Submission of MPI to the Government Inquiry on the WPC Contamination Incident Parts B&C (October 2013)

This document has been proactively released to supplement the final report of the Government Inquiry into the Whey Protein Concentrate (WPC) contamination incident and the Government's response to that report.

Some information in these documents is withheld in line with the following sections of the Official Information Act (as applicable):

- s.6(a) – prejudice of international relations;
- s.6(c) – prejudice of the maintenance of the law, including investigating offences;
- s.9(2)(a) – to protect the privacy of natural persons;
- s.9(2)(b)(ii) – prejudice of the commercial position of the subject of the information;
- s.9(2)(ba)(i) – protect information which is subject to an obligation of confidence;
- s.9(2)(c) – prejudice the role of the Government Inquiry as a measure to protect health and safety of the public
- s.9(2)(h) – legally privileged information

Ministry for Primary Industries
Manatū Ahu Matua

Submission of the Ministry for Primary Industries to

The Government Inquiry on the Whey Protein Concentrate Contamination Incident

October 2013

New Zealand Government

Growing and Protecting New Zealand

Contents

[Withheld under s.9(2)(ba)(ii)]

1 Executive summary

The Ministry for Primary Industries (MPI) is strongly committed to protecting the public by maintaining and strengthening our food safety system. New Zealand's system has an excellent international reputation and underpins the good reputation of New Zealand's food products in overseas markets.

Our food safety system has been recognised by both the European Union and the United States via mutual recognition arrangements that few other countries have achieved. However, we must continuously adapt our food safety system to meet new challenges and opportunities, both here and overseas.

The creation of MPI brought together experts in the regulation of the primary sectors, biosecurity and food safety. We are able to leverage a wide range of skills and capability across the organisation to support work in the food safety portfolio. Ultimate responsibility for food safety rests with the Director-General.

MPI supports the food safety system through activities across all our branches, including:

- developing policy advice and legislation;
- developing and implementing food safety and suitability[1] standards that are science-driven and risk-based as appropriate, and communicating them to those who must comply with them in a clear manner;
- verifying that all food produced, processed and consumed in New Zealand meets relevant domestic, import and export standards;
- providing export markets with assurances that food is safe and suitable through the effective implementation of science-and-risk-based standards;
- progressing international trade negotiations to enhance market access for New Zealand food businesses;
- monitoring compliance with relevant standards and investigating food-related incidents;
- overseeing traceability and recalls of products by industry, and exercising recall powers where necessary;
- managing non-compliance through a range of compliance tools;
- influencing international standards for food in trade so that they reflect New Zealand interests; and
- communicating with stakeholders and consumers.

The Food Operational Co-ordination Group (FOCG) is a cross-organisational leadership group charged with integrating and coordinating MPI's work across the food system. The role of FOCG, along with other operational co-ordination groups for biosecurity and primary production, is currently being reviewed and we will be reconstituting the groups in a different form, giving them a stronger strategic leadership focus on the performance of our regulatory systems.

[1] Suitability refers to product attributes that include defects, composition and labelling, that are not related to food safety but are covered by the food safety legislation.

1.1 OUR DYNAMIC ENVIRONMENT

Every year brings new food technology, new products and processes, new diagnostic techniques and new scientific knowledge about food safety and risk. The food safety scene is continuously evolving. Part of this change is also due to growth in our food exports to new and developing markets such as China and India that have different expectations and requirements to our traditional trade partners.

There is also continuous change in consumer expectations about food. Some of these expectations are not related to safety or suitability, but they are an important part of the food regulatory environment and influence overseas regulators and private standards (such as the standards imposed on manufacturers by large overseas supermarket chains).

International food safety standards (such as maximum residue levels) change in response to science or, as we saw in the case of dicyandiamide (DCD), lag behind scientific and technological advances. At the same time, diagnostic techniques are becoming much more efficient, sensitive and accessible.

Social media makes the transfer of information – and misinformation – extremely rapid and allows consumers to share knowledge without the input of government regulators or the filter of scientific commentary.

Industry is understandably keen to take advantage of market opportunities domestically and overseas, and we are committed to facilitating this. For example, industry is moving to develop new food products that have scientifically verifiable health benefits and we are developing processes for assuring consumers and overseas regulators that the products do what manufacturers claim they do. We negotiate market access agreements on behalf of industry, and we invest in innovation within the industry.

In some areas we need to lift our capacity and capability. For example, technical expertise in dairying, is hard to come by, and turnover of staff in these areas can be costly. All of this is reflected in our People and Capability Strategy (see Appendix G).

Our key role is to regulate this operating environment to ensure the safety and suitability of food. When making judgements that require us to balance interests, we are clear that we must err on the side of safety.

We need to have excellent links with consumers, industry and regulators, here and overseas. We are developing new strategies for communicating better with New Zealand and overseas consumers to alert them to risks when they arise, to build confidence in our food safety system, and to help consumers themselves take responsibility for some aspects of food safety that are within their control. We are continuing to build links with regulators in new markets. We are also working with industry to help it work within the requirements of our regulatory system, and to understand where industry is heading so we can adapt the regulatory system to cover new and emerging risks.

To maintain New Zealand's reputation for transparency and openness we have to take a broader approach to risk communication than we have done previously – we need to

understand better what food safety risk means in overseas markets. We are currently in the midst of developing our new approaches and thinking around risk communication.

1.2 OUR REGULATORY APPROACH

Our regulatory approach requires food operations to take responsibility for the food they manufacture or handle. This approach provides for a high degree of regulation by MPI. It allows us to place highly prescriptive requirements on businesses that trade in high-risk foods, while allowing us to be less prescriptive for low-risk operations. It provides us with a wide range of tools that we can use to incentivise and enforce compliance with our requirements, and gives us several points of regulatory contact where we can intervene in the food supply chain:

- through audits, inspections and verifications of manufacturing, retail and food service operations;
- through controls on inputs into the food production system such as agricultural compounds and veterinary medicines (ACVMs) and animal welfare requirements; and
- at the border, dealing with imports and exports.

Our regulatory approach for food safety and suitability enables industry and government to jointly manage the risks associated with food products in order to meet international standards and market demands. Because we export to many countries and continents, it is important for us to understand food safety regulation through a multilateral lens. This means that we have had to develop a food safety system that protects domestic consumers, is recognised by a wide range of overseas markets as good practice, and is flexible enough to allow us to add export requirements for particular markets (Overseas Market Access Requirements, or OMARs).

New Zealand's current regulatory approach applying to food products has been developed over many years and in a manner broadly consistent with key trading partners like Australia, the European Union, Canada and the United States. Feedback from overseas regulators indicates that the regulatory framework is a trusted example of good practice food safety regulation. Over a number of years, we have negotiated access to numerous markets based on the reliability of our food safety system, including our regulatory and risk management models. In some cases, this has required us to persuade overseas regulators to shift their thinking about good food regulation towards the internationally accepted model on which our system is based.

We continue to look closely at our regulatory and operational systems. Our system provides a high level of assurance. Despite this, aspects of the current regulatory framework, particularly the Food Act 1981, fall short of best practice. The Food Act needs to be replaced with more modern legislation – the Food Bill is intended for this purpose. Our subordinate legislation (regulations, notices, specifications, etc) is also overly complex and needs tidying and simplifying.

1.3 RESPONSIVENESS

One of the strengths of MPI is the scope and breadth of its expertise. The recent WPC incident was the biggest food safety response the Government has mounted – within hours of it arising we had 60 staff on the response team. The team peaked at over 110 members, including staff drawn from other agencies such as the Ministry of Health, the Ministry of Foreign Affairs and Trade, New Zealand Trade and Enterprise and the Department of the Prime Minister and Cabinet.

We operate a highly developed response management model that we can apply in our other areas of regulatory responsibility. We have well-established processes and procedures for initiating responses and communicating risk in response situations, and our size gives us breadth and depth of expertise in managing responses. Our response model is based on the Co-ordinated Incident Management System (CIMS), which allows us to coordinate rapidly across Government.

During a food safety response, our principal focus is on protecting the health and safety of consumers. For this reason, we give priority to transparency and openness. Our legislation gives the Director-General powers that are intended for communicating risk to consumers and other regulators.

1.4 CONCLUSION

We welcome the Inquiry's views on how we can improve our regulatory and operational systems. Any findings from the Inquiry and recommended changes to New Zealand's system will be carefully scrutinised by consumers, industry and our trading partners.

We strongly support continuing to apply a science-and-risk-based approach to food safety that protects consumers, meets our multilateral trading needs and is closely aligned with international standard-setting organisations. Such an approach will also support our trading partners.

We have also identified areas where we can tighten up the system to give consumers even greater comfort in the safety of our food. These can be summarised as follows:

- taking a stronger leadership role;
- clarifying regulatory requirements, particularly around risk management programmes (RMPs);
- calibrating the performance of verifiers so that they are all performing at a consistently high level;
- changing the relationship between food operations and verifiers to remove a perception of conflict of interest;
- progressing the Food Bill;
- developing new compliance tools and a framework for using them across the organisation;
- better monitoring and analysis about how the sector is performing;
- shifting our understanding of risk communications and the importance of consumer expectations here and overseas.

1.5 SUMMARY

In this submission we outline current policy to date and how we are implementing this policy, including actions underway to address areas where we have identified a need for improvement. Our policy and actions will be reviewed in light of recommendations made by the Inquiry and any decisions made by Government. We have also made suggestions for further policy and regulatory work for the Inquiry to consider; these are not Government policy, but MPI's suggestions.

1.5.1 Governance

Actions currently under way

- We have increased our strategic and operational focus on food safety.
- We are reviewing the role of our Food Operational Co-ordination Group, along with other operational co-ordination groups for biosecurity and primary production, and we are likely to reconstitute the groups in a different form, giving them a stronger strategic leadership focus on the performance of our regulatory systems.

1.5.2 Monitoring and continuous improvement

Actions currently under way

- We are reframing how we monitor and assess risk across the organisation.
- We are improving our monitoring and review across the sector, including third parties such as district health boards, territorial authorities and the Ministry of Health.
- We are keeping requirements for food safety under continual review, recognising that significant changes to standards will have cost implications for consumers, industry and the Crown.

1.5.3 Regulatory framework

Actions currently under way

- We are continuing with our Standards Integration Programme. This work has been given a higher priority across MPI pending the outcome of the Government Inquiry into WPC.
- We are continuing working with Food Safety Australia New Zealand (FSANZ) to simplify and clarify the Food Code.
- We are aligning the application of primary, secondary and tertiary legislation, and the use of guidance material to assist industry with compliance.

Suggestions

- Amend the Animal Products Act regime as follows:
  - ensure Risk Management Programmes (RMPs) focus on food safety and suitability regulatory requirements and not non-regulatory aspects of quality;
  - review the requirements that apply to RMPs in light of the regulatory principles MPI will develop, and elevate core RMP requirements from tertiary to secondary legislation where appropriate;
  - require operators to provide a copy of the full RMPs to MPI when applying for registration. Operators should also have to provide any updates to MPI. MPI will keep a copy of these documents.
- Tighten up the process for verifying RMPs within the third party verification framework, and the monitoring of this part of the food safety system.
- Align the compliance and verification requirements and tools in the Food Bill and APA including penalties and infringement notices.
- Explore additional certification options for high-risk food products.
- Strengthen legislation providing for export assurances for overseas market access requirements. This reflects an increasing drive from our markets (particularly new markets) for assurances that reflect their food safety and suitability standards.
- Examine the relationship between the principle of transparency and openness in food safety issues and industry's reporting requirements under the Financial Markets Authority Act 2011.

1.5.4 Risk communication

Actions currently under way

- We are developing an MPI-wide risk communications framework to provide a clear and unambiguous basis for a single organisation-wide approach to risk communication across the food safety, biosecurity and primary production systems. We will prioritise this work.
- We are prioritising work with MFAT and NZTE on developing appropriate communications infrastructure in China to communicate about New Zealand's food safety system.
- We are re-developing our web to provide easier access to food safety and compliance information.

1.5.5 Verification

Actions currently under way

- We have agreed to review contestability (competition) in the third party verification market, pending the conclusion of the Government Inquiry.
- We are investigating options to realise greater efficiencies in the verification process e.g. verification of private standards, streamlining requirements for multi-ingredient foods.

Suggestions

- MPI to assume responsibility for the contractual relationship with third party verifiers to remove perceptions of a conflict of interest between verifiers and the businesses they verify.
- MPI to calibrate verification across our food statutes to ensure consistency between regulatory areas.

1.5.6 Compliance

Actions currently under way

- We are applying a graduated compliance model (the VADE model) to the food sector.
- We are continuing to explore expanding our suite of tools to incentivise and direct compliant behaviour.
- We are continuing to improve our processes for escalation where non-compliance is identified.
- We are continuing to improve communication about regulatory requirements and responsibilities, and the consequences of non-compliance.

Suggestions

- Progress the Food Bill to ensure tougher penalties, a broader range of penalties, including the use of administrative penalties, and a wider range of compliance tools than currently available under the Food Act.
- MPI to improve capability for systems audit and evaluation of the food safety system, and for monitoring programmes and recognised agencies.

1.5.7 Recall and tracing

Actions currently under way

- We are currently trialling increased product and ingredient tracing through our dairy interim measures in response to the WPC contamination incident.
- We are currently transitioning the dairy industry into the rebuilt animal products certification system. This will enable full traceability information to be collected for all dairy material and dairy products that require export certification but will require change to regulatory instruments to mandate use of this functionality.
- Our Exercise Programme includes tracing exercises with industry involvement.

Suggestions

- Align MPI's recall powers in food legislation while retaining industry's obligation to initiate recalls itself.
- Strengthen the primary food legislation, including Food Bill and APA, to clearly outline industry's responsibility to have robust systems in place to ensure traceability for ingredients and products that they sell.
- Investigate making full traceability mandatory for all domestic and export dairy.
- Develop requirements for the timely exchange of product and ingredient tracing information between industry and MPI.

Recommendations made by the Inquiry are likely to have resourcing implications for MPI and industry. The costs of change to our food safety system are ultimately passed on to consumers through the price of food or taxes. These are considerations that will need to be weighed up as the Government responds to the Inquiry.

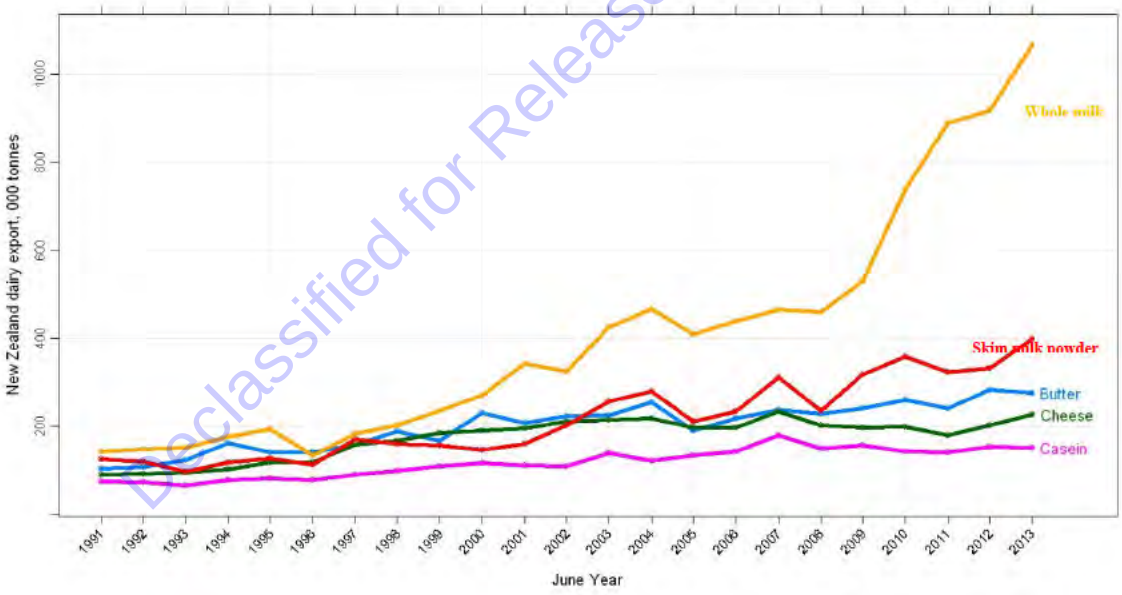
2 Our operating environment

2.1 THE GLOBAL ENVIRONMENT

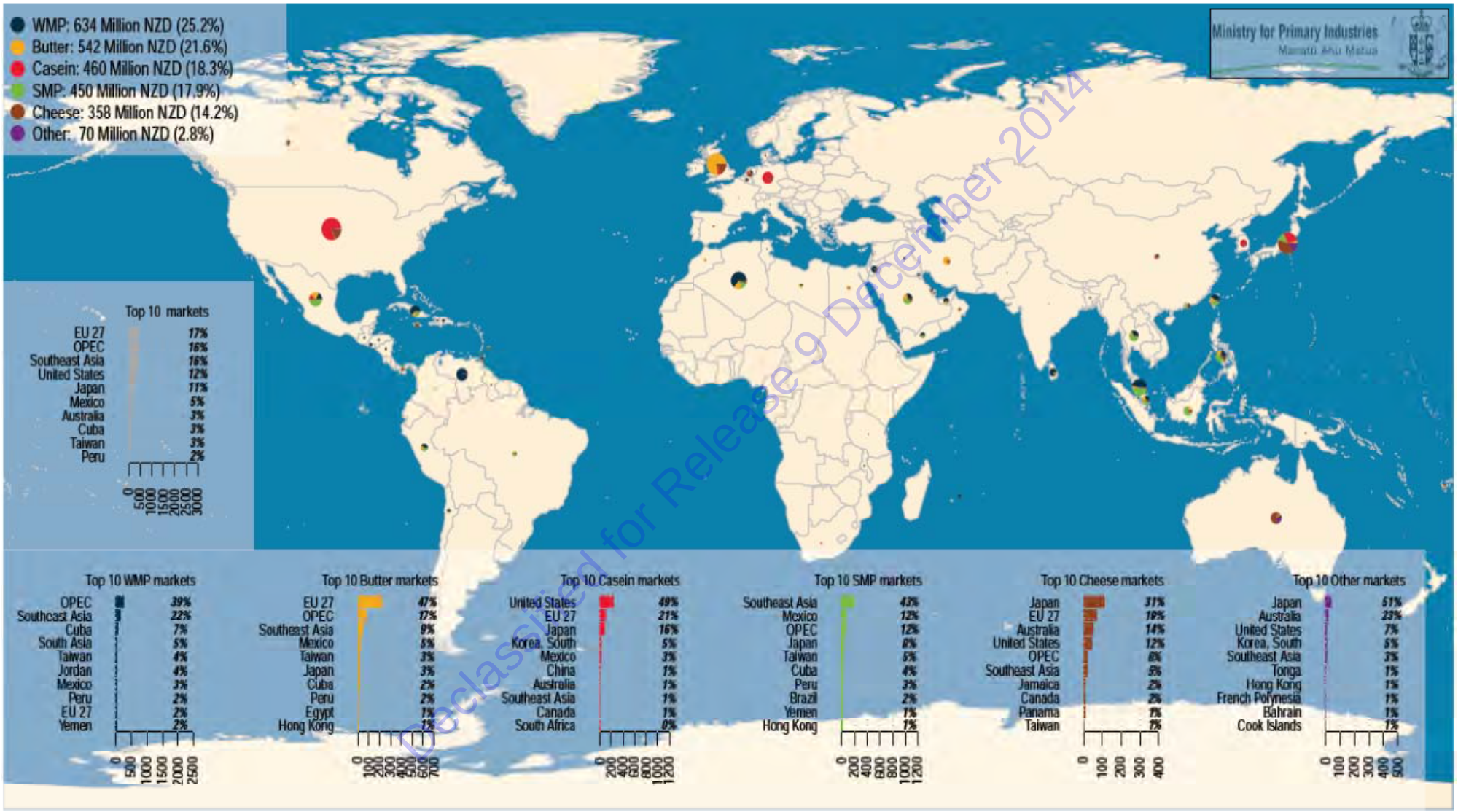
The prospects for New Zealand's food production sector are promising. There is strong and growing global demand for food products, especially meat, fish, aquaculture and dairy, with particular growth in the Asia-Pacific region. Demand for high-value foods is also expanding, particularly with continued growth in emerging Asian markets.

These market trends are clearly illustrated in the dairy sector, which has undergone substantial change over the last 20 years. In 1990/91 New Zealand dairy export revenue totalled NZD2.5bn, with the European Union representing New Zealand's largest dairy market (17%). Nearly half of export revenue was earned by selling whole milk powder and butter. Twenty years later dairy export revenues have increased to nearly NZD14bn, and are forecast to increase to NZD17.7bn by 2017. New Zealand is now exporting significantly more whole milk powder than any other product, and China has replaced the European Union (EU) to become New Zealand's single biggest dairy market. The diagrams below illustrate these changes.

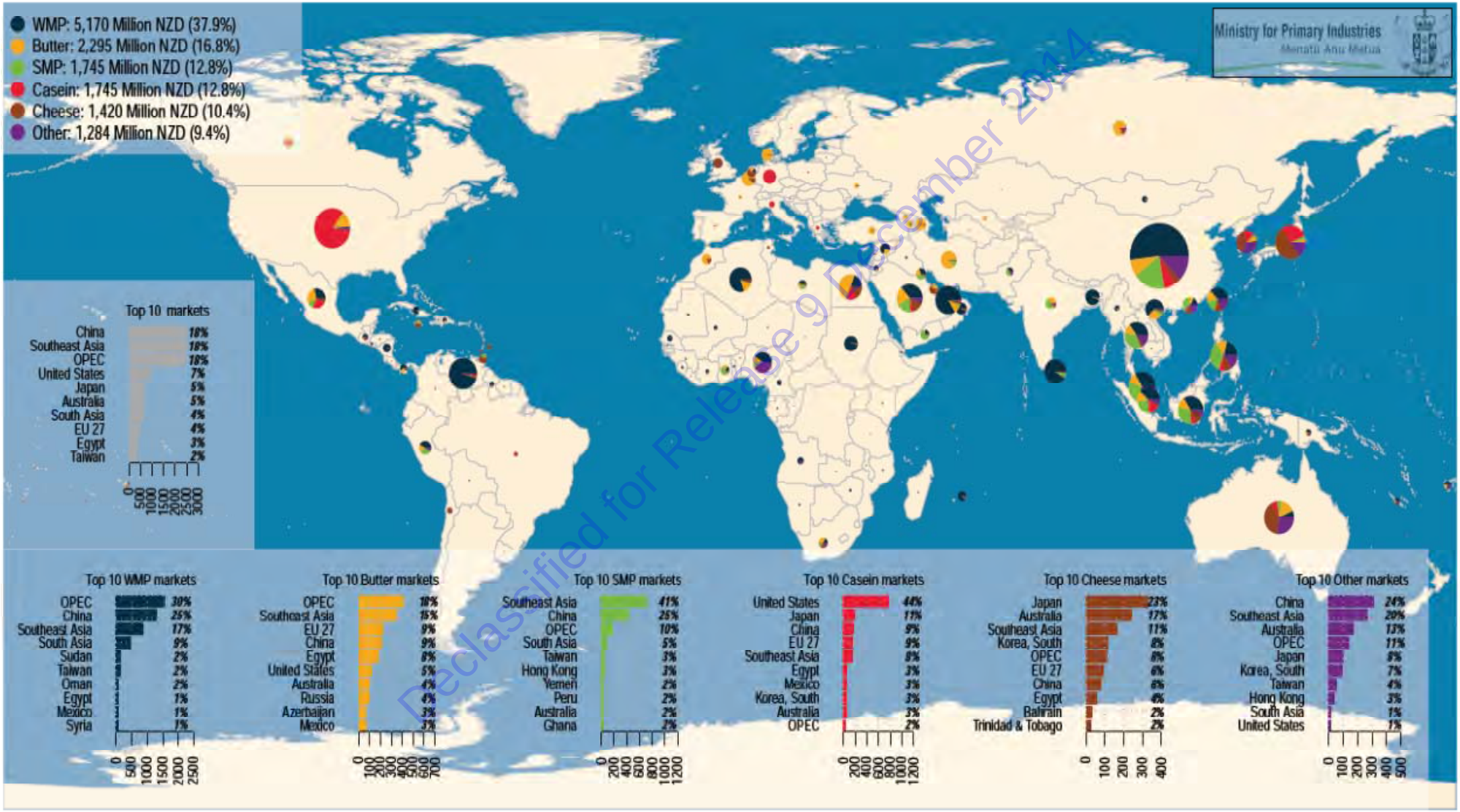
NZ's dairy exports in the past 20 years (five key products)



New Zealand Dairy Exports, Jul 90–Jun 91



New Zealand Dairy Exports, Jul 11–Jun 12



2.2 SOME OF THE OPPORTUNITIES AND CHALLENGES IN OUR OPERATING ENVIRONMENT

The complex and dynamic nature of the food industry and the rapid increase in trade with new markets underpins the need for a flexible and responsive food safety system. The ability to respond and adapt to changing food safety risk profiles and market/consumer expectations is critical in maintaining New Zealand's reputation as a safe and trusted supplier of food.

Some of the key opportunities and challenges that are shaping our thinking now and into the future are set out below.

2.2.1 Changing production and manufacturing techniques

Changing consumer demand and efficiency requirements are driving a number of changes in food production and manufacturing techniques. This includes both on-farm developments, such as the growing use of animal housing and automated milking systems; and manufacturing changes, such as technology improvements that have enabled milk components to be economically recovered from historic loss streams. New Zealand's dairy sector is recognised as world leading and we are well placed to maintain this advantage. However, while complex modern processes can reduce risks to food safety in some respects, they can also introduce new hazards or additional critical control points.

2.2.2 Increasing complexity of supply chains

The increasing complexity of food production methods and business models is creating challenges for the tracing and recall of food. Modern supply chains frequently involve multiple companies spanning multiple jurisdiction and countries. The complexity of modern supply chains can also be at odds with consumer expectations of a single entity maintaining total control over the production and distribution processes.

2.2.3 Changing markets

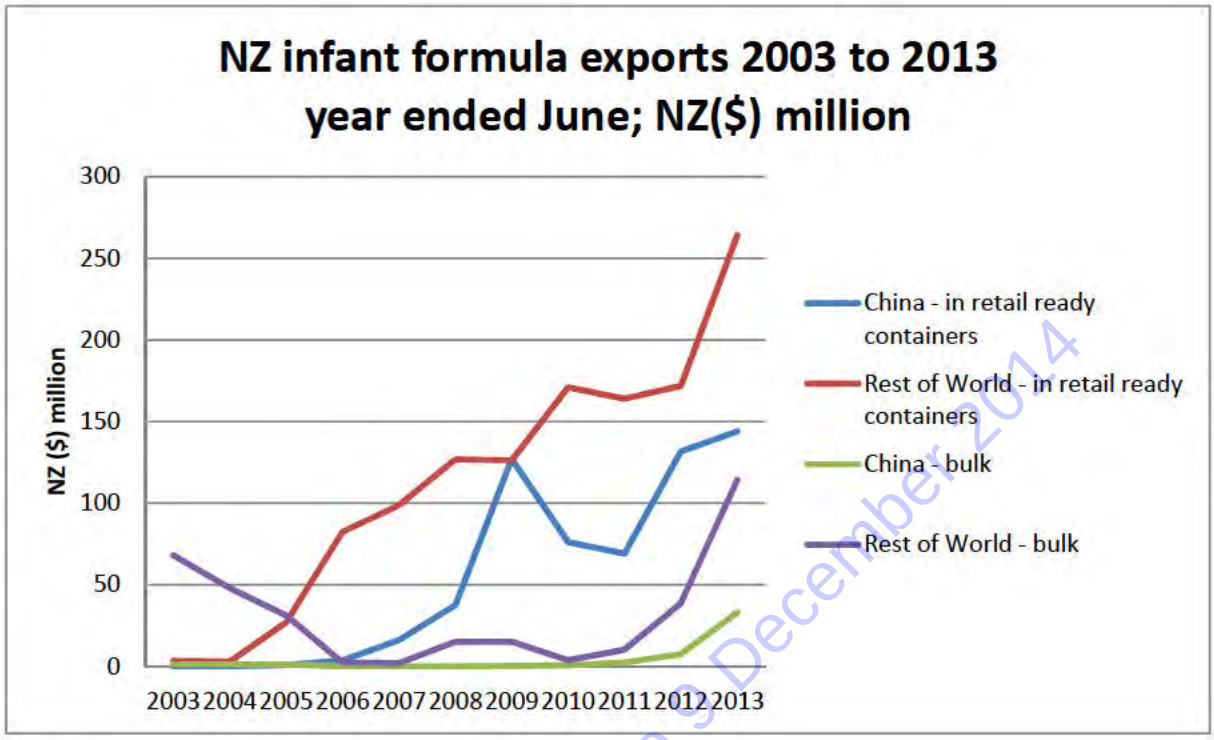
New Zealand exports to new markets have dramatically increased in recent years. New Zealand is trading with more countries than ever before, and consumers and regulators in these emerging markets can have different expectations and resources. This is driving the production and export of an increasing range of different processed foods. As the range of markets grows, there is a wider range of ways in which regulators operate and apply risk management principles, and varying levels of use of dairy science in regulation.

2.2.4 The growing importance of China

China is now New Zealand's biggest goods export market (overtaking Australia in the first quarter 2013) and is critical to New Zealand's future economic development. Food products form a significant proportion of our exports to China. Recent growth has been unprecedented and the Chinese market continues to provide huge opportunities for New Zealand exporters. Growth of infant formula exports has been dramatic, as illustrated in the graph below.

We are taking a whole-of-government approach to work with industry to make the most of opportunities in China. We are increasing our presence in China in order to improve communication both ways and lift our understanding about the expectations of Chinese consumers and how that market operates.

Infant formula exports from 2003 – 2013



2.2.5 Changing consumer expectations

In recent years, the capability of scientific instruments has dramatically increased to allow for the detection of minute quantities of chemical residues that present no safety risk. These chemicals are a by-product of a modern food safety system that focuses on increasingly efficient production. High profile situations such as the detection of DCD in milk have clearly illustrated that some consumers expect food to be free of chemical residues and genetically modified material, and not subject to treatments such as irradiation. These changing expectations challenge us to clearly communicate the risks to allow consumers to make informed decisions about the food they consume.

2.3 SUMMARY

The safety of our food, and our future success as a food exporting nation, depend on how well consumers, industry and the Government anticipate and respond to these opportunities and challenges. Key to this for MPI is gathering intelligence and information, and ensuring it is analysed for risk and shared across the organisation.

MPI has agreed to a common risk management framework for the systems we regulate that is based on ISO 31000. We continue to develop systems to operationalise how we follow this framework. These changes will help us to achieve consistency in the way we identify and respond to risk and bring together the best of the different heritage organisations.

We are also responding to opportunities in the China market. We are building stronger relationships with Chinese regulators, expanding our presence and resource in China, and developing a China Strategy to ensure the effective delivery of our role in the overall trade

system with China. More specific work is being undertaken on infant formula exports to China.

As one of our interim measures in response to the WPC incident, we are exploring ways to improve our ability to receive and analyse data from lab tests carried out by industry – this will help us respond to changing expectations of consumers and overseas regulators as well as giving us an additional way to monitor the health of our food safety system.

Another step we will need to take is to look at increasing our capacity and capability in some technical areas, particularly in dairy and in monitoring and evaluation.

Case study: Infant Formula

Growing demand for New Zealand dairy products, particularly infant formula, is good news story for this country. It also presents challenges for our dairy industry and for government. Chinese consumers expect that MPI, as the government regulator, will guarantee the quality (not just the safety and suitability) of our export products. Other challenges in the marketplace include misrepresentation or counterfeiting of New Zealand product.

The structure of our exports to China is also changing:

- more primary manufacturers are exporting either finished product or base product;
- there has been a growth in secondary manufacturers that receive base product from primary manufacturers and process this into finished product for brand owners; and
- brand owners have emerged who do not own processing facilities, but buy finished product from secondary manufacturers and focus on product marketing.

We currently have registered 17 risk management programmes for infant formula manufacture and there are approximately 230 infant formula brands listed for export to China.

Under our regulatory system, there is no single business model for infant formula manufacturing and export and there may be several companies involved in manufacturing and handling a single product. This is at odds with the expectations of some consumers that a single entity maintains control of the supply chain from the milk production to the product on the shelf.

On 27 June 2013, the Minister for Food Safety announced an inter-agency infant formula work programme. As part of the work programme, MPI will review food safety standards and systems for production and processing of infant formula products and, where appropriate, develop enhancements to these standards and systems. In consultation with industry, the Ministry of Foreign Affairs and Trade (MFAT) and New Zealand Trade and Enterprise (NZTE), we will also develop options for brand protection for New Zealand infant formula and investigate mechanisms to better collaborate and communicate with consumers in China. MPI is working closely with MFAT and NZTE to progress the work programme over the 12 months.

MPI is also supporting the development of expert advice to inform the revision of the international Codex Alimentarius Standard on Follow-Up Formula.[2]

More detail about this work programme can be found in Appendix B.

[2] The Codex Standard for Infant Formula has already been reviewed – this was completed in 2007

3 What is an effective food safety system?

A food safety system must ensure the safety and suitability of food. The food system needs to be trusted by consumers and trading partners, and the standards and assurances that we provide as the regulator need to be robust.

3.1 PURPOSE OF A FOOD SAFETY SYSTEM

3.1.1 Safe and suitable food

The primary purpose of a food safety system is to maintain an acceptable level of food safety and suitability for food that is traded. Food safety risks can never be eliminated entirely because the production, handling and consumption of food always involves risk; some of these risks are so insignificant that they are acceptable to the general population, and some risks are manageable through regulatory tools or risk communication measures.

Food may also carry different risks for different segments of the population, or even for different populations. For example, the vast majority of the population accepts the food safety risk associated with the consumption of soft cheeses such as camembert, but pregnant women are advised through public health messages to avoid soft cheeses as the risks to unborn children are significantly higher than for the general population.

3.2 OTHER FACTORS

3.2.1 Facilitation of trade

An effective food safety system helps to facilitate trade in food both within New Zealand and across our borders. Consumers want safe food and we need to protect and build on our reputation as a leading producer of safe and trusted food. Our food safety system needs to take into account the cost of any interventions on businesses that are producing and trading in food, and it needs to take account of the requirements of foreign regulators.

This requires flexibility in our system. A rigid food safety system would not meet the needs of food businesses or food consumers because it would struggle to adapt to new and emerging food safety risks. It would not effectively manage food safety risks in the dynamic environment we live in, nor would it allow for business innovation and ‘continual improvement’.

New Zealand is a signatory to the WTO and we have obligations that are reflected in Free Trade Agreements, sanitary agreements and overseas market access requirements. We operate in the context of global and expanding trade, so we have adopted a multilateral approach to food safety. Our system needs to accommodate the highly divergent expectations of overseas regulators about how food safety should be regulated. The expectations of overseas regulators can be driven by legislative requirements, their cultural context, their domestic food safety concerns, and/or politics.

3.2.2 Adaptability of the system

An effective food safety system must be a living system that is continuously adapting and changing to meet new risks, changing views about food safety, new foods and technology, and the ever changing requirements of overseas regulators. An effective food safety system

therefore needs to be a learning system with good performance monitoring, efficient feedback loops and systems to incorporate change.

An effective food safety system should also be effective in areas other than food safety. For food safety risks to be managed effectively by the industry and government, it is important to build operational efficiency and cost effectiveness into the system.

3.2.3 Responding to food safety incidents

An effective food safety system needs to be appropriate for both core work and when there are food safety incidents.

MPI is moving to a single integrated and scalable response model for all its responses and incidents. Our response model is based on the Co-ordinated Incident Management System (CIMS). CIMS is based on the Incident Command System developed in the United States in the 1970s. This is the model that was used to address the WPC contamination incident.

During a response there are clearly defined functions such as incident control, operations, planning and intelligence, logistics and communications. It is a generic framework that can be adapted for each situation that arises. The incident itself determines the size of the incident management team. In an isolated incident, a single officer may perform all of functions and in a very complex incident functions can be subdivided.

As most emergency management agencies have adopted CIMS it has facilitated better multi-agency responses.

The actions of MPI during the first three days of the WPC contamination response illustrate how our systems work (see Appendix D).

3.2.4 Codex Principles and Guidelines

The Codex Alimentarius Commission has recently adopted a set of principles and guidelines for national food control systems.[3] The principles recognise that it is not desirable to prescribe one system for all circumstances, and that different approaches will be appropriate, in accordance with different national circumstances.

3.3 COMMENT

MPI considers that the primary purpose of a food safety system is to protect consumers from harm and to ensure food is fit for purpose. Other essential features are that it must facilitate trade in food and it must be adaptable to deal with changing circumstances and risks.

There is no single model for an effective food safety system, but there is broad international agreement on the key principles and guidelines. New Zealand's WTO and SPS obligations and multilateral approach to trade and international relations makes it important for us to be consistent with these principles and guidelines and to encourage other countries to move towards their adoption.

[3] Codex Alimentarius Commission, *Principles and Guidelines for National Food Control Systems*, CAC/GL 82-2013

3.4 MEASURING EFFECTIVENESS OF OUR FOOD SAFETY SYSTEM

3.4.1 Monitoring, evaluation and audit

Monitoring and evaluation systems are critical for measuring the effectiveness of the food safety system, assessing the performance of the system against the outcomes and objectives for food safety, and ensuring continual improvement. This section discusses MPI's approach to monitoring and evaluating performance within the system, and our current approach to measuring food safety.

3.4.2 Epidemiological data

Epidemiological data is generally not helpful in assessing the effectiveness of a food safety system. This is because most foodborne illnesses are also transmitted through non-food vectors (such as person-to-person transmission) and because public health monitoring systems only record those incidents that are reported to the authorities. For example, while E. coli O:157 can be transmitted through food, New Zealand's high reported rate of this disease is attributable to farming, outdoor lifestyle and other factors. After adjustment for these factors, the estimated rate of foodborne E. coli O:157 infection in New Zealand is thought to be lower than in Europe and North America. More information can be found in papers provided to the Inquiry about "Food safety record and risks" (provided 19 September) and "Notes on international comparisons of notifiable enteric disease rates" (provided on 8 October).

As part of our ongoing programme of scientific work we have undertaken a search of foodborne illnesses linked to dairy products in New Zealand over the past five-and-a-half years. Other than some cases linked to consumption of unpasteurised milk, we were only able to identify one case where a dairy product containing a pathogen was linked to an illness. In this case, the pathogen listeria was found in feta cheese that had been consumed at home. Even in this case it is possible that the contamination did not occur during production, but occurred through cross-contamination in a fridge or on a household surface such as a chopping board.

Other sources of information provide us with better information about the safety of the food we are producing and the systems we are using to produce it. These include feedback through the testing and monitoring programmes, our compliance programme and our verification system, and audits by MPI and overseas regulators.

3.4.3 Monitoring programmes

In New Zealand, we focus on monitoring and evaluation of food safety processes rather than end-point testing. We focus on managing risk at critical points along the food chain by maintaining good food safety processes during manufacture.

Nonetheless, we undertake over 1 million tests a year to monitor the safety of our food and the health of our system. In addition to this, industry tests its products for safety and quality on an ongoing basis. See Appendix E for details about the testing regime.

It is not possible to compare the number of tests that New Zealand undertakes with that of comparable countries that take a risk-based approach. New Zealand exports over 80 percent

of our product, whereas other countries (such as Canada and the US) sell most of their product domestically so their products are not routinely subject to testing to meet overseas market access requirements.

Rather than monitoring their food safety systems, some countries still focus on end-point testing to check particular food products are safe. They may undertake more tests but this does not mean that their food is safer.

Our monitoring programmes play a crucial role in ensuring food produced and consumed in New Zealand is safe and suitable by:

- verifying that the regulatory framework is managing risks to food safety effectively;
- establishing safe levels for residues, contaminants and other hazards; and
- scanning for emerging risks due to changes in the production environment.

The programmes cover an extensive range of food products from production and harvest to the point of sale. The following two programmes are in place for the dairy sector:

- National Chemical Contaminants Programme (NCCP) – monitors chemical residues and contaminants in dairy products and raw milk at the farm;
- Independent Verification Programme (IVP), which verifies the accuracy and integrity of sampling and testing plans contained within the risk management programmes of dairy manufacturers.

MPI also periodically undertakes a Total Diet Survey measuring the chemical and compositional attributes in a basket of foods. This programme includes some common dairy products.

3.4.4 Compliance monitoring

We have four main processes to monitor compliance with our regulatory regime (more information on these areas can be found throughout this submission):

- Reporting of export non-compliances
- RMP exception reports
- Systems audits
- Verification activities.

Exporters are required to notify MPI of non-compliances (ENCs) when they become aware that dairy products they have exported:

- are no longer fit for the intended purpose;
- are refused entry by a foreign government;
- no longer meet export or OMAR requirements notified by MPI; and
- no longer have or meet the required official assurances.

Export non-compliances (ENCs)

Each ENC received is reviewed by MPI to determine the nature of the issue and the potential impact on New Zealand reputation or trade. The action taken in response to a notification is determined based upon the nature and significance of the issue. Most ENCs relate to quality and labelling, not food safety.

Failure to comply with ENC reporting obligations, even unintentionally, can result in compliance action.

RMP exception reports

RMP exception reports are raised by RMP operators when they become aware that an operational non-compliance has occurred or product is found to be, or is reasonably suspected to be, no longer fit for purpose. This is not limited to food safety, and can cover any aspect of compliance with the RMP system, including labelling issues. Any product affected is then managed according to MPI requirements.

We are currently exploring how we can obtain additional data and analyse it in a way that gives us a deeper and more critical view of how the system is operating, including performance against such measures such as timeliness of reporting and completeness of reporting. This includes all ENC and RMP exception reports.

MPI has been developing different performance measurement tools over the past year that may point the way forward – these tools triangulate data to better help us understand trends in performance. Work on performance measurement is highly technical and requires specialist expertise that is available across MPI

We are talking to other organisations involved in food safety, including industry, DHBs and territorial authorities, to see how they can assist in the monitoring of the food safety system.

Systems audits

MPI undertakes regular audits of aspects of our food safety system (including audits of particular premises, recognised agencies, sub-sectors and processes) to ensure adherence with New Zealand and international food safety standards.

The systems audit function has the potential to provide comprehensive, ongoing assurance of the health of our system, and can be used to identify areas of risk that other parts of MPI can address, for example, through education or compliance action.

We have identified some ways to get more value from the systems audit function:

- There is not a clear process for integrating the findings from the systems audits into MPI's work programme. We will identify a way to address this, which may include closer alignment between the systems audit and compliance functions.
- We do not systematically follow-up or monitor recommendations from systems audits. We will ensure responsibility for this is allocated at a senior level of the organisation.

We will also look at ways to make better use of our evaluation capability in assessing the design and performance of our food safety system.

3.5 AUDITS BY OVERSEAS REGULATORS

New Zealand also welcomes periodic assessment of the New Zealand food safety system by overseas regulators. Teams of auditors from overseas authorities visit New Zealand numerous times each year to assess our food production systems, our export facilities and, above all, our food safety system, including MPI's performance as a regulator. A list of recent and forthcoming audits is attached at Appendix A.

The results from these audits give us great comfort in our system, but also periodically indicate areas where we need to adjust our system to meet the expectations of regulators from new markets. In December 2012, for example, New Zealand's food safety system was selected by the United States of America's Food and Drug Administration (US FDA) as the pilot for a new scheme of 'systems recognition'. In the FDA's own words:

> "Recognition under this new program, which we continue to pilot test, is a high bar to reach. These are countries that have preventive, risk-based programs in place and can respond and follow up on any food safety incidents that may occur. In recognising countries under this program, we want assurance that the country's authorities will be able to swiftly track down the source of a foodborne illness and take corrective actions as necessary to stop it in its tracks—and to help prevent such an incident from happening again."[4]

New Zealand's food safety system was the first to successfully pass the systems recognition assessment, and MPI signed a recognition agreement with the US FDA in December 2012. Our rapid and strong response to the WPC contamination incident this year was perceived by the US FDA as validation of their findings in the systems audit:

> "New Zealand authorities had acted swiftly and effectively, exhibiting a level of detail, commitment to communication, and sophistication that confirmed FDA's assessment of their food safety system. The New Zealand authorities brought the same care to notifying other countries that had received the recalled product, as well as any other product that contained the whey protein as an ingredient."[5]

Not only does the recognition agreement with the US FDA reassure us that our system meets the high expectations of international food safety experts, it also helps exporters gain access to the US food market without having to leap through costly regulatory hoops.

New Zealand has a similar agreement in place with the European Union. This agreement is based on a recognition that Animal Products Act 1999 and European legislation are equivalent (in terms of the WTO's concept of equivalence). European auditors make regular visits to New Zealand to ensure that our systems under the Animal Products Act continue to provide a high level of food safety.

These assessments are important for us because regulators from the European Union and North America have traditionally been at the forefront of food safety science and thinking. The views expressed by audit teams from these countries reflect a sophisticated understanding of food safety science and systems analysis. Positions taken by these jurisdictions influence the global direction of food safety.

One of the biggest challenges we face in our regulation of exports is that different countries regulate food safety differently (Appendix F provides a brief comparison of our system to the systems of comparable countries – Australia, USA, Canada, EU and Ireland). Part of our challenge is one of translation: providing context so that regulators can understand how and why our system works in New Zealand. We also need a clear understanding about the

[4] http://blogs.fda.gov/fdavoice/index.php/2013/09/fda-systems-recognition-ensuring-imported-foods-are-safe/?source=govdelivery&utm_medium=email&utm_source=govdelivery

[5] Ibid.

regulatory drivers in jurisdictions with different regulatory systems so that we can fine tune our food safety system (including export assurances) in a way that satisfies the expectations of those markets.

Feedback from overseas regulators forces us to look at our system. One example of where this is happening is in the relationship between food businesses and third-party verifiers. For some overseas regulators, our system contains an apparent conflict of interest because of the financial relationship between the food business and the third-party verifier, so we are suggesting that this relationship be changed (refer to suggestions in the section on verification).

3.6 SUMMARY

MPI has a suite of tools to monitor the effectiveness of our food safety system, including monitoring programmes, systems audits, and evaluations by overseas regulators. These tools show us that our food safety system is performing well. More importantly, they help us identify where we can keep strengthening our system.

What we currently lack is deep monitoring of some important performance measures that would allow us to fine tune and calibrate our system. We are moving to develop tools and measures that will allow us to understand the system better, but this work will need resource and prioritisation.

One step we will take is to ensure that the systems audit function is better resourced and we make better use of systems audits (refer to suggestions in the compliance section).

3.6.1 Actions underway

- We are reframing how we monitor and assess risk across the organisation.
- We are improving our monitoring and review across the sector, including third parties such as district health boards, territorial authorities and the Ministry of Health.
- We are keeping requirements for food safety under continual review, recognising that significant changes to standards will have cost implications for consumers, industry and the Crown.

4 Overview of New Zealand's regulatory regime

The dairy industry has been regulated since the commencement of refrigerated shipping in the late 19th century. Four Dairy Industry Acts were passed between 1892 and 1908, helping contribute to an increase in product standards and price premiums in the British market.

For fifty years, the Dairy Industry Act 1952 was the primary legislation for food safety in the dairy industry. It introduced restrictions on unsafe practices (such as selling milk from diseased stock) and provisions relating to product quality. Under this Act, product safety was typically set by prescriptive government regulations and maintained through manual inspections by official inspectors. Consequently, business innovations or new products often required government approval and involve lengthy regulatory or standard changes.

Developments in the 1980s and 1990s began driving regulatory change internationally and in New Zealand. Quality control through end-point inspection was being replaced with process control and management, designed to prevent problems arising in the first place: a greater onus was being placed on industry to have safe systems producing safe food, rather than a reliance on passing inspections. Management systems such as Hazard Analysis and Critical Control Point (HACCP) were being increasingly adopted by industry.

HACCP principles

Under the HACCP approach, the food operator identifies the points in the food production system where hazards are most likely to arise. The operator then puts in place systems to manage those hazards. These systems are recorded in a plan. Under the Animal Products Act 1999, this is a risk management programme (RMP), and under the proposed Food Bill it will be a food control plan (FCP). The food operator is periodically audited (or 'verified') against the plan to ensure that the systems are being followed and that new hazards haven't emerged.

HACCP principles internationally

The principle that food businesses have the primary responsibility for achieving food safety is widely recognised in other jurisdictions, along with the related requirement to apply HACCP principles in meeting that responsibility:

- The key European Union regulation on food safety recognises that "a food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary responsibility for ensuring food safety"[6].
- In Australia, dairy export establishments must have in place a documented food safety programme that is based on HACCP principles, Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP).
- The United States of America and Canada have both passed recent legislation that will enable those jurisdictions to require greater use of HACCP principles by food businesses.

[6] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

The Dairy Industry Regulations 1990 enabled the adoption of quality control systems, increasing innovation and product diversification. The Regulations included:

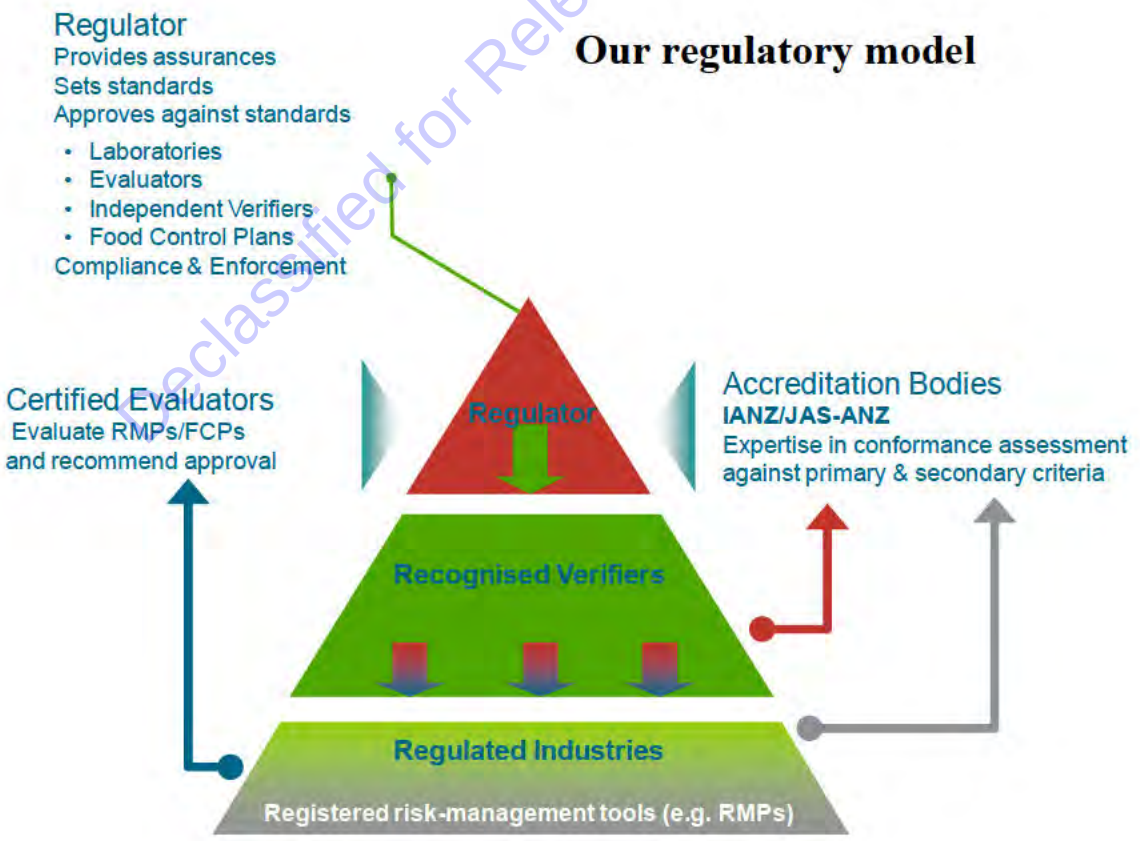
- a general obligation to take reasonable steps to ensure the safety of products;
- a requirement to operate with a product safety programme tailored to individual operators and approved by the regulator;
- the registration of manufacturing premises, stores and laboratories; and
- tiered regulations and circulars and manuals to setting out particulars, such as provision for approval of third-party laboratories and inspection bodies to provide services under the supervision of government auditors.

The Dairy Industry Act 1952 and Dairy Industry Regulations 1990 were revoked in 2005 when dairy regulation was placed within the framework of the Animal Products Act 1999.

4.1 THE CURRENT REGULATORY REGIME

The 1990s saw the progressive introduction of the current regulatory model that forms the basis of New Zealand food safety statutes: the Animal Products Act 1999 (which included dairy produce from 2005), the Wine Act 2003 and the Food Bill. The regulatory model maintains the role of the Government as overall regulator, but requires other parties to take responsibility for implementating regulatory requirements.

The regulatory model consists of three participants: the regulator, the verifier and industry.



The responsibility of the **regulator** (MPI) is to:

- set standards that industry must comply with;
- provide official (government-to-government) export assurances;
- develop resources and guidance materials;
- undertake compliance action; and
- monitor overall system performance.

Verifiers are generally third parties operating under contract to carry out verification services, but the Verification Services directorate of MPI also provides verification services, particularly to the meat industry. Verifiers are agencies recognised by the regulator to be responsible for independently verifying that food operators:

- are complying with regulatory requirements; and
- have adopted suitable food safety practices.

Industry operators are responsible for producing food that is safe and suitable for human consumption. They do this by complying with regulatory requirements, standards and food safety practices. Under the Animal Products Act the primary mechanism for ensuring this is a Risk Management Programme (RMP), and the other food related Acts have RMP equivalents[7].

4.2 PRIMARY LEGISLATION

MPI is responsible for several food related statutes:

4.2.1 Animal Products Act 1999

Protects human and animal health and facilitates access to overseas markets by regulating production and trade in animal materials and products - from production and harvesting to processing, transport, storage and export.

4.2.2 Food Act 1981

Regulates the production, processing and sale of all food in New Zealand, including food imported into New Zealand and food exported from New Zealand. While the Food Act does not reflect the risk-based regulatory regime set out in the Animal Products Act, food businesses can voluntarily implement Food Safety Programmes (FSPs) which are risk-based measures introducing the principles of HACCP and third-party auditing. The requirements of the Food Act are primarily met by operating under prescriptive regulations that focus on where (rather than how) food is prepared – as such, these regulations are relics from a past regulatory era prior to the introduction of science-and-risk-based principles.

4.2.3 Wine Act 2003

Sets standards for the making of wine in New Zealand, including identity, truth in labelling and safety. Aims to minimise and manage risks to human health associated with the making of wine and facilitate the entry of wine into overseas markets.

[7] RMP equivalents in the Wine Act equivalent are Wine Standards Management Plan, and for the Food Act 1981 a Food Safety Programme, and for the Food Bill high risk products will be subject to Food Control Plans. Low-to-medium-risk operators will be covered by National Programmes, Levels 1-3, which will be set out in regulations.

4.2.4 Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997

Controls the agricultural compounds and veterinary medicines used in association with animals and plants by regulating the import, manufacture, sale and use of such compounds to ensure compliance with domestic food residue standards.

While each statute has its own distinct purpose, there are also areas of overlap. The Food Bill will further align our regulatory system by implementing a risk-based system for the wider food sector that is similar to the regime already applying under the Animal Products Act.

The Food Bill

The Food Bill is currently before the Primary Production Select Committee for consideration. The Bill will replace the Food Act and associated regulations (including the Food Hygiene Regulations) in their entirety. The Food Bill will align all New Zealand food legislation, as it uses a similar regulatory model to our other modern food-related statutes. The respective roles and responsibilities of MPI and verifiers and industry would then be similar to the Animal Products Act.

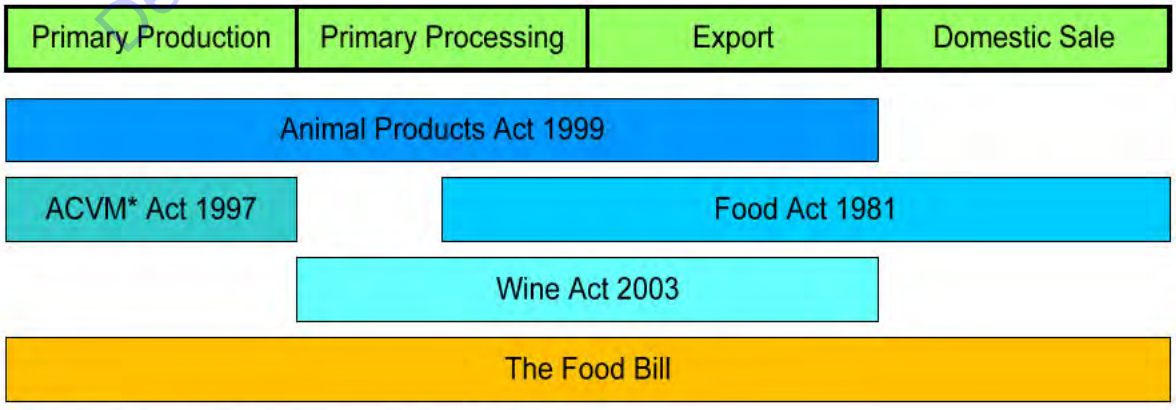
Under the Food Bill the food sector would be divided into categories regulated at different levels primarily dependant on the food safety risk. Processors of high risk products (such as dairy products) will be subject to risk-based Food Control Plans that are equivalent to FSPs and RMPs.

Medium-risk operators will be covered by National Programmes, Levels 1 to 3, which will be set out in regulations and cover the systems a food business needs to have in place to produce safe food.

Low-risk operators (such as sausage sizzles) will simply be required to ensure the food they sell is safe and suitable for human consumption.

The following diagram illustrates how our legislation covers the sector:

Scope of food related legislation



* Agricultural Compounds and Veterinary Medicines Act 1997

4.3 COMPARISON OF REGIMES

The Animal Products Act introduced a risk-based approach based on the regulatory model to the regulation of food in New Zealand. Central to this approach is the requirement for industry to operate under an RMP. This approach was adopted in consultation with industry which supported the move away from prescribing how to manage risks in the legislation. Regulations set outcomes and any prescriptive technical requirements provided for in tertiary legislation.

Food Safety Programmes are risk-based tools similar to RMPs and were introduced into the Food Act in 1996. In 2004, a Food Safety Programme for food service was introduced as an interim measure in anticipation of the development of new risk-based food legislation (the Food Bill). The Food Act does not fully provide for the implementation of Food Safety Programmes.

The Food Bill further develops the risk-based approach introduced by the APA, adapts Food Safety Programmes (renaming them 'Food Control Plans), and introduces new regulatory tools (National Programmes) to manage lower risk food activities.

The Food Act and the Food Bill both provide for limited equivalence with the Animal Products Act, meaning that some Food Safety Programmes or Food Control Plans are accepted as equivalent to RMPs. There is a limit on equivalence between the statutes because neither the Food Act nor the Food Bill explicitly provide for a scheme for export assurances.

4.4 SECONDARY AND TERTIARY LEGISLATION APPLYING TO THE DAIRY INDUSTRY

The export dairy industry is regulated under the Animal Products Act and its associated regulations (including some standards) and tertiary instruments (such as notices, orders, specifications and some standards).

The intent of the regime is to have core requirements prescribed in primary legislation while having a more flexible framework of outcome-based regulations with specific technical requirements that the industry must meet in tertiary requirements. In principle these specific requirements focus on managing risks at critical points in the production/processing chain and are included in legislation only where necessary (e.g. where there is only one appropriate way to meet an outcome).

The dairy industry demonstrates how they will meet the legislative requirements through their RMPs.

The dairy industry is tightly regulated through tertiary requirements, which reflects that dairy products are a higher risk food. The Dairy Roadmap, attached as Appendix C, provides a detailed overview of the requirements that the dairy industry must meet. The table below provides a high level overview of the regulatory regime under which the dairy industry operates.

Legislation	Animal Products Act 1999 Animal Products (Ancillary and Transitional Provisions) Act
Regulation	Regulations and Orders Dairy Regulations/Exemptions & Inclusions Order/Fees
Tertiary	Specifications / Notices Risk Management Programme Specifications / Dairy Processing Specifications / Recognised Agencies and Persons / Official Assurances / Export Requirements / Monitoring Requirements
	Approved Criteria General Dairy Processing / Farm Dairies / Storage and Transportation / Manufacture / Recognition of Agencies & Persons / Conditions for Recognition

4.5 RISK MANAGEMENT PROGRAMMES

An RMP is a written programme designed to manage and ensure the food safety and suitability of animal material and products. Hazards may be biological, chemical or physical. The RMP sets out how the operator will identify and control, manage, eliminate or minimise food safety hazards and other risk factors in relation to processing to ensure products are safe, suitable and truthfully labelled. Companies may include any overseas market access requirements that the product must meet in order to get an official assurance or they may choose to keep these outside their RMP.

An RMP is a legally binding document that must be developed and implemented in accordance with the Animal Products Act and other relevant New Zealand legislation. All RMPs must be registered with MPI. Prior to registration, RMPs must be evaluated by an approved third party. When applying for registration, the operator must supply either a copy of the full RMP or an outline along with the evaluation report to MPI. MPI assesses all RMPs (either the outline or the full RMP) and the evaluators' reports and, if, appropriate approves, registers and adds the RMP to the public list of registered RMPs.

MPI provides industry with standard guidance on mandatory RMP requirements, such as the RMP Manual. Template RMPs are provided to assist mainly smaller operators. However, the RMP system allows for flexibility around the scope and format of an RMP. The intent of flexibility is to ensure that hazard-control processes can be put in place for any food process, no matter how complex or novel. Flexibility also allows industry to develop RMPs to cover multi-businesses, or the whole supply chain.

Industry operators are required to ensure processes are carried out in accordance with their registered RMP, all the risk management activities are working effectively, and records are

kept. The recognised agency verifies the processing operation and operator records regularly to confirm that the RMP delivers product that is fit for intended purpose on an ongoing basis. Frequency of verification depends on product type and performance of the operators.

For products verified by third-party agencies, MPI scrutinises the RMP by reviewing a report on the RMP by the third-party verifier. MPI is also able to review compliance with the RMP through systems audits. For all Dairy operators, MPI works with the recognised agency to ensure that the RMP continues to manage the food safety risks in accordance with mandatory food safety standards.

4.5.1 Improving RMPs

There are opportunities to improve the RMP process as follows:

- **Some RMPs have become unwieldy and confusing**

Operators are increasingly using the RMP as a quality assurance tool as well as a regulatory tool. This scope-creep of RMPs may be diluting the focus of the RMP away from its essence as a food safety tool. This creates problems for MPI and verifiers to assess and verify the RMP for completeness, and it can create difficulties for industry to know what is essential activity for the purposes of food safety and what is not, and it creates difficulties for MPI to know what compliance tool should be used.

Complex food manufacturing processes require a significant level of detail in the RMP to ensure that risks are adequately defined and managed. On top of that, industry clearly sees a benefit in having a single process management tool that combines RMP requirements with other process requirements. However, we are intending to ensure that RMPs focus on their fundamental purpose, which is to ensure food safety.

- **Elevating the requirements for RMPs**

Many of the requirements for RMPs are currently set out in tertiary legislation – for example the Animal Products (Risk Management Programme) Specifications. As part of a wider project to improve the clarity of our secondary and tertiary legislation (see below), we are proposing to elevate the level at which we specify fundamental RMP requirements from tertiary to secondary legislation. This will improve clarity and certainty for the public and for industry, and it will give us a greater range of compliance tools to deal with any non-compliance.

- **Improving visibility**

Currently, in many cases, we rely on third-party reports about the RMP to inform us how well they are working. This makes it difficult for us to monitor RMPs for consistency and quality and it may create perception issues for our overseas trading partners whose regimes have a higher level of direct government intervention.

We are intending to tighten up the process for monitoring and evaluation of RMPs.

We are also intending to require that full copies of RMPs be provided to MPI so that we have immediate access to them if we require it, we have absolute certainty about their contents, and we are able to monitor them for consistency, quality and trends.

We are intending to investigating whether the RMP process can be amended to give us clearer oversight of high-risk products, sensitive products and products consumed by vulnerable populations. This will be a challenge, because it is difficult to link some basic food ingredients (e.g. milk powder) with their use in end products (e.g. baby formula). Despite this, there may be opportunities to further prescribe the process to increase MPI scrutiny.

4.6 CLARIFYING AND IMPROVING OUR REGULATION

The flexibility in our system is achieved by placing detailed requirements in tertiary instruments that can be varied as needed to adapt to new food safety risks or changes in the industry and export markets. This approach has been generally supported by industry.

However, MPI is conscious that these instruments have not been developed in a consistent or transparent manner, and it is hard for industry to navigate through them. Tertiary requirements have developed over time to respond to specific issues and an industry demand for more certainty about what is expected. We recognise that there are several problems with the current system:

- customers currently need to visit several different websites to access information they need on legal requirements for import, domestic production and export;
- documents are not clear as to what are requirements and what is guidance;
- there is a proliferating amount of requirements and guidance;
- requirements and guidance are not developed in a consistent structured manner – so finding individual important pieces of information is often difficult; and
- finding important related documents is not intuitive.

The profusion of subordinate legal instruments in the form of notices and standards, as well as non-binding guidance material, creates problems for verifiers and risks for MPI as a regulator.

We are working to minimise duplication, inconsistency and confusion caused between overlaps in the different regulatory regimes that have be caused by the development of food legislation over time. One of the aims of the Food Bill is to improve the interface with other food legislation, including the APA.

To improve the regulatory regime MPI is undertaking several pieces of work, including:

- The development of **regulatory principles** that will guide the use of primary, secondary and tertiary regulation. It was intended that this work focus on the Food Bill, but MPI now intends to broaden the scope of this work to help us align our regulatory regimes across all food legislation and the other regulatory regimes we administer.
- The **Standards Integration Programme (SIP)**, which is being applied to dairy regulation in the first instance but will subsequently be rolled out to other areas of regulation.
- SIP aims to improve the way MPI interacts with New Zealand businesses. It focuses on clarifying MPI's tertiary legislation and guidance so that they are easy to find, easy to understand, and developed in a consistent and transparent manner.
  SIP is a key strategic initiative for MPI, and is monitored by the MPI senior leadership team. It is a five year programme of work. Recently the dairy component was put on hold pending the outcome of the WPC Inquiry.

- A programme of work has been set up to work through issues related to the export of **infant formula.** See Appendix B (Infant Formula Work Programme) for more detail on this work programme.

We will give all of this work priority and coordinate from a central point in the organisation. This will ensure the entire regulatory framework is aligned with one set of principles and we are using the right instruments to regulate the right activities.

4.7 SUMMARY

4.7.1 Actions currently underway:

- We are continuing with our Standards Integration Programme. This work has been given a higher priority across MPI pending the outcome of the Government Inquiry into WPC.
- We are continuing working with Food Safety Australia New Zealand (FSANZ) to simplify and clarify the Food Code.
- We are aligning the application of primary, secondary and tertiary legislation, and the use of guidance material to assist industry with compliance.

4.7.2 Suggestions

- Amend the Animal Products Act regime as follows:
  - ensure Risk Management Programmes (RMPs) focus on food safety and suitability regulatory requirements and not non-regulatory aspects of quality;
  - review the requirements that apply to RMPs in light of the regulatory principles MPI will develop, and elevate core RMP requirements from tertiary to secondary legislation where appropriate;
  - require operators to provide a copy of the full RMPs to MPI when applying for registration. Operators should also have to provide any updates to MPI. MPI will keep a copy of these documents.
- Tighten up the process for verifying RMPs within the third party verification framework, and the monitoring of this part of the food safety system.
- Align the compliance and verification requirements and tools in the Food Bill and APA including penalties and infringement notices.
- Explore additional certification options for high-risk food products.
- Strengthen legislation providing for export assurances for overseas market access requirements. This reflects an increasing drive from our markets (particularly new markets) for assurances that reflect their food safety and suitability standards.
- Examine the relationship between the principle of transparency and openness in food safety issues and industry's reporting requirements under the Financial Markets Authority Act 2011.

5 Risk communications

5.1 DEFINITION OF RISK COMMUNICATION

Risk communication is the interactive exchange of information concerning risk between government, industry and consumers that occurs throughout the risk management framework process. It begins with the exchange of information and ideas between risk assessors, risk managers and other stakeholders involved in particular issue. It continues through to the communication of risk decisions to interested parties including industry, consumers and other regulators.

The nature and urgency of the risk information to be conveyed drives the communication messages and approach. It ranges from predominantly one-way communication with the public to warn of a particular risk (as in the WPC incident) to full two-way engagement with a number of stakeholder groups over a period of time.

5.2 CURRENT STATUS

Risk communication occurs throughout MPI and across all three of its systems – food safety, biosecurity and primary production. It occurs as part of business as usual activity, such as standard setting, and compliance activity. It occurs as part of ongoing public education and social marketing programmes around the border, food safety in the home and fisheries. It also occurs in response scenarios where significant events require a specific regulatory response and consumer information.

The merger brought together different risk communication approaches from the different heritage organisations. Risk communication is a dynamic activity and we are continuously learning, particularly in new markets. We are developing skills in risk communication across the organisation and throughout the systems we regulate.

5.3 RISK COMMUNICATIONS FRAMEWORK

Over the last two years, there have been useful learnings from one significant biosecurity exercise, one real biosecurity response and three significant food safety responses, including the WPC incident. There has also been an assessment of the overall state of MPI's communications as inherited in the merger, and the development of a strategic direction for them in to the future.

As a result, MPI is now at the point where it can begin codifying its approach to risk communications in to a single framework across all systems, regardless of where risk communication occurs in the organisation. MPI has also developed a good understanding of the preparedness work it needs to undertake for communications in crisis scenarios.

The recent WPC incident has underscored the need for both these pieces of work, and they are priorities.

The framework will seek to guide the organisation around the following key aspects of risk communications:

- the important role of science and scientists in risk communications;

- the difference between the risks that harm, and the risks that upset and how they must be managed differently;
- the tension between technical accuracy and audience comprehension;
- the difference in communications to inform, and communications to change behaviour;
- the judgement required about when to wait for more information, and when to communicate incomplete information;
- the importance of giving the public something they can do to mitigate risks; and
- communicating scientific uncertainty.

We will also need to consider how to better integrate risk identification by, and communication from stakeholders to MPI.

All of these dimensions have arisen in the various issues MPI has had to deal with over the past two years.

5.4 ACCESS TO INFORMATION

Alongside the development of a Risk Communications Framework and improved preparedness, MPI is also investing in the redevelopment of its channels and general communications to improve easy access to its information for all audiences.

First, MPI has implemented an in-house contact centre with the express purpose of better connecting people contacting MPI to the right technical experts and sources of information relevant to their enquiry. The development of this contact centre has deepened the capability behind the former NZFSA's Food Safety Consumer helpline, improving the hours of coverage and also the ability to manage after hours enquiries in response scenarios. The helpline is an important tool for risk communication to consumers.

Second, MPI is radically overhauling its web presence and is consolidating the seven websites it inherited (with an estimated 25,000 pages of content) into a single user orientated website, which has been explicitly designed to improve accessibility to, and consistency of, information for those who use MPI's services most often. A large part of the focus of the web project is to rationalise content, and introduce clear step by step processes to support compliance with MPI's regulations, and to improve access to information on relevant risks and mitigations across MPI's systems.

Construction of the architecture and much of the functionality of the new website will be complete by December 2013, and the overhauling of content will be largely complete by June 2014.

In undertaking this work, MPI is pioneering the use of the government's new Common Web Services platform and undertaking much of the initial development of it on behalf of the public sector. It is also working closely with the Better Public Services programme to improve digital services to citizens and companies.

5.5 NEW CONSUMER COMMUNICATIONS APPROACH FOR CHINA

A key learning from both the DCD and WPC events has been the need for improved consumer risk communications from 'NZ Inc' in China around food safety issues, aligned with the Chinese regulator.

Both events highlighted the fact that in today's interconnected world, New Zealand needs to be equipped to communicate about food safety risks not only domestically but also to consumers internationally.

5.6 GENERAL FOOD SAFETY COMMUNICATIONS

5.6.1 Responses

During a response, MPI develops and implements a response communication plan that is fit for the event. We take the following steps with industry as appropriate:

- Define messages approach clearly
- Identify and prioritise audiences
- Identify and optimise channels
- Identify and prepare spokespeople, sometimes scientists
- Plan to monitor.

MPI also has access to media specialists to support and advise the internal teams on communications issues. While we work with the industry groups involved on communicating risks, our primary focus is protecting the health of consumers both in New Zealand and overseas and we utilise the regulatory tools we have available when appropriate.

Communications forms part of our response model. Where there is a multi-agency response, we work closely with other government agencies, such as the Ministry of Health and the Ministry of Foreign Affairs and Trade, on the communications, messaging and plan. This was the approach taken for the WPC response.

5.6.2 Consumers

MPI runs a Food Safety Public Information Programme to educate consumers on safe food practices.

We focus our communications on those audiences that are considered most at risk from foodborne illness – the young, the old, pregnant women and those who are immune-compromised – and those that undertake activities more likely to expose them to high risk activities such as hunting or seafood gathering.

We use a range of channels including advertising, printed resources, media releases, information on our websites, and the release of research and aggregated test results.

We also provide agencies which interact with groups that require targeted communications, with relevant published material so they can pass this on to their clients. An important user group for much of our collateral is district nurses.

We also provide additional support for all those activities through the Food Safety Consumer helpline.

Following the merger, the Food Safety Public Information Programme underwent a significant evaluation, and extensive research was conducted to orientate it around the former MAF's social marketing philosophy of risk and compliance communication. A new programme was developed, which has been kept in a maintenance phase until the completion of an updated Campylobacter Strategy, when it will be reviewed for investment.

In future we are also looking to get better feedback from consumers to inform our risk management systems, particularly to understand the different consumer segments and their differing needs. This includes research to better understand the expectations of Chinese consumers.

5.6.3 Industry

MPI utilises industry forums to engage with industry in matters related to food safety risk. These focus on key developments with policy and standard setting and may focus on evolving hazards, or recent incidents. MPI also has statutory consultation obligations to help decide on changing requirements.

MPI works on engagement with industry to ensure implementation of change is pragmatic and fit for purpose. We communicate with industry stakeholders on risks by identifying those affected and which channel is best suited to reaching them effectively.

MPI provides static risk information and prescriptive requirements to industry, such as guidance material based on Hazard Analysis and Critical Control Points (HACCP).

5.6.4 Ministers

MPI informs Ministers of food issues when the issue meets certain criteria. There are currently management actions being undertaken by MPI's Senior Leadership Team to develop a protocol setting out the criteria and thresholds for assessing and escalating risks to Ministers.

5.6.5 Overseas regulators

Where information indicates there is a risk to the health of consumers overseas, we release information as soon as possible. MPI and the Ministry of Foreign Affairs and Trade (MFAT) work directly with the appropriate regulator and posts which disseminate and release the information. MPI will also revoke any official assurance which has been provided to trading partners for the product concerned.

MPI contacts MFAT on a near-daily basis on trade risks. The assessment of trade risk by MPI is made by individual experts using informal criteria. Usually decisions are made following advice from other experts (within MPI and in other Ministries). MPI is moving from recording issues with trade risks weekly in a written internal report, to a simple risk register

in a shared database. MPI will also be formalising the process for contacting MFAT on issues, outlining best practice and rationale for communications.

We work closely with counterparts in importing countries to ensure they remain comfortable with New Zealand's handling of food safety. For example, MPI works with the United States Food and Drug Administration, the US Department of Agriculture's Food Safety Inspection Service, and with different European Commission Directorates, as well as those in Asia.

This ensures that where a problem is identified, those agencies look first to MPI for an explanation, rather than assuming the worst and stopping imports. It also means that they are more prepared to accept our reassurances and/or corrective actions.

We work closely with MFAT on international trade issues, whether these involve unsafe food or perceptions that food may be unsafe. However, it is sometimes unclear when MPI receives a test result or other information whether there will be international implications. We evaluate the information and decide whether it will present a trade risk and if so whether it is serious enough to warrant a formal trade response. MFAT officials are included on responses that might present a risk to trade.

5.7 SUMMARY

5.7.1 Actions currently underway

- We are developing an MPI-wide risk communications framework to provide a clear and unambiguous basis for a single organisation-wide approach to risk communication across the food safety, biosecurity and primary production systems. We will prioritise this work.
- We are prioritising work with MFAT and NZTE on developing appropriate communications infrastructure in China to communicate about New Zealand's food safety system.
- We are redeveloping our web presence to provide easier access to food safety and compliance information.

Beijing News Editorial

29 August 2013

"The false alarm set off by the Fonterra dairy product contamination incident has been very instructive. This event has provided a model for businesses and governments to follow when faced with food safety incidents.

"According to a Xinhua report, on 28 August, the New Zealand Ministry of Primary Industry (MPI) made an announcement that the Fonterra dairy products contamination incident of early August was a false alarm. Final tests had confirmed that the bacteria in 3 batches of WPC were common c. spirulosa and not c. botulinum.

"The conclusion that this was a false alarm has allowed us all to heave a sigh of relief. The impact of the Fonterra incident can't be said to have been insignificant. China's supervisory bodies were all geared up. AQSIQ, FDA and other government agencies quickly met with those in charge in the implicated dairy companies, and recalled the problem milk powder from throughout China, and initially issued an open-ended ban on the import of New Zealand dairy ingredients. Also, the New Zealand Government placed the highest importance on this incident and sent high level officials to China to provide explanation.

"The Fonterra milk powder incident could be said to be this year's food safety incident with the greatest impact. Although this was a false alarm, for all those concerned it was precisely to protect the safety of infant formula and what was needed to be done was done. Where food safety is concerned it is better to have a false alarm than to take a lax approach.

. . . .

"Of course, New Zealand government departments have also demonstrated a highly responsible attitude. After the Fonterra milk powder contamination incident broke out, in the first instance the New Zealand Ministry of Primary Industries got involved in tracking developments, and to fulfill its responsibilities MPI not only undertook as many as 195 tests on the suspected products, it also sent them for laboratory testing in the United States in order to ensure that the eventual test results would be accurate, objective and credible.

"The false alarm triggered by the Fonterra dairy contamination incident is very instructive. Faced with food safety incidents this incident has provided a model for businesses and government on exactly what should be done."

. . . .

6 Verification

The integrity of our food safety system depends on the effectiveness of verification, which is our window to how food businesses are maintaining food safety. Likewise, New Zealand's reputation and market access for our primary products is dependent on the integrity of our assurances and the robust verification systems that support them.

Verification is the process of confirming that operators are meeting their regulatory requirements, and determining whether they would likely be able to meet those requirements in the period between the current and the next verification. It covers a range of auditing activities, tests and other checks to confirm ongoing compliance with approved risk-based management plans, New Zealand standards, and relevant overseas market access requirements.

There is no international best practice for food safety verification. Food safety verification varies from country to country, from highly prescriptive command and control approaches to outcomes-based approaches such as in New Zealand. This variety creates an additional level of complexity - New Zealand exporters and verifiers must meet prescriptive overseas market access requirements.

6.1 NEW ZEALAND'S REGULATORY MODEL FOR FOOD SAFETY VERIFICATION

New Zealand law specifically provides for third parties to undertake verification services. It was expected when this model was set up that Government would step back and a competitive market, with multiple third party suppliers, would develop over time. There was widespread consensus at the time that private sector services would be more efficient and cost-effective than that provided by government agencies. The model also establish incentives for industry to take greater responsibility for compliance through a performance-based approach.

Third-party verification overseas

Third parties are involved in the food safety system in several overseas jurisdictions. Three examples are:

- In Ireland, the Food Safety Authority of Ireland has overall responsibility for the enforcement of food safety legislation, and manages this through a range of contractual arrangements.
- In New South Wales, third party auditors are used at some businesses. The auditors have to meet the National Food Safety Audit Policy, and have their contract with the food business.
- In Victoria, third party auditors are also used at some businesses. MPI understands that the auditors have their contract with Dairy Food Safety Victoria.

Under Part 8 of the Animal Products Act, MPI recognises the competency of recognised agencies and persons to provide independent evaluation and verification services, according to the requirements set out in specifications and approved criteria. The Act sets out the requirements, procedures for recognition, duties of recognised agencies and persons, when

their recognition can be suspended or withdrawn. It also provides for keeping a register of recognised agencies or persons. Further details on requirements are set out in tertiary documentation (specifications and approved criteria).

Organisations that wish to be recognised for the purposes of verification under the Animal Products Act must be accredited to ISO/IEC 17020 (General criteria for the operation of various types of bodies performing inspection). Accreditation requires ongoing assessment by an accreditation body. Verifying agencies are required to provide MPI with copies of any assessment reports.

In addition, all verifying agencies must have a documented quality system. This is assessed by the accreditation body and a technical expert. The assessment includes a visit to the agency head office and any regional offices where the agency may operate. The assessment also includes on-site observation of agency personnel performing the function that they wish to be recognised for.

New Zealand has worked closely with its trading partners to assure them that the New Zealand system meets international standards equivalent to alternative approaches to risk management and verification. International confidence in the system is reflected in bilateral agreements for food safety with the European Union and United States.

MPI Verification Services (MPI VS)

MPI VS is a directorate within the Verification and Systems Branch of MPI. MPI VS is accountable for verifying that meat, seafood and other animal products and by-products, meet both the New Zealand standards and additional standards of importing countries. MPI VS also performs imported foods clearance procedures.

There are more than 280 staff MPI VS located throughout New Zealand, about 200 of whom are registered veterinarians. MPI VS work throughout New Zealand in locations where meat, seafood and other primary products are processed and stored.

Verification and certification services are provided to about 700 food processing companies (for example, meat, seafood, game and dairy), with the export meat sector accounting for 80% of activities.

MPI VS is a recognised agency under the Animal Products Act, and is accredited to ISO17020. MPI VS is audited annually by International Accreditation New Zealand (IANZ).

In a contestable market where a third-party verifier is not available MPI Verification Services is the ‘verifier of last resort’, thus supplying a safety net for verification.

6.2 SUPPORT FROM MPI RELATED TO VERIFICATION

Because of the importance of verification in our system, MPI actively works to maintain the quality of verification. Here are some of the actions we take:

- We work to clarify requirements for industry and verifiers, such as through joint development of codes of practice and template RMPs.

- We hold workshops with verifiers (including MPI Verification Services) for 'calibration' purposes. The purpose of calibration is to ensure consistency of verification across our different food-related statutes.
- We have implemented a number of long-term strategies to improve RMP compliance rates, such as verification online (GEN 1 & 2), training initiatives and e-learning.

6.3 CHANGES TO VERIFICATION

6.3.1 Contestability

The Animal Products Act specifically provides for third parties to undertake verification services in contest with the government verifier. It was expected when this contestable model was established that Government would step back and a competitive market, with multiple third-party suppliers, would develop over time.

In the 14 years since the Act was enacted, very little competition has emerged. In the dairy sector there are only three verifiers with AsureQuality verifying over 75% of the dairy industry, and MPI Verification Services the majority of the remainder. In other sectors, MPI Verification Service and AsureQuality are the dominant or only providers, with the exception of the wine and food sector.

Sector	Verification required by New Zealand law	Verification required for overseas market access	Verification Providers
Animal Products (non dairy)	Animal Products Act	yes	2 MPI and AsureQuality
Animal Products dairy	Animal Products Act	yes	2-3 MPI, AsureQuality and Eurofin
Plants	None	yes	3
Wine	Wine Act	no	Many
Food Act	Food Act	yes	Many
Live animals & germplasm	Animal Products Act	yes	2 MPI and AsureQuality

There are a number of characteristics associated with the New Zealand food industry that may have constrained the development of a competitive verification market. Some of the key factors include overseas mandating requirements for government supplied verification (red meat), sectors such as dairy with few processors, scale economies of MPI and AsureQuality, established business relationships, high entrance costs for new verifiers and the verifier costing strategies.

MPI has reviewed the criteria governing the role of MPI VS in the verification market to address some of these issues. However there is a case for evaluating the current contestable verification market relative to the original policy objectives and considering whether the market supports food safety objectives.

6.3.2 Multiple regimes for some products

A further issue is that some multi-ingredient businesses have to operate under multiple regimes (e.g. dairy, wine, seafood or the Food Act) and may require multiple verifications and more than one verifier.

The Food Bill will go some way to addressing this because it will introduce a regime that is far more compatible with the Animal Products Act than the current Food Act. In the long-term a better solution may be to move towards a single food statute.

6.3.3 Verification of private standards

Private standards, such as organic schemes or the requirements of overseas retailers often overlap with regulatory requirements. Third-party verifiers may verify to the regulatory standard and provide additional services to industry by verifier to one of several private standards. MPI Verification Services, however, only verifies to the regulatory standards.

We are considering whether MPI Verification Services could broaden its scope to include verification of private standards. This could reduce costs to businesses.

6.3.4 Contractual relationships between MPI and verifiers

In our system, food businesses contract verifiers directly to assess their operations against RMPs. MPI supports industry being able to choose verifiers as this is a key component of the contestable market. Auditors from other competent authorities have expressed views about the direct relationship between third-party verifiers and industry and the potential for conflict of interest.

We believe this is only an issue of perception, but it is an important one to overseas regulators, so we propose a change to the system that would remove the contractual element of the relationship between industry and third-party verifier. A potential solution could involve industry selecting their verifier of choice from a list of verifiers contracted to MPI. This change will demonstrate to trading partners the clear separation between industry and verifiers and promote transparency.

6.4 MONITORING AND EVALUATION OF VERIFICATION IN NEW ZEALAND

MPI periodically assesses the extent to which third party verifiers ensure compliance with food safety standards through the Systems Audit process. Previous systems audits have identified areas for improvement:

- Accreditation bodies may identify corrective actions when they carry out their assessments of third-party verifiers, but reporting of these actions to MPI, and follow-up, is ad hoc and needs to be systematised.
- Third-party verification related to overseas market access requirements can be improved to ensure requirements of overseas auditors are satisfied.
- We monitor the performance of verifiers closely. From time to time, we need to work with Agencies and verifiers to lift their performance. We rarely need to take further action, but there have been seven cases in the past five years where MPI has moved to refuse or remove recognition, or where we have imposed conditions on recognition.

6.5 SUMMARY

6.5.1 Actions currently under way

- We have agreed to review contestability (competition) in the third party verification market, pending the conclusion of the Government Inquiry.
- We are investigating options to realise greater efficiencies in the verification process e.g. verification of private standards, streamlining requirements for multi-ingredient foods.

6.5.2 Suggestions

- MPI to assume responsibility for the contractual relationship with third party verifiers to remove perceptions of a conflict of interest between verifiers and the businesses they verify.
- MPI to calibrate verification across our food statutes to ensure consistency between regulatory areas.

7 Compliance

An effective and robust compliance system is essential to ensuring that New Zealand's food safety regulatory framework is implemented effectively.

MPI applies the 'VADE' model as the basis of its compliance system. The VADE model depicts a proportional, risk-based approach that builds on an understanding of the drivers of compliance behaviours. The model segments the regulated sector according to different compliance behaviours:

- Voluntary – Voluntarily comply and informed;
- Assisted – Attempting to comply and uninformed;
- Directed – Propensity to offend (opportunistic);
- Enforced – Criminal intent and illegal activity.

The model enables the use of a broad spectrum of activities, tools and interventions to influence the compliance behaviours of our primary sectors. It has been recognised as representative of the best practice compliance principles[8] agreed by the New Zealand Compliance Common Capability group.

Over the past several months, MPI has been adapting the VADE model to the food system. The Food Bill will introduce a risk-based approach to food safety in some parts of the food sector that are not already regulated under the Animal Products Act. It will also provide MPI with a wider range of compliance and enforcement tools, including registration requirements and food control plans for some food operations, and a power to issue infringement fees. The Bill will also allow MPI to apply some of these tools based on compliance behaviour. So, for example, the frequency or intensity of verification and system audit could be increased depending on how well a food operation is managing food safety risks.

Several of these approaches are already available and applied under the Animal Products Act. For example, as one of its interim measures in response to the WPC contamination incident, MPI recently announced that it was stepping up performance-based verification in the dairy sector. The APA also currently provides statutory powers to enable Animal Products Officers to (among other things) enter, inspect, sample, seize and require corrective actions.

The wide range of compliance and enforcement tools available allows MPI to create a pathway of incentives to encourage voluntary compliance as well as an escalation pathway leading to enforcement action, should a food operation fail to comply. MPI is able to select tools based on what motivates food operators in particular circumstances. MPI will investigate options to expand those tools to include the use of administrative penalties, for example, the ability to recover costs from industry where MPI has had to take compliance action.

Under the APA, approved verifiers have verifier rights if the terms of an operator's Risk Management Programme (RMP) are not being followed. These are identified through exception reports and non-conformance reports to MPI. Verifier rights fit under the

[8] Principles include: Risk-focused, graduated and proportionate, results-oriented, collaborative and cooperative with the regulated sector, use of the media, project-based approach to solving problems.

"Voluntary" and "Assisted" parts of the VADE model. Food safety businesses are assisted to quickly rectify any discrepancies identified by the verifier rather than immediately being directed or enforced by way of penalties or prosecutions. If compliance is subsequently necessary then this is undertaken by an Animal Product Officer and may be followed by prosecutions.

7.1 CO-ORDINATED IMPLEMENTATION OF THE VADE MODEL ACROSS MPI

MPI has made a commitment to support New Zealand businesses to grow, innovate, and take on new export markets. At the same time, MPI is the biggest regulator in New Zealand, with compliance responsibilities across several portfolios. It is a challenge for MPI officials to manage the distinction between the roles of regulator and enabler of industry, and it is important for industry to be left in no doubt about what role MPI is playing at any given time.

One way MPI can improve the performance of the food safety system is by providing more clarity about its role as a regulator and ensuring that the industry understands its responsibilities to MPI and to the public as producers of safe food.

Following the creation of MPI, a single compliance branch was established. The transfer of compliance functions has necessitated a cultural adjustment across the organisation as compliance activities had been undertaken differently by the legacy agencies, and some functions that had been carried out by NZFSA's compliance branch have been split off and allocated to other teams.

Co-ordination between MPI branches involved in food safety could be strengthened, to ensure the compliance framework under the VADE model is fully integrated and coherent across all of MPI. In the Compliance Business Plan, MPI is currently reviewing how individual branches contribute to each of the service delivery categories in the VADE model, to identify opportunities for improved co-ordination and consistency of decision making. This work is being progressed as a matter of priority in the 2013-14 year.

7.2 SUMMARY

7.2.1 Actions currently under way

- We are applying the VADE model to the food sector.
- We are continuing to explore expanding our suite of tools to incentivise and direct compliant behaviour.
- We are continuing to improve our processes for escalation where non-compliance is identified.
- We are continuing to improve communication about regulatory requirements and responsibilities, and the consequences of non-compliance.

7.2.2 Suggestions

- Progress the Food Bill to ensure tougher penalties, a broader range of penalties, including the use of administrative penalties, and a wider range of compliance tools than currently available under the Food Act.
- MPI to improve capability for systems audit and evaluation of the food safety system, and for monitoring programmes and recognised agencies.

8 Recall and Tracing

8.1 RECALL

A core function in any food safety system is the ability to recall potentially unsafe or unsuitable food. Food recalls protect public health by facilitating the efficient and rapid removal of unsafe food from the distribution chain, and (where necessary) informing consumers of the presence of potentially hazardous food in the market.

Recalls are usually initiated where there is a reasonable possibility that the use or consumption of the food would cause adverse health consequences (e.g. the presence of pathogenic organisms such as *Listeria monocytogenes*) or if the product has serious defects that pose a potential health risk (e.g. incorrect labelling that does not declare the presence of an allergen).

There are two levels of product recall:

- Trade-level recall –the removal of unsafe food from the distribution chain but does not extend to food sold to the consumer.
- Consumer-level recall – the removal of unsafe food from the distribution chain and extends to food sold to consumers and therefore involves communication with consumers. Consumer recalls are more extensive than trade recalls.

8.2 TRACING

The tracing and tracking of potentially unsuitable or unsafe product is becoming increasingly integral to both food safety and quality assurances. The ability to trace product through the manufacturing and distribution processes is a well recognised part of any recall procedure. It is also integral to New Zealand's assurance programme for animal products. The exception to this is for dairy products, which currently have limited traceability requirements, and through-chain product movement within New Zealand is only visible to MPI and third-party verifiers for product intended for certain markets (EU, Russia, Belarus and Khazakstan). Dairy product tracing information is increasingly being required for responding to market access issues, as overseas regulators seek assurances about the integrity of New Zealand products. This was demonstrated during both the DCD response and the WPC response.

The increasing complexity of modern manufacturing, distribution and supply chains presents significant challenges to the efficiency and effectiveness of product tracing. These challenges are well evidenced in the dairy sector where the complexity of industry structures and supply chains means a product may move through several different entities and manufacturing cycles (both domestic and overseas) prior to reaching consumers. This process is often at odds with consumer expectations of a single entity maintaining total control of the supply chain, with an easily identifiable company or person to hold accountable should an event arise.

8.3 REGULATORY ENVIRONMENT

8.3.1 Role of industry

Under the Food Act and Animal Products Act (APA), primary responsibility for the recall and tracing of potentially unsafe products rests with the food industry. This is achieved through compliance with regulatory requirements, standards and food safety practices relating to recall.

Regulatory requirements for the recall and tracing of animal material and products are provided for under the APA, and are primarily administered through Risk Management Programmes (RMPs). Section 17(2) of the APA requires RMP operators to include recall procedures as part of their RMP. These procedures must include criteria for deciding when a recall is required, how the retrieval and disposition of the recalled product will be managed, and who needs to be notified in the event of a recall9. The RMP should also provide for appropriate corrective actions including recall of product, together with appropriate and auditable documentation and record keeping.

Regulations also require RMP operators intending to process dairy material for export, and for which an official assurance is required, to keep traceability records. Additional (full) traceability requirements currently apply to dairy products intended for EU and Customs Union markets, in line with Overseas Market Access Requirements.

The recall of food products is administered through the Food Act, with recall and tracing procedures detailed in Food Safety Programmes (FSPs), akin to RMPs under the APA. While the use of FSPs is voluntary, a number of large scale domestic and international food retailers require suppliers to have FSPs, particularly for high risk products. Operators that do not have FSPs are encouraged to prepare recall plans and to seek advice from Food Act officers.

All RMP and FSP operators are required to ensure recall procedures are carried out in accordance with their registered RMP or FSP.

8.3.2 Role of the verifier

All RMPs and FSPs, including provisions relating to recall and tracing, are verified regularly by recognised agencies (including MPI's Verification Services) to confirm companies are complying with the provisions. The level and expectations of verification are different under the two regimes (e.g. export meat processing and export dairy RMPs are verified at least quarterly, export meat slaughter plants have fulltime VS veterinary presence).

In the event of a recall, the role of the verifier is determined on a case by case basis, depending on the scale, health risks and complexity of the recall. Verifiers under the APA would typically assist with co-ordination and the verification of product disposal. However auditors under the Food Act are not typically involved in recall events.

[9] The Animal Products (Risk Management Programme Specifications) Notice 2008

8.3.3 Role of the regulator

MPI is responsible for setting regulatory standards and developing guidance material[10] about product recall and tracing. The Director-General also has the authority to direct a recall of an animal product (noting that a lesser authority sits with the Minister of Food Safety under the Food Act). Alternative or supporting instruments include Notices of Direction in which the Director-General can direct operators to perform certain actions (e.g. not to release product out of the operator's control). Under the Food Act, the Director-General can also issue Privileged Statements, which are typically used to inform or warn the public about potentially unsafe products.

In the event of a recall MPI is responsible for co-ordination, including verifying the affected product has been removed from the system and appropriately treated or disposed.

8.4 INITIATIVES UNDERWAY TO IMPROVE TRACEABILITY AND RECALL

While New Zealand's recall and tracing regime was recently assessed and considered comparable with US FDA systems, a number of improvements are in train (both industry and MPI led) to improve tracing and recall practices.

8.4.1 Regulatory Alignment: The Food Bill

Regulatory inconsistencies between the Food Act and the APA, including those relating to recall and tracing, have underpinned the development of the Food Bill. The Food Bill is intended to replace the Act in its entirety and will align the roles and responsibilities of MPI, verifiers and industry with those in the APA. The Bill will also make amendments to the APA to improve the interface of regulatory processes across the food sectors.

Specific changes proposed to tracing and recall procedures include:

- Mandatory requirements for processors of high risk products to include tracing and recall provisions in Food Control Plans (akin to FSPs and RMPs), which will be subject to external verification. Recall and tracing provisions will also be required of medium risk operators, including distribution companies.
- Strengthening of recall powers for foods by enabling the Ministry's Director-General to recall food or food related accessories on reasonable belief that they are not safe or mislabelled.

These changes are expected to deliver significant improvements to the effectiveness and efficiency of product recalls under the Food Act, and underpin the need for the timely passage of the Bill.

8.4.2 Traceability and certification system improvements

Certification of dairy products is currently administered through MPI's Milk Products electronic certification system (MP e-cert). This system does not capture traceability information for dairy products. Where traceability is required for certain markets, such as for dairy exports to the EU and Customs Union, this traceability is currently undertaken through

[10] Refer www.foodsafety.govt.nz for recall guidance material

paper means. As part of a long-term plan to improve New Zealand's certification of animal products, and in line with recommendations in the Systems Audit on Infant Formula (April 2012), MPI is rebuilding its Animal Products electronic certification application and is transitioning the dairy industry into the rebuilt system, which covers most other animal products (meat, seafood, honey, hides, skins and wool). Transition to the AP ecert system will allow full traceability information to be collected for all dairy material and dairy products but will require change to regulatory instruments to mandate use of this functionality. This change would align the dairy industry with traceability requirements in the seafood industry.

MPI has been working with dairy industry operators to ensure industry compatibility with the new AP e-cert system. This includes Fonterra, which is currently redesigning its inventory and export systems. As with inventory systems of many other industry stakeholders, the new Fonterra system has been designed to interface with the new e-cert system, and is expected to deliver significant tracing improvements across the company's production and distribution chains.

The transition of the dairy industry from the MP cert to AP cert system is expected to be completed by mid 2014.

8.4.3 Mock Recalls and Auditing

MPI has recently announced a number of interim measures that will be implemented in the dairy sector while it awaits the outcome of the Government Inquiry into the Whey Protein Concentrate Contamination Incident. These measures are targeted to manufacturers and exporters of potentially high risk dairy export products and include a targeted audit of company traceability and recall systems. This involves third party verifiers taking a product and getting the company to trace back and forward to check they have the traceability systems in place. Verifiers would also get the company to set up mock recall to test recall procedures.

While the audit of tracing and recall systems is a requirement under the current regulatory framework, mock recalls are not currently a regulatory requirement. They are however recommended in MPI guidelines and are also required of some manufacturers in specific customer specifications, such as Woolworths.

It is expected that MPI will reconsider the regulatory framework around mock recalls, following completion and evaluation of these interim measures.

8.4.4 Improving traceability – managing the rise of unregulated exporters

A number of measures have recently been implemented by MPI to address issues relating to the unlawful export of infant formula by unregistered exporters. Under the APA, only registered exporters can export dairy material, including products such as infant formula.

In addition to contributing to the integrity of the official assurance system, exporter registration provides important information for product recall and tracing. The recent challenges identifying infant formula exporters is symptomatic of the increasing complexity of the industry, and the rise in the number of players in the industry. MPI is now confident that all commercial infant formula exporters are now registered with MPI.

8.4.5 GS1 Product Recall System

GS1 ProductRecallNZ is an industry led initiative designed to improve industry communication with distributors and regulators during recalls. It is an online, subscription based service that is being currently being rolled out NZ, following its development and launch in Australia.

8.5 SUMMARY

The above analysis illustrates that while there are robust tracing and recall system in place for food safety and market access, the system may benefit from further refinements.

Analysis against the objectives for food safety shows that:

- Inconsistencies between regimes under the APA and Food Act, particularly the RMP and FSP frameworks, has led to significant variability in the regulatory regimes, roles, accountabilities and industry preparedness for recall and tracing.
- Transformation of key sectors, particularly the dairy industry over last 10 years has challenged the ability of tracing and recall systems to respond to complexities of current markets. This issue has implications for public health and trade as tracing information is increasingly required to address market access issues.

While a number of improvements to the regulatory regime have already been signalled through the Food Bill, timely progression of the Bill through the legislative process will be critical to ensure adequate provisions are in place to effectively manage the recall and tracing of unsuitable or unsafe food.

As part of our ongoing review of industry preparedness, MPI will reconsider the regulatory framework around mock recalls, following completion and evaluation of current trials (as part of the Dairy interim measures). Future consideration may also be given to increasing mandatory requirements for recall and tracing procedures if, following implementation of Food Act, significant risks remain. This issue is not currently anticipated and further work would be required to determine the value of any such proposal.

There may also be an opportunity for MPI to further consider full traceability for dairy products, irrespective of specific market access requirements. This would require further analysis but could possibly be achieved through a tertiary instrument. At this stage it is unclear how practically or financially feasible this option would be, given the substantial complexities of the current market. It is likely that further engagement with industry would be required before any decision was made to progress these investigations.

8.5.1 Actions currently under way

- We are currently trialling increased product and ingredient tracing through our dairy interim measures in response to the WPC contamination incident.
- We are currently transitioning the dairy industry into the rebuilt animal products certification system. This will enable full traceability information to be collected for all dairy material and dairy products that require export certification but will require change to regulatory instruments to mandate use of this functionality.
- Our Exercise Programme includes tracing exercises with industry involvement.

8.5.2 Suggestions

- Align MPI's recall powers in food legislation while retaining industry's obligation to initiate recalls itself.
- Strengthen the primary food legislation, including Food Bill and APA, to clearly outline industry's responsibility to have robust systems in place to ensure traceability for ingredients and products that they sell.
- Investigate making full traceability mandatory for all domestic and export dairy.
- Develop requirements for the timely exchange of product and ingredient tracing information between industry and MPI.

[Appendices withheld under s.9(2)(ba)(ii)]