin the regulatory approach are largely still meeting the desired object as articulated by Cabinet in the 1990s when the legislation was passed. However, this is not without its challenges.

5.1 Overview

Most of New Zealand's largest dairy manufacturers operate with a predominant focus on producing for the export market. The key legislation setting out the requirements that they need to meet for export of their products is the Animal Products Act. While the focus of this review has been on how the object of the Animal Products Act is being met, the review did consider the interaction with the Food Act 2014.

This report comments on the development of regulation and how it contributes to setting the frame for MPI's regulatory interventions. The section highlights the challenges to continuously adjust the regulatory system to meet the ever-changing needs of those in the systems (verifiers, operators and businesses), to reflect the changing world in which these entities operate, and to keep the system as simple and effective as practicable.

This section also highlights the challenges of a regulatory model where contracted third parties and operators are a feature of the regulatory system. Operator oversight is undertaken by the verifier and regulator, but limited resources and other organisational responsibilities and priorities can impact the extent of this oversight.

This section also highlights the challenges posed by the way in which the regulatory function framework has evolved in MPI over the last eight years. It comments on the benefits and challenges of the third party verifier model and considers whether this is the most appropriate model for verifying the safety and suitability of operator practices.

5.2 Animal Products Act 1999

5.2.1 Historical approach to regulating dairy

Up until the latter part of the 20th century the underlying approach to regulation and enforcement for all animal products including dairy in New Zealand was inspection based with oversight of standards and performance in the hands of the New Zealand Dairy Board. From the late 1990s the government's approach to food safety regulation shifted to a risk-based approach focusing on the food safety outcomes food businesses are required to achieve.

In 2001 the New Zealand Dairy Board merged with Kiwi Co-operative Dairies and New Zealand Dairy Group to form Fonterra. At that time, the New Zealand Food Safety Authority took over the New Zealand Dairy Board's role in the regulation of dairy export.

This risk based approach is grounded in the international standards and guidelines for food safety risk management developed by the Codex Alimentarius Commission (Codex)[11]. New Zealand was heavily involved in this Codex work and an advocate for food safety risk management concepts, including Hazard Assessment Critical Control Point (HAACP). The WTO Agreement on the Application of Sanitary and Phytosanitary Measures that came into force in 1995 references Codex standards as the basis for regulation of food safety in trade. New Zealand also chaired the Codex Committee on Milk and Milk Products.

The Animal Products Act was developed alongside the Australia New Zealand Food Standards Code, which sets the composition and labelling requirements for food on the New Zealand and Australian markets, and was key for the inclusion of food within the Trans Tasman Mutual Recognition Arrangement (TTMRA).

5.2.2 Object and principles of the Animal Products Act 1999

In many ways the Animal Products Act was something of a milestone, focusing on the processing and production element of animal material and animal products. While dairy was not initially covered by the Animal Products Act, it was brought under its auspices through the Animal Products Amendment Act 2005. The object of the Animal Products Act remains to:

- minimise and manage risks to human or animal health arising from the production and processing of animal material and products by instituting measures that ensure so far as is practicable that all traded animal products are fit for their intended purpose; and
- facilitate the entry of animal material and products into overseas markets by providing the controls and mechanisms needed to give and to safeguard official assurances for entry into those markets.[12]

The reforms that resulted in the original Animal Products Act embodied the principle that the regulatory model:

11 Specifically CAC IGC 82 2013

12 Animal Products Act 1999, section 2: Object of the Act, http://www.legislation.govt.nz/act/public/1999/0093/latest/DLM33510.html?search=qs_act%40bill%40regulation%40deemedreg_food+act_resel_25_h&p=1

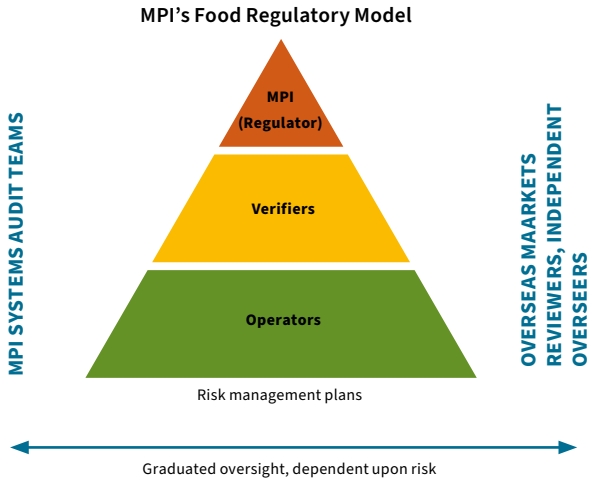
- provide for regulation that is enabling rather than prescriptive;
- wherever possible, rest responsibility for risk management on industry;
- provide for the contestable delivery of inspection services, and
- have a framework which incorporates:
  - a government policy coordination function;
  - an integrated regulatory function;
  - the capacity to contract or accredit competent services to supply food administration services; and
  - wherever possible, industries taking responsibility for managing the quality and safety of their products.[13]

The Animal Products Act places responsibility for risk management on producers and processors, and introduced a three-tiered food safety model (Figure One). The system relies on a balance of prescriptive process and outcomes-based regulatory tools including RMPs. In addition to other regulatory requirements e.g. DPC3: Animal Products (Dairy) Approved Criteria for the manufacture of dairy material and products, RMPs set out how an operator will identify, control and eliminate hazards and other risk factors relevant to its production and processing of safe food, like dairy products.

5.3 Operation of the dairy manufacturing food safety regulatory system

5.3.1 Three-tiered food safety model

Figure One: Food Safety Dairy Manufacturing Regulatory Model



The three-tiered food safety model established by the Animal Products Act sets out responsibilities of:

Regulator – MPI holds powers and authorities under the Animal Products Act, (as well as the Food Act and the Agricultural Compounds and Veterinary Medicines Act 1997) to, for the dairy industry:

- set standards;
- register RMPs and exporters;
- recognise third party agencies and persons, including evaluators, verifiers and laboratories;
- provide official export assurances;
- develop resources and guidance materials;
- undertake compliance and enforcement action; and
- monitor overall system performance.

Recognised agencies and recognised persons, including:

- **Verifiers** – recognised persons and agencies responsible for verifying that dairy manufacturers operate in accordance with their risk management programmes and use of suitable food safety practices. Two recognised agencies (AsureQuality, and Eurofins) provide these services for dairy manufacturing operators. MPI Verification Services operates as a verifier of last resort. AsureQuality undertakes the majority of verification for most of the large dairy processors – they are contracted to provide verification services for all Fonterra processing plants, which account for approximately 80 percent of dairy exports.
- **Laboratories** – recognised agencies responsible for pathogen and contaminant testing of food products samples, in accordance with regulatory requirements. This includes testing dairy products to ensure they comply with regulated food safety requirements and relevant overseas market access requirements. All recognised laboratories are required to comply with the Animal Products Notice: Laboratory Specifications. There are approximately 50 laboratories recognised under this notice.

Operator – Dairy manufacturers who are responsible for producing safe dairy products by designing and implementing appropriate RMPs, which are reviewed by the verifier under a set of requirements described by the regulator.

5.3.2 Requirement for risk management programmes for animal product business operators

The Animal Products Act provides several risk management tools to minimise and manage associated food safety risks to human and animal health and to facilitate trade. MPI as the competent authority under the Animal Products Act, has responsibility for ensuring that food safety objectives are met, and that is done through the requirement that manufacturers operate under an approved and registered RMP.

RMPs are specific to a particular operator's business, setting out how that operator will identify, control and eliminate hazards and other risk factors in the production and processing of safe food. They also set out the required actions for when products do not conform to legal requirements, including the method of notification and product recall.

RMPs are required to meet regulatory requirements. At a minimum RMPs should document biological, chemical and physical risks associated with the operation of a food business and sets out how those risks will be managed. RMPs require specific hazard analysis and critical control point (HACCP) principles to be used to identify hazards and determine effective controls to mitigate those hazards. Operator RMPs are evaluated by a recognised agency against specific HACCP criteria and must be approved by MPI. The specific HACCP criteria for dairy manufacturing are set out in the document "DPC 3: Animal Products (Dairy): Approved Criteria for the Manufacturing of Dairy Material and Product"[14].

13 CIE (94) M2/1A Cabinet Minutes: Framework for Food Administration

14 https://www.mpi.govt.nz/dmsdocument/10157-dpc-3-animal-products-dairy-approved-criteria-for-the-manufacturing-of-dairy-material-and-product

5.3.3 Evaluation of risk management programmes

Dairy processing RMPs require independent evaluation by a recognised person prior to registration with MPI, or when significant amendments are made. RMPs are required for farm dairies, dairy processing, stores and transport operations.[15]

Evaluation is an important step to provide independent oversight of significant RMP changes. Evaluators provide details of deficiencies, mitigating actions and any registration or amendment conditions. In practice, evaluation of amendments is not a frequent practice and there is no regular RMP re-evaluation process. Further work could be done by MPI to better understand the impacts of not doing this.

5.3.4 Verification of risk management programmes

Verification of risk management programmes is carried out by recognised agencies and persons and is a fundamental requirement of the regulatory model – the regularity of this verification is dependent on the assessment of the level of risk associated with each operator. Performance based verification (PBV) uses a seven-step scale which sets out these requirements. Some operators, through sustained demonstration of substantial compliance, are at a ceiling step that means they only require quarterly verification.

Figure Two: Performance Based Verification Steps interval

Verification step	Verification interval
00	To be determined by Manager Animal Products or Manager Food and Live Animal Assurance
1	2 weeks
2	1 month
3	6 weeks
4	2 months
5	3 months
6	6 months
7	1 year

The initial frequency for processors of dairy products is step 2 and the ceiling frequency is step 5.

- To move from Step 2 to 3 an operator must achieve two consecutive acceptable outcomes;
- To move to higher steps an operator must achieve three consecutive acceptable outcomes between each step; and
- In the event of an unacceptable outcome, the operator will be moved to a lower step.

Acceptable outcome means the verifier is satisfied:

- that the operator is substantially complying with applicable regulatory requirements; and
- where there have been any departures from requirements, that the operator's corrective and preventative actions have been, or are being applied appropriately and are effective.

5.3.5 Accreditation

All recognised agencies and persons who carry out verifications must be accredited. This involves initial recognition, followed by annual assessment of technical competency and quality management by the International Organization for Standardization (ISO)[16] accreditation bodies. In New Zealand, this accreditation is done by two bodies; International Accreditation New Zealand (IANZ) and the Joint Accreditation System of Australia and New Zealand (JASANZ). Technical experts from MPI's System Audit Team attend these accreditations.

5.3.6 Fit and proper persons

In addition to the registration of dairy manufacturer's RMPs, the Animal Products Act requires dairy exporters to register with MPI. A core consideration in both RMP and exporter registration processes, is that company directors and managers are fit and proper persons to either "operate an animal product business" or "export any animal material or product". In making this determination the Director-General must take into "account whether the applicant or any directors or managers of the business concerned have been convicted, whether in New Zealand or overseas, of any offence relating to fraud or dishonesty, or relating to management control or business activities in respect of businesses of a kind (whether in New Zealand or elsewhere) that are regulated under this Act"[17].

Once an RMP or exporter is registered, that registration can be disqualified or removed if, among other reasons, the person/s responsible can no longer be considered a "fit and proper person".

This requirement is a central element to gaining confidence that animal product and materials manufacturers and exporters are fit to operate such food businesses. Fit and proper person tests should be redone over time, as company directors and managers (and their status) changes.

5.4 Legislative design and system outcomes

5.4.1 Design and implementation of regulatory systems

Effective design and implementation plays an important part in ensuring administration of a regulatory system delivers on the object of the primary legislation.

Treasury's Good Regulatory Practice guide advises that effective design practices should take account of potential change (environmental, social, economic etc.) resourcing, international regulatory models, and involve the public and affected parties such as regulated parties. Before any substantive regulatory change, there is a need to:

- clearly identify the nature and underlying cause of the policy or behaviour that the regulation is trying to address;

15 Animal Products Act 1999, section 17: Contents and requirements for risk management programmes
16 https://www.iso.org/home.html
17 Animal Products Act 1999, section 54: Application for registration, paragraph 2(a)

- carry out systematic impact and risk analysis of how the change might interact;
- alignment with international commitments and domestic requirements; and
- identify the costs, benefits and consequences of change.

Mechanisms like Regulatory Impact Analyses are used to solicit the views and understand and respond to the needs of those affected by regulatory change. Like other agencies, MPI develops Regulatory Impact Statements (RIS) to provide a summary of the agency's best advice to its Minister and to Cabinet on the definition of the regulatory problem, provide an analysis of a range of options for a solution, and suggest implementation arrangements. RIS provide an objective and balanced presentation of options and impacts, with any conclusions reached by the agency explained and justified.

The legislation that underpins the regulatory environment needs to be sufficiently focused as to effectively provide the framework for more detailed regulations, guidelines and codes of practice, but equally sufficiently broad to allow for flexibility as industries and the operating environment changes.

5.4.2 History of changes to the legislative framework for dairy manufacturing

MPI's current regulatory practices for the dairy manufacturing industry are still very much based upon the legislative powers and practices that were granted within the Animal Products Act. This primary legislation has been subject to some amendment over the years, most notably when dairy regulation was placed within the framework of the Animal Products Act in 2005 and more recently, in March 2018 when the Food Safety Law Reform Act 2018 addressed concerns identified by the WPC80 inquiry reports.

The WPC80 review of the dairy manufacturing system concluded that the outcomes-based standards and process-based regulations provided a good balance for all parties including industry. Regular audits by trading partners against their import requirements, and equivalence recognition by the likes of the United States, also supports the assertion that New Zealand's dairy manufacturing system is viewed by other countries as fundamentally sound.

5.4.3 Challenges of making significant change to the dairy manufacturing legislative framework

While there has been limited change to the way the regulatory system for animal products operates since the Animal Products Act was extended to dairy in 2005, there continues to be the need to address changes in the wider operating environment for regulating food processing and production through changes to legislation. It is recognised that areas like technological change, ways of doing business, changes in consumer expectations, and overseas regulator demands for assurances on safe products all necessitate the need to move more quickly to review and change regulation.

Minor adjustments to the dairy manufacturing regulatory system may be made to resolve discrete issues, providing such changes fall within current policy and legislative settings. Other changes must take account of the intricate framework of market access arrangements that rest on the current regulatory system and approach, which allows New Zealand dairy manufacturers to trade globally. Keeping in mind MPI's strategic objectives of sustainability, prosperity and growth, any regulatory change must be carefully considered and designed so as to support the continued overseas market access on which the success of the dairy sector depends. Access to markets is also premised on the system being designed based on international risk management principles and standards. Any proposals for significant change would also need to follow these international principles or risk undermining market access for New Zealand exports.

Understandably, regulatory resourcing tends to be proportional to industry size and economic return, and consequently risk. Due to the small size of New Zealand's domestic market, relatively more resource is directed to regulatory systems that enable export-oriented industries. In terms of primary sector exports, dairy manufacturing has provided the highest annual export revenue since the late 1990s and this looks set to continue. Access into overseas markets for dairy exports depends on the Animal Products Act system and MPI as regulator continuing to provide trading partners with the confidence and assurances that dairy products exported from New Zealand will meet their food safety requirements. In this respect confidence among trading partners in New Zealand's food safety system, and MPI's role as regulator, has been established through years of high-level engagement on technical issues – bilaterally, in regional meetings, and, importantly, through significant strategic contributions to the development of international food safety standards.

Any wholesale change to core components of the current food safety regulatory system could require trading partners to reassess their rules for importing New Zealand products. Any such process would require careful management of the risk of interrupting trade. This would likely include close scrutiny of the consistency of any changes with New Zealand's international commitments, and the renegotiation of impacted market access requirements with individual trading partners.

Therefore, there are reasons not to fundamentally alter the system. Less fundamental change does occur, which reflects the fact that regulation must continue to evolve in response to changing regulatory demands. While the system is currently well regarded, any advantage it provides could be lost if it does not evolve fast enough to effectively manage emerging risks and opportunities.

5.4.4 Business and operator concerns about the complexity of regulation

One of the aims of the Animal Products Act was to be more enabling and less onerous for operators, introducing a more principles-based approach to this regulation. In particular, risk management programmes, regulated control schemes, product standards and specifications as well as overseas market access requirements (OMARs) are consistent areas of tension. Smaller manufacturing firms that are not highly capitalised may find it more challenging to navigate and comply with regulatory requirements for dairy manufacturing, setting a high bar for new entrants.

International Policy and Market Access work with trading partners to agree and improve trade policy and technical sanitary and phytosanitary import requirements. Nonetheless, technical requirements set by New Zealand's trading partners and reflected in OMARs can be oblique. This can make it more complex for

manufacturers to meet importing market entry requirements. It can also lead to differing interpretations of requirements between verifiers, operators, and the regulator, and may consequently drive inconsistency both in practice and in the assessment of compliance with practice.

The concerns around the complexity, and to a lesser extent the practicality, of complying with regulation has been highlighted in stakeholder research carried out for both MPI and the Food Safety Assurance Advisory Council (FSAAC) by Colmar Brunton over the last three years.

The interaction between, and consequent application of, the Food Act 2014 and Animal Products Act 1999 adds a layer of complexity to the regulatory landscape that dairy manufacturers are required to navigate. Section 6 of the Food Act sets out the relationship between the Food Act and Animal Products Act.

Section 6(1) of the Food Act recognises "the general equivalence of [the] food safety [regime] under [the Food] Act and the Animal Products Act 1999… in terms of their ability to ensure the safety and suitability of any food to which they apply." Section 6(3)(a) sets out that the Food Act applies to "an animal product that is processed under the Animal Products Act 1999 (whether the animal product is for sale on the domestic market or is to be exported), if the animal product is also a food".

Further, to address any legislative overlap between food safety regimes Section 6(4) of the Food Act provides for exemptions from Food Act requirements, including for certain exports (Section 345 to 347), and certain persons covered by the Animal Product Act from operating under an applicable risk-based measure (Sections 349 and 350). Finally, as applies to dairy processors, Section 6(6) establishes that if "there is any conflict, duplication, or inconsistency between the requirements of [the Food Act] and the requirements of the Animal Products Act… in relation to an animal product… the requirements of [Animal Products Act 1999 prevails].

While Section 6(5)(b) of the Food Act recognises "the general equivalence of food control plans and [Animal Products Act] risk management programmes" as apply to the production of food products, this provision only applies to secondary processors of animal products as defined under the Animal Products Act. Dairy processors, however, are defined as primary processors.

MPI has recognised this and is co-designing fit for purpose solutions with the operators, industry good bodies, and other related stakeholders, which also seek to address barriers to compliance. A current example of this is the stakeholder involvement in the Regulatory Redesign programme which aims to implement the key changes brought about by the Food Safety Law Reform Act 2018. The Food Policy Team is holding workshops and engaging with relevant parties prior to designing the regulation changes to ensure it understands any unplanned impacts and addresses the key regulatory matters. This is a relatively new way of redesigning regulation.

Some of the related concerns raised by operators can arise from their interest to reduce compliance costs, improve efficiencies, and to ensure the continued profitability of their operations. As a regulator, MPI must balance the need to have regulation sufficient to ensure safe and suitable food and products and have the power to correct and challenge non-compliance, but at the same time make it simple and straightforward for regulated parties to comply.

5.4.5 Legislative change

The Food Safety Law Reform Act 2018 introduced significant changes to the regulatory environment for safe and suitable food and was passed on 1 March 2018 – the regulatory design element of the law is required to be completed by March 2022.

The Food Safety Law Reform Act introduced a range of important changes to strengthen response to food safety incidents, create a more consistent and fair approach to enforcement for non-compliance, and improve the Government's access to information from third parties (across the existing Animal Products Act, Food Act and Wine Act 2003). The new legislation was to:

- Enable regulations to set the content and format of the parts of custom risk management programmes and plans that must be provided to MPI for registration, and allow the Director-General to require amendments to programmes and plans if they are not able to be easily understood; and
- Enable regulations to provide more detailed traceability obligations by the operators and provide the ability for the government to set recall requirements as needed, given the importance of traceability to New Zealand's food safety and reputation.

New Zealand Food Safety's Animal Products Team is working with Policy and Trade's Food Policy Team in the Regulatory Redesign Project to establish the necessary regulations and notices. This is to ensure a clear cascade of legal requirements from the Food Safety Law Reform Act into secondary (regulations) and tertiary (notices) regulation. Currently the project is on track to complete the required regulations and notices on time. This is important because after March 2022, the current legal instruments will no longer be valid.

5.5 Organisational structure and regulatory functions

5.5.1 Role of MPI as regulator in managing the dairy manufacturing food safety system

MPI's role across the food safety system is similar, irrespective of whether the food being produced is dairy, meat or indeed any other animal product. The regulatory activities in support of its role includes:

- providing technical and policy advice;
- developing legislation, regulations and notices;
- developing and setting the standards that food businesses must meet;
- approving and registering food businesses and relevant risk management programmes;
- defining the competency criteria for, and approving or recognising, agencies and persons to undertake specialist roles such as evaluation, verification and laboratory analysis;
- developing resources, providing information and guidance to promote food safety;
- monitoring the safety of food produced in New Zealand and ensuring that non-conforming food is managed appropriately;

- monitoring and managing the on going verifying that food businesses are following their risk-based programmes;
- providing official assurances that exported products meet relevant OMARs;
- conducting compliance and enforcement activities;
- auditing, evaluating, and monitoring the performance of the overall system; and
- initiating, coordinating and providing information on food recalls.

These regulatory activities are based on a robust and transparent Food Safety Risk Management[18] framework which has been in place for a number of years.

Table One below sets out the key functions for MPI as the regulator and the area of the business responsible for that function.

Table One: Roles and functions of MPI as regulator of dairy manufacturing

Function	Who
Policy development, advice and legislative drafting,	**Policy and Trade** – International Policy Directorate, Food Skills and Science Policy Directorate, Agriculture, Marine and Plant Policy Directorate
Negotiation of international standards, and multilateral, plurilateral and bilateral free trade agreements	**Policy and Trade** – International Policy Directorate
Setting standards and developing regulations	**New Zealand Food Safety** – Food Regulation Directorate – Animal Products Team
Setting requirements for official assurances and general requirements for export	**New Zealand Food Safety** – Assurance Directorate – Food and Live Animal Assurance Team
Developing and negotiating official assurances and technical SPS market access requirements	**Policy and Trade** – Market Access Directorate
Granting recognised agencies and persons status to third party verifiers and laboratories	**New Zealand Food Safety** – Performance Oversight and Approvals – Approvals Team
Granting approvals, risk management programmes, and exporters	**New Zealand Food Safety** – Performance Oversight and Approvals directorate – Approvals Team
Oversight of recognised agencies and persons under the Animal Products Act	**New Zealand Food Safety** – Assurance Directorate – Food and Live Animal Assurance Team, System Audit Team
Providing electronic certification system and managing access to the system	**New Zealand Food Safety** – Assurance Directorate – Food and Live Animal Assurance Team, Chemical and Microbiological Assurance Team
Issuing official assurances and e-certificates	**New Zealand Food Safety** – Verification Services Directorate – Certification Unit
Re-issuing official assurances due to problems in market etc.	**New Zealand Food Safety** – Assurance Directorate – Food and Live Animal Assurance Team, Chemical and Microbiological Assurance Team
Performance monitoring of dairy industry and management of product non conformances	**New Zealand Food Safety** – Assurance Directorate – Food and Live Animal Assurance Team, Chemical and Microbiological Assurance Team, Systems Audit Team
Assessing compliance, and enforcement, prosecuting non-compliant organisations or individuals	**New Zealand Food Safety** – Assurance Directorate – Food and Live Animal Assurance Team, Chemical and Microbiological Assurance Team, Systems Audit Team **Compliance and Governance** – Food Compliance and Compliance Investigations teams, Legal Services
Food fraud and food defence risk assessments and deep dives	**Biosecurity New Zealand** – National Intelligence Team

18 New Zealand's Food Safety Risk Management Framework 2010

5.5.2 Need for an integrated regulatory framework

The intent of the reforms that introduced the Animal Products Act was to develop a regulatory model with a framework which included an integrated regulatory function. Equally an important part of being an effective regulator is having an effective supporting structure for regulatory activities which clearly designates roles and responsibilities. Having a structure that best allows the application of transparent, consistent and risk-based approaches to regulatory decision making and delivery of front-line regulatory services is fundamental.

MPI's current structure could better fulfil the elements and expectations of an integrated regulatory function. It requires some understanding of the history of the development of MPI since 2012 to understand how this might be possible.

5.5.3 2012 restructure of MPI functions

MPI was established in April 2012 – this followed the merger of three predecessor agencies in July 2011 comprising:

- Ministry for Agriculture and Forestry (including Biosecurity New Zealand)
- Ministry of Fisheries
- New Zealand Food Safety Authority

Following this merger, policy, compliance and market access functions were separated away from the regulatory implementation and service delivery functions of the predecessor agencies and established as functional branches designed to work across MPI.

The aim of this approach to structural design was intended to reflect MPI's key activities, prevent silo behaviour and improve collaboration across the organisation.

5.5.4 Establishment of business units to manage regulatory systems

Following the September 2017 election and change of government, there was some further consideration of the ways that MPI was structured. In April 2018 MPI's structure was changed to give greater visibility to the then three branches of the business responsible for implementation of the food safety, biosecurity, and fisheries regulatory systems. This was done through "rebranding" these branches into three publicly identifiable business units:

- Fisheries New Zealand
- New Zealand Food Safety
- Biosecurity New Zealand

A new business unit was established to manage the forestry regulatory system -Te Uru Rakau – New Zealand Forest Service: responsible for implementation of forestry regulation.

In 2019 the Agriculture and Investment Services business unit was established to give greater visibility to the delivery of agriculture, animal welfare, adverse events recovery and primary sector innovation and investment services.

5.5.5 Dispersed responsibility for elements of regulatory system roles

While various internal restructures have occurred since 2012, policy and enforcement functions have largely remained outside the current business units responsible for implementation of food safety, biosecurity, fisheries, forestry and agriculture regulation. Policy and enforcement responsibilities sit with:

- **Policy and Trade**: responsible for policy advice, legislative design and international engagement. Policy and Trade also undertakes regulatory stewardship activities. The International Policy and Market Access Directorates, for example, are the primary interface with the Ministry for Foreign Affairs and Trade (MFAT) and other agencies, on international, trade policy and technical market access matters related to agriculture, forestry and fisheries. They are also responsible for providing advice across MPI on policy and programme consistency with New Zealand's international commitments.
- **Compliance and Governance:** among other things, responsible for core legal and compliance components of all MPI's regulatory systems, including food safety. These activities range from providing internal legislative advice, through to issuing infringements, and undertaking compliance investigations and prosecutions through the courts.

In addition, there are teams in Biosecurity New Zealand responsible for centralised readiness and response, operational planning and intelligence services. These teams provide key roles in ensuring a responsive regulatory system.

5.5.6 Challenges for integrated regulatory functions given MPI's structure

Having components of MPI's regulatory systems dispersed across the agency's business units increases the potential for misaligned regulatory activity. This may be exacerbated by differing views about what a regulatory system is, and who is ultimately accountable. Beyond the Director-General, there is an absence of a single "owner" with responsibility for all components of food safety regulation, including dairy manufacturing, requiring all components to take collective responsibility for achieving the outcomes desired. The business units and agency functions holding responsibility for regulatory system components must collaborate to effectively and efficiently operate the regulatory system. Effective and continuous feedback between MPI's dispersed regulatory system components is, therefore, not only essential to day to day operations, but also to achieving continuous improvement. Feedback systems that are systematic, rather than reliant on individual contributions would be ideal.

Articulating these accountabilities in a form which incentivises the various business units to collaborate, and jointly set the regulatory expectations is one way that MPI could ensure alignment of activity.

5.6 Verification of dairy manufacturing operators

5.6.1 Intent of the legislation relating to contestable delivery of verification services

Core principles of the reforms that led to the Animal Products Act are that the regulatory model:

- provides enabling rather than prescriptive regulation, that, wherever possible, rests responsibility for quality management on industry; and
- allows for qualified and competent third party service providers to supply food administration services to the market, including verification services.

Verification is a core component of the food safety regulatory system, including for dairy products, and is one of the key requirements of the Animal Products Act. Under the Animal Products Act, commercial third party verification service providers, when recognised by MPI as able to demonstrate the required service delivery competence, are able to provide verification services directly to dairy manufacturers. Any recognised verification agency or person must be recognised by MPI.

Since the introduction of the Animal Products Act such recognised agencies and recognised persons have been engaged by RMP operators, including in dairy manufacturing, to periodically verify that operators are acting in accordance with their RMPs and in so doing are complying with New Zealand regulations, and importing country requirements as set out in OMAR notices. The Animal Products Act provides verifiers with the right to access processing plants, documentation, and data for the purpose of checking operations against RMPs. Reviews undertaken by recognised agencies and persons can include PBV covering people, processes, programmes and management. PBV determines whether:

- the regulated party operates in accordance with the MPI registered RMP and the requirements of the Animal Products Act and its subordinate legislation;
- factories and stores continue to comply with RMP requirements;
- factories (establishments) where on an importing country's establishment list, continue to comply with the requirements for that listing; and
- the records of results of sampling programmes confirm that the systems managed by manufacturers for the verification of product conformance, generate credible information for the provision of official assurances.[19]

5.6.2 Third party verification of dairy manufacturing risk management programmes

The third party recognised agency system model is heavily reliant on AsureQuality and Eurofins as the two providers of verification services for dairy manufacturing. The degree of contestability and competition envisaged in the model's design has not eventuated and this does give rise to a number of issues. The WPC inquiry team highlighted these issues in their reports; MPI signalled at that time that it planned to more generally review third party verification including contestability.

In August 2017, MPI's then Regulatory Review Oversight Group (RROG) commissioned MPI's Policy and Trade to undertake a review of MPI's role in the establishment and oversight of third party verification services. That review provided a preliminary view to a group of MPI Food Directors in February 2018. It highlighted a number of issues, and some of these remain unaddressed.

Some of those issues raised during this review include:

- **Operator pays for the verifier:** the design of the regulatory model recognises there is potential for verifier conflicts of interest and capture due to verifiers (recognised agencies) being contracted and paid directly by the food business/dairy manufacturer that they verify on MPI's behalf. This is managed in the regulatory model by MPI's requirements and oversight for recognised agencies, including accreditation to ISO standards. To further reduce perceived risks of verifier capture by the manufacturer, MPI could contract third party verifiers and charge operators for the cost of services provided. Such a centralised approach would, however, come with additional costs.
- **Contestability:** there is limited competition amongst dairy manufacturing recognised agency verifiers, which is often attributed to the relatively small size of the New Zealand market and the size of New Zealand's largest dairy company. The supplier of verification services to New Zealand's largest dairy company has an incumbent advantage in contract negotiations due to the difficulties for a competitor in scaling up to provide those services. However, the dairy company also has significant leverage in contract negotiations on price and service conditions.
  There are two main providers of verification services for dairy manufacturing in New Zealand – AsureQuality and Eurofins – with MPI Verification Services acting as the "verifier of last resort" including for manufacturers that have product lines across different sectors. AsureQuality undertakes the majority of verification services, including for New Zealand's largest dairy company. There is a growing number of smaller dairy companies that require verification services. In this respect, the market for verification services is now bigger than it was when dairy was brought into the Animal Products Act regime in 2005. Nevertheless, the presence of only two verification service providers for dairy manufacturers indicates the contestability envisaged for these services when the Animal Products Act was developed has not been fully realised. This has the potential to increase the cost of services, while increasing the need for MPI to exercise greater oversight of registered agencies and persons providing verification services to ensure services are provided to the appropriate level.
- **Frequency of verifier visits and checks:** MPI sets the rules around the frequency of verifier visits based upon a well established stepped PBV process. For dairy manufacturing, the PBV process works in such a way that those processing plants considered well run are visited less frequently. Those dairy processing plants that pass the checks and are considered well run may only be subject to a verification once every month to three months. This is a well established risk management framework, balancing regulatory oversight burden against risk of non-compliance.
- **Scope of verifier visits:** the scope of the areas covered by verifiers during visits is constrained by the time available during the visit – checks cover elements of processing plant operation, including documentation and operator management review. Not every element of processing plant activity can be covered in a single visit. Further, most verifier visits are well signposted in advance which means that there is less element of surprise for operators (one in four verifier visits are required to be unannounced). For announced visits, operators can work to potentially ensure that on the day/s of the visit, processing staff have been suitably prepared to comply with expectations of the verifiers. Operators can also use independent consultants to check current processes and practices prior to the verifier visit and resolve any issues before the visit. This does not incentivise

19 New Zealand Regulatory Framework for Dairy Products, MPI, September 2016

the operator to build capability and understanding of what constitutes good practice. In 2017 the FSAAC commissioned research on Food Safety Culture which identified that positive culture and related practices often improve after verifier visits. This research identified that operators often request advice from verifiers about how to improve their practices. While it is understandable that operators seek advice to improve their risk management practices, this is not the role of verifiers. If a verifier acts as an adviser to RMP operators, this can be expected to divert attention from core verification duties and blur the distinction for operators and verifiers between verification and consultation.

Any modification of the current verifier model would likely require significant resourcing to support policy options development, consultation, legislative/regulatory change and implementation. For instance, moving verifier contracting to MPI would require the establishment and administration of supporting management systems. This would introduce operating uncertainty for verifiers, RMP operators and MPI. Further, such changes would need to be carefully worked through with trading partners to ensure access to overseas markets is maintained and enhanced.

5.7 MPI legislative powers and responsibilities

5.7.1 The context of delegation of powers by the Director-General

MPI is responsible for administering approximately 60 Acts of Parliament. Each Act of Parliament confers specific powers and responsibilities to the portfolio Minister (e.g. Minister for Food Safety), agency head (e.g. Director-General), or to a specified role (e.g. Chief Technical Officer). While certain powers conferred by an Act of Parliament may be required to remain with the portfolio Minister, or with the Director-General, most often powers are able to be further delegated within the responsible agency. In MPI the Director-General approves all delegations of powers regardless of where in the agency they reside, and while certain powers are conferred by legislation to specific roles, the Director-General is responsible for signing off appointments to such roles.

There is an effective process in place describing powers and authorities from the Minister to the Director-General and to named roles within MPI and we comment further on this below.

5.7.2 Dairy manufacturing and the delegation of powers by the Director-General

MPI administers three Acts of Parliament that apply to food safety in dairy manufacturing: Animal Products Act, Food Act and Agricultural Compounds and Veterinary Medicines Act.

Powers under these Acts of Parliament have been delegated to relevant MPI officials, reflecting the scope of duties assigned to the role. Further, powers delegated to tier three, tier four or tier five managers will usually be delegated to responsible tier two Deputy Director-Generals. This ensures that there is appropriate senior oversight of how delegated powers are managed and discharged.

The Director-General approves all delegations for MPI. It is not uncommon in other agencies for second and third tier roles to sub delegate their delegated powers to officials under their charge. That approach has the advantage that it places responsibility and accountability for delegated powers in the roles responsible for managing regulatory system components i.e. Deputy Director-General New Zealand Food Safety, Deputy Director-General Biosecurity New Zealand, Deputy Director-General Policy and Trade and so forth. This is one mechanism that can provide clarity to Deputy Director-Generals on their delegated powers and therefore their regulatory system component responsibilities. This could provide a clear framework for ensuring the smooth functioning of a full regulatory system by incentivising alignment in the legislation that MPI is responsible for. Legal Services is looking at how this might be done.

5.7.3 Legislative powers that remain with the Director-General

Under the three Acts of Parliament that govern the manufacture of dairy products, secondary and tertiary instruments (regulations and notices) have been established which set out rules applying to the production of animal materials and products, including dairy products. These range from general rules which cover all animal products to rules that address specific areas of risk in dairy manufacturing, such as raw milk and infant formula.

The majority of powers and authorities under the Animal Products Act, the Food Act, and the Agricultural Compounds and Veterinary Medicines Act, have been delegated to relevant roles within MPI. However, there are powers relating to 24 sections of those Acts that currently rest with the Director-General.

Of these, only the powers relating to two sections cannot be subdelegated. These relate to two sections of the Food Act: Section 410 “Power to issue emergency notice” and Section 411 “Notification and duration of emergency notice”. The other powers can be delegated to relevant roles below the Director-General.

6 Monitoring, oversight and reporting

Monitoring and reporting on the effectiveness of New Zealand's regulatory interventions including risk management programmes, chemical and microbiological controls and practices, helps maintain the confidence that consumers and trading partners, in particular, have in New Zealand's regulatory system.

6.1 Overview

Monitoring, oversight and reporting are central to ensuring that the food safety system and its components like the dairy manufacturing system, are operationally robust and effective, and that the identification and management of food safety risks and issues is operating effectively. This requires:

- governance and accountability mechanisms to ensure that the strategic and high-level objectives of the regulatory system are being met;
- monitoring of day-to-day regulatory operations including verification activities, monitoring and surveillance programmes;
- information, insights and intelligence gathering mechanisms to identify regulatory risks and issues which are communicated to management and governance;
- compliance and enforcement practices to ensure that participants are complying with the requirements of the regulatory system; and
- regulatory stewardship practices to provide a more medium to long term view of how systems are working.

6.2 Governance and accountability

6.2.1 Aims of governance

MPI has a dispersed structure of responsibilities. This regulatory function set-up makes it vitally important that well defined system leadership, governance arrangements and systems roles supported by clear objectives and outcomes are in place for both the food safety system and its dairy manufacturing sector component. Critical generally recognised elements of good governance include:

- Stewardship of the agency:
  - create a clear vision of the future and aim for it;
  - improve performance and get better financial results;
  - discover and act on the right new opportunities.
- Staying ahead of risks:
  - better understand current risks and get insights about possible future risks;
  - create strategies for reducing or avoiding risks;
  - learn from other people's experience and mistakes.
- Improving compliance:
  - better understand your legal responsibilities, especially when they change;
  - reduce time, money and effort on compliance and enforcement activities;
  - ensure accountability for what's happening at an operational level.
- Improving trust and reputation:
  - manage conflict;
  - show customers that your agency is responsible and ethical;
  - prove to stakeholders that you're doing things sensibly and safely.

6.2.2 Governance of public sector agencies[20]

Unlike private sector companies, the governance of public sector departments/agencies works differently, in that responsibilities are shared between the responsible Minister and the Chief Executive/ Director-General.

In general terms, Ministers are responsible for determining and promoting policy, defending policy decisions, and answering questions raised in the House of Representatives on both policy and operational matters. Ministers, however, as representatives of the Crown as owner, should not be involved in the day-to-day operations of their agencies. MPI, as with other government agencies, is required to provide information to its Ministers about its strategic intentions.

Chief executives are responsible to their portfolio Ministers, under the Public Services Act 2020, for a range of matters, including:

- the operation of the agency including carrying out the purpose of the public service under section 11 of the Act;
- giving advice to Ministers;
- the integrity and conduct of the employees for whom the chief executive is responsible;
- the efficient and economical delivery of the goods or services provided by the agency and how effectively those goods or services contribute to the intended outcomes; and
- improving ways of working across public service agencies.

Chief executives' responsibilities also include stewardship of the legislation administered by the agency.

In practice, chief executives have dual roles as both governors and managers of their agency. This means they are required to balance how they develop and maintain the long-term (strategic) capability, with day-to-day running of the agency's administration

20 Reflections from our audits: Governance and Accountability, Controller and Auditor General, April 2016, https://oag.parliament.nz/2016/reflections/part3.htm

of legislation, including delivery of policy advice, programmes, and services. This duality is also present in the roles of agency leadership teams, which are expected to function as both governance and management bodies.

Chief executives and leadership team members therefore must navigate the challenge of clearly distinguishing between when to act as a governor and when to act as a manager.

Constitutional conventions and norms also play an important role in guiding how the system of public service responsibility to Ministers works. The public service is politically neutral; it serves the Government of the day and its neutrality is protected by the Public Services Commissioner.

6.2.3 MPI governance structure for food safety and dairy manufacturing

The role of the Senior Leadership Team

Overall responsibility for the food safety regulatory system ultimately sits with the Director-General, but with responsibility for the operation of the regulatory system delegated to the Deputy Director-General Policy and Trade, Deputy Director-General New Zealand Food Safety, Deputy Director-General Compliance and Governance and Deputy Director-General Biosecurity.

The Senior Leadership Team is responsible for high-level strategic direction, performance and risk monitoring across MPI's regulatory systems, including governance of food safety which encompasses dairy manufacturing. Given the breadth of MPI's regulatory responsibilities (approximately 60 primary Acts of Parliament, and numerous regulations and notices to support), Senior Leadership Team must necessarily prioritise and delegate oversight activity.

Senior Leadership Team could consider the day to day performance of individual regulatory system components, and longer-term governance arrangements.

Role of the Food Safety Steering Group

In order to support Food Safety system oversight, the Food Safety Steering Group (FSSG) was established in June 2019.

Using good governance principles, the FSSG includes members of other business units including Compliance, Internal Audit, Policy and Trade, Business Technology Information Systems.

However, the only regulatory matters raised in these forums are emerging risks or issues. There is no regular reporting on the different food sectors.

The current FSSG is mandated to provide oversight and coordination of MPI's food safety regulatory system and was meeting quarterly up until December 2019. However, the focus of meetings has been more on the operational risks than on specific sector-based matters. Through the Covid-19 response this group has not been able to meet. The FSSG could play a role in escalating matters to Senior Leadership Team where necessary.

Oversight of food safety risks and issues

An important element of any regulatory stewardship role is the consideration of strategic and key operational risks. Senior Leadership Team and FSSG are generally only appraised of food safety issues evaluated as significant enough to warrant such escalation. Within New Zealand Food Safety, risks and issues judged by managers to be business as usual have not generally been escalated to the Deputy Director-General, or to Senior Leadership Team. This is appropriate if good judgement is being exercised and this is arguably the intention of delegating responsibilities and authority to Deputy Director-Generals, and from Deputy Director-Generals to his or her level 3 and level 4 managers.

Senior Leadership Team reviews top enterprise risks which currently includes risks which are actively managed by New Zealand Food Safety. Discussion on these risks at Senior Leadership Team is wide ranging and thorough. The Senior Leadership Team collectively interrogates mitigations and explores opportunities to gain traction on the outstanding matters.

Following the WPC80 incident, in 2014 (on the recommendation of the inquiry team) MPI developed a high-level risk register for food safety risk which was reported quarterly to the Food Safety Board and Dairy Products Standards Advisory Council (DPSAC). Collating a dairy sector regulatory risk register and ensuring its regular review at governance level would help to inform regulatory adjustment.

There are well defined mechanisms within MPI for escalating relevant emerging issues. This does allow MPI some ability to be flexible and nimble in the way it responds and to avoid overly bureaucratic and burdensome processes that would reduce efficiencies. Following the WPC80 incident MPI developed internal guidance on escalation criteria. This guidance was to be used to provide a more standardised approach to issue escalation, through the application and evaluation of food safety issues across eight impact areas:

1. human health;
2. health and safety;
3. economic and trade;
4. environmental;
5. trust and confidence in New Zealand's regulatory system;
6. MPI delivery;
7. Crown Maori relationship;
8. MPI financial.

This 2014 escalation procedure and criteria generally remains fit for purpose, although it could be better communicated to staff, and periodically reviewed and updated as necessary.

6.2.4 Role of external parties in providing oversight of dairy manufacturing

The Food Safety Assurance Advisory Committee and Dairy Products Safety Advisory Council were established to provide oversight of regulatory systems, and ensure that technical and operational expertise held by external persons and industries, is sought to inform governance decisions.

Food Safety Assurance Advisory Council

The FSAAC was set up in late 2014, in response to WPC80 incident. It meets quarterly. The FSAAC membership includes a chair and four members drawn from cross food regulation, public health, science, business and international relations.

FSAAC is tasked with providing MPI with "high quality, independent, strategic advice on how to ensure New Zealand's world-class food

safety and assurance system is maintained and enhanced." It is to do this by:

a) advising on how the food safety and assurance system as a whole, and/or any specific aspect of this system, can be strengthened to:
   - protect consumers;
   - enhance New Zealand's economic, productivity and trade outcomes; and
   - protect and promote New Zealand's reputation as a producer of safe and suitable food, including ensuring consumers have confidence in the system and MPI.
b) proposing performance measures for the food safety and assurance system;
c) identifying future trends, issues, current and emerging risks that may impact on the performance of the food safety and assurance system;
d) advising on how MPI, industry, and third parties can position themselves to protect New Zealand from these risks and issues, take advantage of the opportunities, and remain a world leader in producing safe and suitable food; and
e) advising on any food safety and assurance systems and matters that the Director-General has requested.

While these FSAAC advisory functions remain relevant, the FSAAC members acknowledged at the 30 August 2019 meeting that the "terms of reference may not be representative of the current purpose of the Council". The Director-General has recently set out his expectations of this Council.

Since then FSAAC has met twice (December 2019 and June 2020). Only meeting quarterly does make it challenging for members to fully carry out their duties in any meaningful way and gain the knowledge to be best placed to provide the advice that MPI requires on food and assurance systems.

The FSAAC noted at the December 2019 meeting that the Council needed to build its knowledge and understanding of specific topics and develop a work plan that added real value and has yet to refocus efforts to provide the advice mandated. The FSAAC secretariat is working with the members to develop such a programme and a paper was presented to the June 2020 meeting which suggested a focus for work on e-commerce and risks of changing demographics on food security. This paper was driven by the ideas of MPI/New Zealand Food Safety staff, not the views of the FSAAC. These are both useful areas of risk to consider but only provide limited insights in very specific areas of food safety risk including dairy manufacturing.

Dairy Products Safety Advisory Council (DPSAC)

The DPSAC was established in 1999 to promote communication between MPI and industry, provide advice to MPI and assist in developing standards and policies. Its purpose is to promote the safety and suitability of dairy products (processing and export) through the promotion of two-way exchange of information and is an important element of stakeholder engagement. It is not a decision-making body, nor does it have any decision-making powers in relation to the dairy manufacturing regulatory system.

The scope of its activities includes production standards for raw milk, processing and export standards for milk products and market access issues for exportable milk products.

Its three main objectives are:

- alignment of MPI and industry on strategic objectives and the means to achieve these;
- continuous improvement of the regulatory system for food safety and suitability of dairy products (policies, standards, verification and operational procedures to administer the dairy processing and /or exporting requirements of the Animal Products Act and the Food Act); and
- provision of comprehensive and balanced advice to MPI on matters relating to the regulatory control of food safety and suitability of dairy products.

DPSAC has a membership of up to 25 persons and includes dairy sector regulators, verifiers and industry representatives. It includes representatives from Federated Farmers, Food Standards Australia New Zealand, Infant Nutrition Council, nationally significant dairy processors (including Fonterra), AsureQuality and Eurofins. MPI provides the secretariat function from within Food Regulation. The DPSAC meets at least four times a year. The current chair is Dianne Schumacher (Dairy Companies Association of New Zealand).

DPSAC's intended aims and objectives provide a good framework for their engagement on dairy product regulation and the range of invited parties largely ensures that the views of all engaged in dairy product processing have an ability to be represented – noting that DCANZ represents the views of other less significant member companies. The DPSAC plays a useful role in promoting engagement, and has supported continuous improvement, including through the establishment of working groups to address specific issues.

Standing agenda items include updates on activity from MPI areas with an interest in dairy products regulation (Assurance, Food Regulation, Policy and Trade, Regulatory Redesign Team), updates from working groups and members of the groups i.e. Food Standards Australia New Zealand (FSANZ). As an example, the Food and Live Animal Assurance Team provide a quarterly report on dairy sector performance which incorporates information on performance-based verification, critical exceptions and export non-conformances. The agenda items are a mix of oral and written updates.

These papers provide the ability to support DPSAC conversations and drive exchange of information.

6.2.5 Enhancing governance

It would be good practice for MPI to establish a regulatory governance committee, incorporating independent and industry technical expertise. This would support Senior Leadership Team in discharging its regulatory stewardship obligations. Assuming such a committee was established, expert technical input would be needed to support robust, informed decision making by its members. To be effective it would require regulatory expertise within its membership. The committee would be expected to dedicate itself to understanding how MPI's regulatory systems deliver on the object of the relevant legislation, so that it can advise on good regulatory practice.

6.3 Management monitoring and oversight of dairy manufacturing

6.3.1 Need for effective monitoring, oversight and reporting of dairy manufacturing

Within New Zealand Food Safety there are a number of teams across the Assurance, Regulation and Performance Oversight and Approvals directorates, whose primary role includes some element of responsibility for managing, monitoring and oversight of the dairy manufacturing regulatory system. This includes:

- Verification and operator performance;
- Monitoring and surveillance programmes;
- Laboratory testing programmes.

The operation of each of these components of the regulatory systems have not received significant focus in this review.

6.3.2 MPI oversight of recognised verifier agencies and persons performance

MPI's primary role within the verification system for dairy manufacturing is to maintain oversight of third party verification services provided to RMP operators. Both the Food and Live Animal Assurance Team and Systems Audit Team provide oversight activities.

The Food Regulation Directorate sets the standards for third party verifiers and verification. These standards include the Animal Products Notice: Dairy Recognised Agency and Recognised Persons Specifications 2020, which sets out the key requirements that need to be met by verifiers. The Food and Live Animal Assurance Team and Systems Audit Team in the Assurance Directorate monitors compliance with these standards.

The Dairy Recognised Agency and Recognised Persons Specifications include:

- meeting general requirements such as having quality management systems and documented systems for management activity, competency checking processes for their verifier staff;
- effective records management practices;
- meeting specific requirements around providing operators and MPI with evaluation and verification reports after each verification visit;
- providing MPI with:
  - exception and critical non-compliance reporting within one working day of receipt;
  - monthly reporting on their performance designed to give a complete picture of performance;
  - any accreditation body reports and notifications;
  - exception reporting on critical non-compliance in relation to agency activities.

While the Dairy Recognised Agencies and Persons Specifications empower MPI to carry out audits or investigations for the purposes of determining recognised agency compliance with verifier requirements this power is used infrequently.

All recognised agencies and persons are required to be formally accredited to ISO standard ISO/IEC 17020:2012 Conformity assessment — Requirements for the operation of various types of bodies performing inspection[21]. To continue to be considered a fit and proper provider of verification services, this accreditation is required to be renewed annually. This accreditation assessment activity is done by two bodies; IANZ (Eurofins) and the JASANZ (AsureQuality). This accreditation involves assessment of technical competency and quality management of the recognised agency and its recognised persons. Such annual accreditation provides independent assessment of people, equipment, systems and processes employed by recognised agencies.

At least one member of MPI's Systems Audit Team attends these ISO accreditation assessments as the Technical Expert. The Food and Live Animal Assurance Team also plays a role in reviewing ISO accreditation assessments to ascertain that they provide evidence that recognised agencies continue to meet ISO 17020 and legislative requirements to maintain their recognition.

The Systems Audit Team also carries out a focused triennial review of the three recognised agencies and persons – mainly focused on the quality management systems and other procedures for each of the recognised agencies (AsureQuality, Eurofins and MPI Verification Services). This provides a degree of assurance about the performance of verifier agencies. The last of these reviews was in 2017. Another review is scheduled for 2020.

Systems Audit Team also has numerous other regular and ad hoc interactions with verifiers ranging from processing plant listing audits, trading partner competent authorities audits to workshops and working groups, education activities and industry events. Systems Audit Team keeps a record of these oversight activities, which can be provided to overseas competent authorities as required.

Verifiers (AsureQuality and Eurofins) are required to provide a copy of each RMP verification report to the processing plant operator and MPI. The Food and Live Animal Assurance Team undertakes a desktop review of five percent of the monthly PBV reports verifiers complete. The results of this review and any salient comments from the MPI reviewers are recorded via spreadsheet and inform reporting to Food Safety management. Feedback may also be provided to the recognised agencies. In most instances MPI's comments are positive about the quality of the third party verifier reports. Critical comments are sometimes focused on grammar and writing style, rather than highlighting any substantive concerns related to the verification process itself.

Recognised agency performance in terms of dairy export non-conformances and critical exceptions is also monitored by the Food and Live Animal Assurance Team and Systems Audit Team. Recognised agencies are legally required to monitor and report such incidents in a timely and effective manner. The Food and Live Animal Assurance Team are responsible for following up with operators on major incidents reported by recognised agencies. This allows them to gain some comfort about how recognised agencies manage the monitoring and remedying of non-conformances and critical exceptions.

Reporting of data on PBV assessments and agency management of export non-conformances and critical exceptions forms the

21 See https://www.iso.org/standard/52994.html

basis of internal and external monthly and quarterly reporting to New Zealand Food Safety leadership and DPSAC. These reports provide insights into the performance of verifiers and assists continuous improvement of the regulatory system for dairy manufacturing.

6.3.3 MPI's role in managing monitoring and surveillance programmes

MPI has established a number of monitoring and surveillance programmes to ensure compliance with elements of food safety and good agricultural practice requirements, including the effective management of biological and chemical contamination, including:

- Independent Verification Programme (IVP): a programme that is designed to monitor microbiological, and standard-of-identity parameters[22] in dairy products, according to industry standards. IVP checks that dairy products are safe, wholesome and true to label. Operators who manufacture dairy products and operate under risk-based management plans must include independent sample testing programmes to identify non-conformances and confirm the accuracy of routine monitoring. The requirements of the IVP are set out under the Animal Products (Dairy Processing Specifications) Notice 2011 and DPC3: Animal Products (Dairy) Approved Criteria for the manufacture of dairy material and products.
- National Chemical Contaminants Programme (NCCP): is run by MPI and monitors milk and dairy products to confirm that residue or contaminant levels do not exceed acceptable limits for domestic sale and export, and tests for a wide range of agricultural compounds and veterinary medicines. The programme is authorised under the Dairy Industry (National Residue Monitoring Programme) Regulations 2002.
- Laboratory Monitoring: MPI recognised laboratories carry out testing and regulatory sampling of food products, including dairy products, to ensure products meet New Zealand minimum food safety requirements and any additional OMARs.

6.3.4 Sampling and testing of dairy products

Regular examination, sampling and testing of animal material and products including dairy products to determine their composition, or status, or fitness for intended purpose, or suitability for their intended use, is provided for under the Animal Products Act, and prescribed through regulation. In addition to MPI managed monitoring and surveillance programmes, dairy manufacturers are required to regularly send product samples to laboratories registered with MPI, for regulatory testing in accordance with domestic and export market sampling and testing requirements.

Such sampling and testing is a fundamental component of MPI's risk monitoring and reporting regime, and provides information for official assurances. Sampling and testing requirements and records will be audited during verification audits.

As with the contracting of verification services, dairy manufacturers can directly purchase testing services from recognised laboratories. Some manufacturers also have in-house laboratories that are recognised agencies for this type of testing. Laboratories provide test results back to the contracting manufacturer, and reporting of results of testing required by MPI remains the responsibility of the manufacturer.

Established through the Dairy Industry (National Residue Monitoring Programme) Regulations 2002 and National Chemical Contaminants Programme Operational Code (NCCP), operators of RMP are required to monitor milk for chemical residues and contaminates. Operator monitoring checks the chemical residues and contaminants in animal materials and products, including dairy materials (raw milk and dairy products), to ensure domestic and export market requirements are not breached. The NCCP is statistically designed to provide an assurance for processing plants operating under a risk management programme that at least 99 percent of milk conforms to New Zealand and international requirements and has a confidence limit of 95 percent.

The annual sampling and testing plan for raw milk and colostrum is published on MPI's website (with the minimum required detail) at the start of the dairy season. NCCP limits are published on the MPI website as part of the annual sampling plan. The programme consists of:

- random monitoring of raw milk at the farm bulk milk tank – sample types and numbers provided by MPI in conjunction with annual sampling plan;
- directed surveillance of dairy material (which poses a higher risk of containing chemical residues and contaminants) at the farm bulk milk tank, milk tanker or dairy processing plant; and
- surveys with variable factors, such as time of year geography, etc., designed to assess the chemical residue and contaminant status of a specific population for an emerging or potential residue issue.

Under the NCCP, analysis of raw milk and dairy product samples for chemical residues and contaminants can only be undertaken by recognised or authorised laboratories, using validated and approved methods of analysis. Such laboratories must be:

- a laboratory recognised by MPI;
- contracted to provide testing services to MPI;
- meet the requirements set out in the current edition of the Animal Products Notice: Specifications for Laboratories; and
- meet the requirements set out in the Animal Products Notice: Dairy Recognised Agency and Recognised Persons Specifications 2015.

Where testing indicates non-conformance with a residue or contaminant limit, the RMP operator will be advised without delay[23] and must:

- determine whether a regulatory limit has been breached, should there be any doubt (i.e. to confirm that the dairy material was intended to be eligible for a market to which the regulatory limit applied);
- in the case of a raw milk sample, request that the farm dairy operator be advised and a farm trace back undertaken to determine the source and cause of the residue, with the outcome reported back; and
- advise that the dairy material must be traced forward and any dairy material found to be nonconforming, managed in accordance with the requirements of the Animal Products (Dairy

22 Standard -of-identity parameters relate to the nature, composition and characteristics of a product – these parameters are not always monitored for all dairy products in the IVP.

23 Operational Code: National Chemical Contaminants Programme, MPI, Part 5: Exception Results, 21 September 2016

Processing Specifications) Notice 2011 and the DPC 1: Animal Products (Dairy): Approved Criteria for General Dairy Processing, and that any recipients of non-conforming dairy material be immediately advised.

In addition to regulatory residue limits for dairy material, because a range of regulatory limits may apply to dairy material depending upon the scope of the RMP under which it is processed and the intended market, nominal action limits are also established based upon the regulatory limits of New Zealand, Codex and major export markets.

6.4 Use of information for managing risk and continuous improvement reporting

6.4.1 Context

Having effective and efficient information and intelligence gathering mechanisms that support identification of regulatory risks are valuable tools to support proactive system management.

An effective and joined-up approach to reporting on regulatory system performance and improvement helps to:

- get business/operational improvements;
- re-engineer processes to prevent operator workaround;
- innovate for emerging technologies/products/methods of production etc.; and
- continually improve to meet better practice.

6.4.2 The environment for information and data collection for performance and improvement

The WPC inquiry report identified the systems needs to ensure the fast flow of information and intelligence to the top of the organisation particularly in cases of "bad news". Information and insights are often provided to decision makers on an issue-by-issue basis which does not necessarily stimulate forward, longer term thinking about regulatory system improvement. The use of joined up information systems, and feedback loops to stimulate this improvement could be developed within MPI.

A formal mechanism to consider emerging issues, risks and insights would help to alleviate the reliance on individuals who take personal responsibility for ensuring that such information is provided to those who require it to act.

MPI could prioritise active data and information sharing culture by implementing the right tools and technology to support improved collection and data analysis.

6.4.3 Information sharing across MPI

Front line staff involved in monitoring and oversight activity through their interactions with operators and other dairy manufacturing stakeholders all for different purposes continuously receive information that can provide valuable insights on issues and concerns of the day. Examples include:

- Food Compliance (hot topic reports, daily scans of global recalls);
- Systems Audit Team (system audits and investigations, country listings for plants, recognised agency and person performance assessment, quota compliance programme evaluation);
- third party verifiers (performance-based verification reports);
- recognised laboratories (monitoring and surveillance results) via operators;
- Food and Live Animal Assurance Team (regular export non-conformance reporting etc.);
- chemical and microbiological teams (reports on National Chemical Contaminant Programme related issues etc.).

MPI has a formal intelligence function housed within Biosecurity New Zealand. Within that function there is a National Intelligence Team which is responsible for the development and dissemination of strategic and operational intelligence products to inform decision makers across the breadth of the work MPI does, from the food system to trade, animal welfare and fisheries.

The National Intelligence Team's ability to provide meaningful intelligence and data insights specifically on food safety and dairy manufacturing is evolving. The team has considerable experience in relation to dairy stretching back to 2012, which includes key roles in the Parallel Export of Infant Formula (PEIF) and WPC Responses, Operation Concord (1080 in infant formula threat) and the recent investigation into non-compliance exports. The team has people with specific food safety related skill sets and has undertaken some targeted work like the 2018/2019 analysis of Infant and Young Children Formula exports to determine compliance of the Animal Products Notice – Export Requirements for Infant Formula Products and Formulated Supplementary Foods for Young Children – 01 Feb 2016.

6.4.4 Data, information and insights

Intelligence gathering is a discipline that uses data and information collection and analysis to provide guidance and direction to assist leaders and people in their decisions. In MPI the intelligence gathering process can be applied to help with decision making across all regulatory systems, including the dairy manufacturing element of the food safety system. Intelligence gathering can take the form of data, information and insights collated from a range of domestic and international sources.

The type of information that could be beneficial to share might include:

- information to food manufacturers on emerging issues;
- international emerging risks and issues;
- lessons from complaints and non-conformances; and
- market access requirements.

The various MPI teams involved in the regulatory system could help build a better picture of the performance and support continuous improvement through consistent collection and sharing of such information.

MPI uses a variety of legacy systems and mechanisms for collecting information and insights. These systems are not interoperable. There are opportunities to improve reporting and insights through better use of available data and information, even given current technology constraints. Updating MPI's systems would also support improved use of data and information.

The MPI Food Safety Strategy Action Plan 2020-23 proposes developing a data insights team which will focus on integrating data and identify trends and key findings to drive improvement. It also proposes developing an emerging food safety risks (or

early warning system) function to provide stronger direction and coordination over new hazards. These are actions which should drive greater insights.

6.4.5 Ease with which external parties can share issues and risks with MPI

MPIs website provides an 0800 number which can be used for reporting exotic pests/diseases, illegal fishing and to report concerns on food safety issues, such as food recalls and labelling issues. MPI is also in the process of setting up a more formalised and centralised complaints management process which utilises customer relationship management tools.

While dairy manufacturing operators are required to report food safety and other dairy non-conformances to MPI, there is no formal mechanism that allows anonymous reporting by workers in processing plants to raise concerns with MPI.

6.5 Compliance and enforcement

6.5.1 Expectations of compliance and enforcement

Compliance and enforcement are essential components in providing assurance that a regulatory system is effective. Having a transparent approach to compliance and enforcement activity that is evidence-informed, risk-based, responsive and proportionate to the risks or harms being managed is a fundamental expectation that stakeholders have of the regulator.

An effective compliance and enforcement framework depends on striking the right balance between incentive and punishment, understanding and capability, so as to encourage compliance and discourage non-compliance.

The regulatory system for dairy manufacturing requires a range of internal and external parties to play a role in different types of compliance activity including those that play a role in:

- granting approvals, recognition of verifiers, laboratories, operator risk management programmes and export assurances (compliance through licensing and registration functions);
- monitoring and auditing the performance of verifiers and operators (compliance through verification, audit and inspection assurance oversight functions); and
- undertaking compliance, surveillance and enforcement roles to identify and remedy non-compliance issues (compliance through enforced and directed management activity).

As this report has already addressed a number of the above compliance activities, this section focuses on the role that MPI's Compliance Services directorate plays in dairy manufacturing related compliance and enforcement activity.

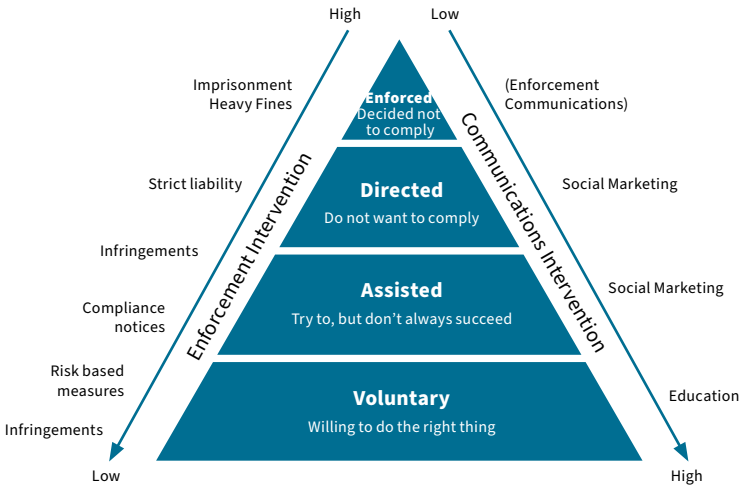
6.5.2 Application of the VADE compliance model

MPI applies a voluntary, assisted, directed and enforced (VADE) approach to compliance and enforcement activities. This approach was adopted from the former Ministry of Fisheries model[24], and subsequently used as the basis for a cross-MPI compliance and enforcement model. The VADE approach supports MPI to take a scalable approach to the management of regulatory compliance issues. This is intended to ensure that compliance action is appropriately weighted to any particular compliance issues. Figure Two sets out how the VADE approach is intended to operate for enforcement type activity.

Figure Two: MPI VADE Model

6.5.3 Role of the MPI Food Compliance Team in regulating dairy manufacturing

The Compliance and Governance Business Unit is the centre of



excellence/leadership for compliance enforcement activities in MPI. Within Compliance and Governance the Compliance Services Directorate is responsible for the operational delivery of compliance enforcement, inspection and prosecution services. The Food Compliance Services Team within the Compliance Directorate has specific responsibilities for dairy and other food related compliance issues that do not fall under the remit of the Assurance Directorate in New Zealand Food Safety. The team has around 30 FTEs.

The Food Compliance Team becomes involved when product recall or potential serious offending is identified. At present the team's approach is generally reactive, however, additional resourcing provided through the 2019 Budget, will likely increase proactive work.

Currently, the Food Compliance Team uses a risk-based, graduated and proportionate approach to compliance enforcement (whether Food Act or Animal Products Act related). This supports a food safety culture that encourages operator compliance and effectively intervenes to address non-compliance where it occurs. The approach also provides for resources to be prioritised according to risk. Priority is given to compliance issues where there is:

- an imminent risk to public health;
- an actual or potential threat to New Zealand's trade reputation;
- an incident that would violate the fundamental basis of the regulatory regime; or
- intense public interest.

6.5.4 Powers available to the regulator to enforce compliance

24 Based on the Braithwaite model

The WPC80 inquiry reports observed that the food safety system in New Zealand had fewer compliance enforcement tools available to it than similar jurisdictions in Australia. The Inquiry team recommended that the Ministry should have a broader suite of compliance tools available to it including both criminal and civil penalties and enforceable undertakings.

Since then the New Zealand compliance and enforcement powers have been expanded for the food sector by new and revised legislation. The Food Act introduced new compliance and enforcement tools, with a graduated compliance regime to support assisted and directed compliance. The Food Safety Law Reform Act 2018 further modernised and standardised these compliance tools so that they also applied to operators and businesses covered by the Animal Products Act and Wine Act. An important change introduced, for the first time, the ability to issue improvement and infringement notices. As part of the Regulatory Redesign, regulations are being developed that will implement these tools.

6.5.5 Food compliance strategy

MPI has acknowledged that it would benefit from a compliance strategy to guide the range of activities that fall within the broad understanding of the concept of food safety compliance.

In late 2019 MPI established a Compliance Oversight Group (COG) to drive a more forward looking, strategic view of regulatory compliance and strategies for compliance activity across the Ministry. The role of the COG will include deep dives to examine compliance plans, priorities, risks and opportunities for food safety, fisheries, animal welfare, biosecurity and ETS compliance. The COG will play an important role in considering how compliance and enforcement can contribute to regulatory stewardship activity. An essential input into the COG's work will be specific direction from New Zealand Food Safety on its compliance priorities.

Pointing to the importance of coordinated regulatory system activity, it was acknowledged at the COG meeting on 17 March 2020 that there is a need to "better incorporate the MPI Compliance Services Directorate as a part of the Food Safety System" – this could include a greater role in dairy manufacturing compliance where required. Benefits of doing so could include:

- New Zealand Food Safety providing a greater degree of direction for enforcement activity.
- New Zealand Food Safety setting priorities for compliance, including enforcement, based on compliance patterns observed across the system including trends in chemical and microbiological assurance monitoring and verification outcomes and insights, although noting this is already done with the Co-Regulatory Panel for compliance under the Food Act 2014.
- Increased input from the compliance teams into the New Zealand Food Safety system to inform future priorities and actions. For example, one mechanism could be to include MPI Compliance Services data in New Zealand Food Safety's Titiro system to allow analysis of the national compliance picture.
- Increased deliberate choice on a range of 'compliance' activities (including education) based on analysis of information held by New Zealand Food Safety, including behavioural patterns and compliance rates.

The COG noted at its 17 March 2020 meeting that the "development of a MPI Compliance Strategy will need to be clear about what type of compliance is desired and what this looks like including which sectors, standards, foods etc. should be the focus, as well as which are the appropriate tools to fix the 'problem'. Whilst outcomes are one aspect (usually 'safe and suitable food') there are 'hard' inputs such as effective operator self-verification and 'softer' inputs such as culture. The strategy will also need to take into account that MPI Compliance Services is only one of the regulatory parties undertaking compliance under the Food Act – in particular the various Territorial Authorities also have a significant role to play. The strategy could also address the various roles and responsibilities for oversight of the entire compliance function," how it moves to adapt for changing environments and new risks. Such a strategy would be expected to support compliance enforcement activities, including in dairy manufacturing.

6.6 Regulatory stewardship within MPI

6.6.1 Requirements for regulatory stewardship

"Regulatory stewardship is a responsibility of government regulatory agencies. It involves them adopting a whole-of-system, lifecycle view of regulation, and taking a proactive, collaborative approach, to the monitoring and care of the regulatory system(s) within which they have policy or operational responsibilities."[25]

Under the Public Services Act 2020, the Director-General is responsible for stewardship of the legislation MPI administers.

The Secretary to the Treasury holds functional responsibility on behalf of the government in ensuring good stewardship within government agencies. In 2017 guidelines were published by The Treasury: The Government Expectations for Good Regulatory Practice, covering both the design of regulatory systems and the regulatory stewardship requirements of government agencies. The aim is to ensure that New Zealand has a durable and effective system of high quality regulation. Regulatory failures continue to highlight that it is incumbent on agencies to proactively identify and manage any risks to their effective administration of regulatory systems under their management.

The Government expects MPI to publish annual descriptions of regulatory systems, views of the important emerging issues for regulation, and plans for new regulation or amendments to existing regulation. This includes expectations around regulatory systems reviews on a rolling basis with regulatory stewardship being built into business as usual.

Recently other government agencies with multiple regulatory responsibilities such as MBIE and NZTA, have established dedicated regulatory stewardship functions. These functions are tasked with monitoring and reviewing regulatory strategies, frameworks, and implementation to support continual improvement.

In MPI, there are roles with specific responsibility elements of regulatory stewardship. These include a small Regulatory Stewardship Team in Policy and Trade, Inspector General Regulatory Systems, and Legal Services. Opportunity exists for

25 Treasury, https://www.treasury.govt.nz/information-and-services/regulation/regulatory-stewardship#:~:text=Regulatory%20stewardship%20is%20a%20responsibility,have%20policy%20or%20operational%20responsibilities

these teams and other parts of MPI to collaborate to further the regulatory expertise and focus within MPI.

6.6.2 MPI's Regulatory Stewardship Team

MPI has a small dedicated Regulatory Stewardship Team (two FTE) situated within the Food, Skills and Science Directorate in Policy and Trade. This team undertakes high-level annual descriptions of MPI regulatory systems as per Government expectations. Additionally, among other activities, as per Treasury's guidance[26], the Regulatory Stewardship Team has undertaken regulatory system health assessments on a rolling four yearly basis considering the effectiveness, efficiency, durability and resilience, and fairness and accountability for each of the overarching systems: food safety, fisheries, biosecurity, animal welfare, agriculture and forestry.
The summaries of these reports are published on MPI's external website and use the following framework.

- **Effectiveness** – the extent to which the system delivers the intended outcomes and impacts;
- **Efficiency** – the extent to which the system minimises unintended consequences and undue costs and burdens;
- **Durability and Resilience** – how well the system copes with variation, change and pressure; and
- **Fairness and Accountability** – how well the system respects rights and delivers good process.

The food safety system was reviewed in this way in 2019, providing a snapshot of the health of the system across the elements above; elements central to ensuring good regulatory practice. In this respect the health assessments support ongoing governance of the regulatory systems reviewed, through assessment of the current operating state of a regulatory system at a macro level. While valuable in assisting system governance bodies to understand the general health of the regulatory system, these reviews do not provide much information on particular regulatory subsystems, such as dairy manufacturing.

Regulatory thought leadership, research on good regulatory practices and deeper proactive regulatory audits or reviews have traditionally been the responsibility of the Deputy Director-Generals responsible for system components.

There is regular work undertaken in Policy and Trade that assists with informing food safety decisions by the Minister, the Director-General, Senior Leadership Team, and New Zealand Food Safety. For dairy manufacturing, this includes strategic policy and legislative change work relating to the Animal Products Act and Food Act, and work by the Research and Evaluation Team, such as "Public Perceptions of New Zealand Food Safety Culture" (June 2019) and "Food Safety Culture in New Zealand Businesses" (November 2017).

6.6.3 Legal Services

In recent months, the Legal Services Team have helped to stimulate targeted regulatory stewardship discussions with MPI Senior Leadership Team. For example, in 2019 the team completed an assessment of regulatory roles played by third parties across MPI's regulatory systems.

6.6.4 System Audit Team's contribution to regulatory stewardship for dairy manufacturing

The systems audit function, which sits in New Zealand Food Safety, has existed since the early 1990s. The function was set up to provide oversight of verification practices and to stimulate improvement across the food safety regulatory system. The current team comprises 13 system auditors, a technical coordinator and manager. It provides assurance over elements of the food safety regulatory system by:

- auditing elements of the regulatory system to assess compliance;
- assessing the suitability and effectiveness of regulatory measures;
- undertaking processing plant listing audits (when a manufacturing plant commences operating);
- accompanying trading partner competent authorities on audits of New Zealand facilities; and
- assisting with investigations of compliance breaches.

Through these functions, the Systems Audit Team provides a vital lens over the operation of elements of the broader food safety regulatory system, not just dairy manufacturing. The resource dedicated specifically to dairy manufacturing is limited – over the last five years much of the effort in the dairy sector has been on special audits of specific dairy processing plant compliance.

End to end oversight of the food safety regulatory system, including for dairy manufacturing, could be strengthened. While Systems Audit Team is not tasked to do this work, it could contribute to gaining an holistic view of how the overall food safety regulatory system is working.

26 Government Expectations for Good Regulatory Practice, The Treasury, New Zealand Government, April 2017, https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf

7 Traceability, and readiness and response

In spite of best efforts, food safety problems will inevitably occur. The first step in putting things right is the identification and removal of all affected items from the food chain. Simple and straightforward food recalls are something that MPI deals with on a regular basis.

7.1 Context

Food recalls are normally managed by New Zealand Food Safety and Food Compliance Team. However, more complex and significant events which could entail the removal of a whole production of a plant or an entire product range from the supply chain require more sophisticated and organised systems of tracing, recall and contingency planning.

7.2 Readiness and response

7.2.1 Readiness and response activity

MPI has a centralised readiness and response capability and resources based within a Readiness and Response Services Directorate in Biosecurity New Zealand. This Directorate brings together critical capability to effectively prepare for and manage responses, and to coordinate recovery and long-term management activities, working across biosecurity, food, primary production and trade systems.

There are trade-offs that this shared portfolio has had to make in driving the focus of its work and resources. The directorate has been situated within Biosecurity New Zealand for a number of years – over time most of its focus has been spent on Biosecurity related response and readiness activity.

Food safety expertise and decisions about when to stand up a food safety response remain the responsibility of New Zealand Food Safety. Indeed, many of the activities that form part of a typical food safety response are managed by the Food and Live Animal Assurance Team and Food Compliance Team without the involvement of the Readiness and Response Services.

Enforcement expertise is provided to New Zealand Food Safety by the Food Compliance Team, from within Compliance and Governance. The National Intelligence Team in Biosecurity New Zealand provides intelligence support in the form of tracing, risk and threat assessments and intelligence work stream leadership.

MPI has a relatively limited focus on food safety readiness and response and could benefit from dedicated resource for food safety preparedness and response planning, whether in relation to incorrect/misleading labelling, food borne illness, or contamination. Readiness and response in New Zealand Food safety could be enhanced by:

- clarifying the protocols for when to initiate a formal response and engage Readiness and Response Services, i.e. criteria for determining when to move from business as usual work into formal response e.g. scale of event; and
- regular assessment of current state of readiness, including use of representative scenarios to determine readiness priorities.

7.2.2 Food safety response simulation

An important element of preparedness and readiness for significant events is simulation and practice exercises. There has been a limited focus on food safety response simulation exercises in recent years. Since the WPC80 incident only one exercise (Exercise Ariadne) has been run in food safety response. Exercise Ariadne was run with Fonterra in 2016 and focused on traceability in the event of food contamination. There have been no exercises since, although a food safety scenario (Simulation Wight) was piloted in May 2018 and is subject to review in 2020.

More focus could be given to food safety related readiness and response. This was raised and considered at the most recent December 2019 Food Safety Steering Group meeting. While activity has been undertaken on some elements of people capability readiness for a response, these could usefully be prioritised within New Zealand Food Safety and the wider MPI.

Prior to the Covid-19 outbreak, the MPI Readiness and Response Directorate and New Zealand Food Safety had started to work together to:

- set expectations about the overall readiness goals for the food safety system;
- establish a benchmark against which food safety system readiness can be strengthened, tested and validated, including through using a programme of exercises;
- focus food safety readiness investment; and
- provide a means for demonstrating to Ministers, stakeholders, consumers and markets, the level of readiness that the System has achieved, building trust and confidence.

More could be done, which has been recognised in the recent work that the Director Food Safety Review has undertaken to identify areas that could be prioritised for funding.

7.3 Traceability

7.3.1 Importance of tracing

Rapid and effective product tracing is well understood to be a core component of a robust and credible food safety system. MPI's product tracing systems have a dependence on manual collation and analysis. A key element of any food safety response is the ability to quickly trace and recall product. This was highlighted by the WPC reports, which noted: "Tracking and tracing implicated food products throughout a complex food chain in times of a food crisis presents enormous difficulties, particularly when a contaminated ingredient has been widely used in the manufacture of different food products" and that it is essential to be able to "rapidly trace and recall products". The report also noted that "nothing could have hamstrung [the response] more thoroughly than" the "failure to trace contaminated products quickly and accurately".

7.3.2 Effectiveness of tracing practices by operators and MPI

Responsibility for product traceability, as with food safety generally, sits with manufacturers and operators of risk management programmes. MPI through New Zealand Food Safety is responsible for checking that manufacturers have the required ability to recall animal material and products for export, where a product may not be fit for intended purpose or in accordance with its labelling.

RMP operators are required to take, at a minimum, a one up, one down approach to tracing. This means they can identify where a product was received from (one up) and where any of that product is then sent (one down). While this seems a reasonable approach, it does mean that a dairy manufacturer may only be able to provide MPI with incomplete information on ingredient origin, or final product destination due to the complexity of supply chains. This gives rise to the issue of information management and how MPI collects, collates and analyses dairy product tracing information.

During the WPC incident, the recall of the potentially affected product was a manual process with data gathered by the tracing team and then mapped by the National Intelligence Team. Since WPC80, this process has remained largely manual, although tracing data is able to be extracted from MPI's animal product electronic certification system (AP E-cert), for all infant formula and formulated supplemented food for young children exports[27], as well as other dairy products that require an official assurance. The notice now requires an exporter to provide an exporter declaration for product that does not otherwise require an official assurance. This does not apply to exports to Australia.

Analysis of AP E-cert data has been supplemented by the use of Microsoft Business Intelligence (BI) Hub reporting tools. While these systems support export product traceability, they are not purpose built for tracing, and BI Hub functionality has not been without issues. For instance, in 2018 upgrades to the AP E-cert system meant that for several months it could not be used for traceability.

Challenges also exist with MPI's ability to access New Zealand Customs Service consignment data through the Joint Border Management System (JBMS). As with AP E-cert, JBMS is not designed as a product tracing tool, and cannot therefore be expected to provide comprehensive dairy products tracing data.

A greater focus could be turned to traceability risks associated with cross-border e-commerce sellers, and grey trade. Given the lack of enforceable traceability controls and paucity of information on exports through such channels, the concept of an "export control act" was put forward as a potential way of effectively mitigating the risks posed by grey trade through e-commerce channels.

A policy development programme on export legislation is being considered currently to address some of these challenges. As New Zealand's food safety regulator, MPI could consider whether the current systems it uses for traceability are sufficient as part of this process.

27 Animal Products (Export Requirements for Infant Formula and Formulated Supplementary Food for Young Children) Notice, 1 February 2016, https://www.biosecurity.govt.nz/dmsdocument/11164/direct

8 How systems improvement is achieved

Improving the operation of the regulatory framework and the components of the management and administrative functions and processes that make up each regulatory system is a constant and evolving process.

8.1 Overview

Having a commitment as a regulator to continuous systems improvement is important; no regulatory system is ever perfectly tuned to address the complexity of human motivations and interactions. In order to remain effective, efficient and durable systems need to be responsive and have the ability to continuously improve in the face of emerging challenges, political, economic, social and environmental change, in order to deliver the intended legislative objectives and outcomes over time.

8.2 How continuous improvement of regulatory systems is achieved

8.2.1 Key contributors to continuous improvement

With any regulatory system, regular evaluation that supports continuous improvement is necessary. Continuous improvement of the system is dependent on a number of factors; it requires the regulator and service delivery agencies involved to have the right structures, mechanisms, processes and capabilities in place to stimulate change. It needs the regulator to have agile ways of working to test out new ways of making and implementing policy and regulation. Each element of continuous improvement needs to be informed and driven by organisational culture, as it relies on people to implement processes, share information, and work collaboratively across regulatory system components.

Importantly it also needs the right mix of monitoring, oversight and reporting around system quality assurance, system performance and system review activity to ensure system decision makers are provided with timely feedback, information on emerging risks and changes in policy to stimulate change and improvement. The structures, mechanisms, processes and capabilities required for continuous systems improvement include:

- Effective regulatory design;
- Effective governance, accountabilities and management;
- Resourcing – capacity and capability;
- Information, analysis and insights to improve systems design and operation;
- Performance management; and
- Assurance over how regulatory systems operate.

This review has already commented on a number of these elements including effective regulatory design (Section 5.4), effective governance, accountabilities and management (Section 6.2), information analysis and insights to improve systems design and operation (Section 6.4) and assurance over how regulatory systems operate (Section 5.3, 5.5 and 5.6).

8.3 Resourcing

8.3.1 Elements of resourcing

Resources in the public sector are always constrained. However, effective operation of a regulatory system requires administering agencies to maintain the capability and capacity to deliver the intended legislative outcomes. This means having the physical and technological infrastructure, and people with the right expertise to operate and adjust regulatory systems to achieve intended outcomes. With approximately 60 Acts of Parliament to administer, for MPI, this is no simple task.

In this regard, MPI is faced with the challenge of operating in a relatively small domestic labour market, with competition for sector specific technical expertise from a relatively large industry. While staff capability and expertise are areas given regular attention at the organisation-wide level, certain dairy technical expertise resides in the heads of only a few people in MPI. In an era where people change jobs regularly, staff attrition is a known risk and challenge for any organisation that depends on specialist technical expertise to function effectively. This is the case for the effective and efficient operation of elements of the dairy regulatory systems. MPI faces increased staff retention challenges in an industry that seeks to acquire capable technical expertise.

The effective operation of the dairy manufacturing regulatory system also requires industry to maintain the regulatory, technical and operational capability and capacity to meet regulatory requirements. This means that both RMP operators and third party verifiers face essentially the same staff recruitment, development and retention challenges as MPI. This may also be further exacerbated by a shortage of suitable and appropriately qualified individuals graduating from domestic universities. One potentially significant difference between private sector and public sector recruitment and retention, however, is the greater willingness and ability of businesses to increase incentives and benefits to attract, train and retain the talent that they require. Operators were interested to understand MPI's role, if any, in growing dairy industry expertise, in particular, regulatory knowledge and skills for New Zealand.

8.3.2 Challenges of resourcing MPI regulatory activities

Many of the human, physical and technological resources that support regulation of dairy manufacturing come from across different parts of MPI, and support the operation of other regulatory systems as well. As a consequence, effort must be prioritised between regulatory systems. In addition, the technology, data and analysis systems are not always purpose built.

8.3.3 Challenges of resourcing in the dairy manufacturing sector

There is a shortage of experienced people with dairy processing or regulatory experience at every level of the dairy regulatory sector. This was something that was highlighted as part of the WPC80 inquiry report. This shortage in expertise is perceived to create challenges across various areas of the system, including for RMP verification, providing credible technical knowledge and regulatory leadership within MPI and to the dairy industry.

As a result of the WPC80 inquiry report, a Dairy Capability Working Group was set up to develop a strategic plan to build sector wide processing and regulatory capability. They reported back in December 2015. Their report made ten recommendations for enhancing dairy capability. At the time, MPI developed a number of initiatives aimed at improving food safety leadership and culture, such as the proposal to develop voluntary food safety governance guidelines for company directors, and for the establishment of a food safety excellence awards scheme; and highlighted proposals for longer term actions such as those to enhance availability and accessibility of food safety education and training and raise the profile of food safety careers. The Skills and Regulatory Stewardship Team in Policy and Trade continue to work on further initiatives to encourage and support people into careers across the whole primary sector.

8.4 Performance management and measurement

8.4.1 Purpose of performance management

The management and measurement of the performance of the food safety regulatory system for dairy manufacturing, plays an important part in helping to deliver continuous improvement. System-wide performance management and measurement would support assessment of whether the object of the Animal Products Act is being achieved, provide staff a sense of direction and purpose, and establish a foundation of trust by helping improve stakeholder understanding and confidence in the agency.

Achieving good performance measurement requires an understanding of the motivation for performance measurement, an understanding of what can be measured and how to deal with the immeasurable, how performance measurement data can be transformed to knowledge and lessons and how it can contribute to goal achievement.

Performance measurement requires a simultaneous evaluation of the performance of each system component, as well as the overall system, against legislative intentions and within the bounds of Government policy. One basic measure that can indicate that a system is no longer preforming is where Government policy no longer aligns with existing legislative intentions. There are various components of performance management, which lie with different parts of the organisation.

8.4.2 Role of Policy and Trade in performance management

In terms of the regulatory system for food safety in dairy manufacturing, Policy and Trade is responsible for undertaking regulatory policy review and redesign work, ensuring that legislation remains fit for purpose. Central to this is supporting Ministers to act as good stewards of the public interest, including by maintaining the currency of legislation administered by the agency and providing advice on the long-term implications of policies[28]. This requires close collaboration across the core components of the Food Safety regulatory system as it relates to dairy manufacturing. Regular feedback on operational considerations and actual outcomes achieved from New Zealand Food Safety and Compliance and Governance is a critical element in this process.

8.4.3 Role of New Zealand Food safety performance management and measurement activity

MPI does not have clear performance measures and systems for monitoring performance of the dairy manufacturing food safety regulatory system as a whole. There are pockets of performance management practice across New Zealand Food Safety activities which include:

- **Food safety related performance indicators** – this includes a suite of measures designed to cover both external reporting requirements and the requirements of MPI to measure its own performance in delivering both strategic and operational outcomes and outputs.
- **Reports on central elements of dairy sector regulatory performance for the Dairy Products Safety Advisory Council** – this is a series of quarterly reports which provide an overview of performance-based verification, critical exceptions and dairy non export conformances.

Ongoing performance management and measurement of the operation of the dairy manufacturing regulatory system is often seen as more reactive. The regulatory system can be considered to be performing well so long as there is not a significant regulatory failure.

MPI could improve performance management and measurement by setting and monitoring regulatory performance measures. Good practice monitoring that supports continuous improvement is considered to include periodic end to end evaluation of regulatory systems. New Zealand Food Safety recently commissioned a review to identify challenges in the food safety regulatory system.

28 Public Services Act 2020, section 52(1)(d)(ii) and (iii): General Responsibilities of chief executives of department and departmental agencies, http://www.legislation.govt.nz/act/public/2020/0040/latest/LMS179758.html

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Te Kāwanatanga o Aotearoa
New Zealand Government