WPC Inquiry Part A submission and additional background documents (3 June 2013):

- **Government Inquiry into Whey Protein Concentrate Contamination Incident: Chronology 2 August 2013 – 3 September 2013**
- **WPC 2013 Response structure**
- **MPI Table of Lessons Learned**
- **MPI Table of Actions to Implement**
- **MPI v Fonterra Ltd – Admitted Summary of Facts**
- **Media Releases and Director-General Statements (3 August 2013 – 12 March 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

3 June 2014

Miriam Dean CNZM QC
Chairperson
Government Inquiry into the Whey Protein Concentrate Contamination Incident
PO Box 144
WELLINGTON

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Dear Ms Dean

SUBMISSION TO THE GOVERNMENT INQUIRY INTO THE WHEY PROTEIN CONCENTRATE CONTAMINATION INCIDENT ON PART A OF THE INQUIRY'S TERMS OF REFERENCE

Introduction and summary

1. The Ministry for Primary Industries ("MPI") is pleased to present its submission on Part A of the terms of reference for the Government Inquiry into the Whey Protein Concentrate ("WPC") Contamination Incident ("Inquiry"). MPI provided a submission on Parts B and C of the Inquiry's terms of reference on 14 October 2013.

2. The WPC Contamination Incident was New Zealand's largest food safety scare in recent times and resulted in the largest food safety response ever mounted by the New Zealand Government. The incident tested the country's food safety system, processes and capacity. MPI met the demands of the incident and responded in accordance with our responsibilities, as the agency responsible for ensuring food safety, for: protecting the public; working closely with industry to minimise risks; ensuring access to overseas markets for New Zealand food exports; and enforcing food safety legislation.

3. As this submission demonstrates, MPI placed the safety of consumers' health and wellbeing at the forefront of its thinking in the WPC incident response. While there is no more important responsibility than protecting the public, doing so also ensures that New Zealand's food exports are trusted and

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valued by our trading partners. The correctness of this approach was acknowledged by the United States Food and Drug Administration when on 5 September 2013 one of its officials commented as follows on the Administration's public blog:

> *Recently, you may have seen New Zealand's food safety system in the news, associated with a potentially contaminated whey protein product commonly used in infant formula and sports drinks. Although the product had not been exported to the U.S., the New Zealand authorities discovered that a package of 21 candy bars containing whey protein from the potentially dangerous batch had been sent to a company here for market testing. As soon as they identified the product, they contacted FDA to let us know that they had traced it to a particular company and had contacted the company. They made sure that the product had not been sold to any consumers in the U.S. and accounted for all of the candy that had been shipped here.*
>
> *In the end, the whey protein that was recalled had not been contaminated after all—it proved to be a false alarm.*
>
> *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.*

4. The Inquiry's report on Parts B and C of its terms of reference confirmed that New Zealand's food safety regulatory system is fit for purpose. Nevertheless, MPI is always considering how it can improve its performance as a regulator. The challenges presented by the WPC Contamination Incident have provided an opportunity for MPI to reflect on how it fulfils its regulatory functions.

5. This submission addresses Part A of the Inquiry's terms of reference, namely:

> *Inquiry into how the potentially contaminated whey protein concentrate entered the New Zealand and international markets, and how this was subsequently addressed.*
>
> *(a) In relation to this incident of potential contamination of whey protein concentrate at Fonterra's Hautapu plant in 2012:*
>
> *(i) the causes of this incident;*
>
> *(ii) the practices used at each stage, from sourcing the raw material to products containing the whey protein concentrate entering the market;*
>
> *(iii) the timeline of steps taken by Fonterra, and any other party, with regard to testing and reporting the potential contamination of whey protein concentrate;*
>
> *(iv) the implementation of contingency plans for food safety incidents by Fonterra;*
>
> *(v) Fonterra's history as a significant manufacturer and exporter of safe dairy products; and*
>
> *(vi) an examination of the response of the regulator (that is, what actually happened).*

6. In response to Part A of the Inquiry's terms of reference, MPI submits that:

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a. the causes of the incident were established in the course of MPI's compliance investigation: the details of the causes of the incident are addressed in the Admitted Summary of Facts provided to the Wellington District Court;

b. the incident response to the WPC contamination incident achieved its intended purpose of protecting consumers' health and protecting New Zealand's reputation as a safe exporter of food and is being used to inform the Ministry's future food safety responses, as well as responses across the breadth of all of our systems;

c. the compliance investigation into the incident resulted in MPI charging Fonterra Limited (a subsidiary of Fonterra Co-operative Group Limited) with four offences under the Animal Products Act 1999;

d. Fonterra Limited pleaded guilty to all four charges and was fined $350,000;

e. we are committed to continuous improvement and consequently has proactively considered how to maintain New Zealand's world-class regulatory systems, to which end we:

   i. commenced an organisational alignment in 2013 (now implemented) that focuses expertise on core activities (including food safety) and improves Ministry-wide governance across those core activities;

   ii. identified the regulatory lessons emerging from the WPC contamination incident, which the Ministry is now addressing; and

f. we are proactively implementing the recommendations from Parts B and C of the Inquiry.

7. Each of the foregoing is addressed in turn below under the following headings:

a. Causes of the contamination incident;

b. MPI's regulatory response to the contamination incident;

c. MPI's compliance investigation and prosecution;

d. What the WPC contamination incident revealed;

e. Work already underway and lessons learned;

f. Implementing the Inquiry's Parts B and C recommendations; and

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g. Conclusion.

8. Please find listed at the Appendix a number of background documents provided to the Inquiry in support of this submission.

Causes of the contamination incident

9. The events surrounding the WPC contamination incident are well-traversed, including in the Inquiry's report on Parts B and C of its work. In February 2012, following the contamination of a batch of WPC with a broken torch lens, Fonterra re-worked 41 tonnes of WPC at its Hautapu plant contrary to the procedures in its Risk Management Programme ("RMP"), which was registered under the Animal Products Act 1999. The re-worked product caused the contamination incident. The details of the causes of the incident are addressed in the Admitted Summary of Facts, which MPI provided to the Wellington District Court, a copy of which is included with this submission.

MPI's regulatory response to the contamination incident

10. MPI's involvement with the contamination incident began on 2 August 2013 when Fonterra informed the Ministry about the contamination. Fonterra informed MPI of a positive test result for *Clostridium botulinum,* specifically:

a. contamination of WPC with Sulphite Reducing Clostridia ("SRC") at levels ranging from 110-950 cfu/g was confirmed as *Clostridium botulinum*;

b. testing via mouse bioassay on a composite of the nutritional powders all using the WPC product confirmed the presence of *Clostridium botulinum*;

c. included in the market product were products intended for vulnerable populations: infants and children in the 0-3 years age brackets;

d. this product was circulating in the market; and

e. Fonterra was in the process of alerting its customers to the issue.

11. Immediately on receiving Fonterra's notification, MPI mobilised a wide range of experts and other officials from across the Government to lead the official response. The response structure was based on the Co-ordinated Incident Management System ("CIMS") model, which has been adopted by a number of New Zealand government agencies. The CIMS model ensures there are clearly-defined functions for incident control, operations, planning, intelligence, logistics and communications. The

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model is scalable, in that the scope of the response will determine how many people are needed to perform the functions. MPI's customisation of CIMS incorporates a market access dimension, which is particular to biosecurity and food safety responses. Our CIMS response also draws in scientific expertise (through a Technical Advisory Group) and operational components such as diagnostic laboratories. In this incident, as with all food safety and biosecurity responses at MPI, the response operated at two decision-making levels:

a. The Response Strategic Leadership group ("RSL") which co-ordinated the regulatory response from a government-wide perspective and made high-level decisions. The RSL comprised the MPI Response Manager, senior officials from MPI and representatives from the Department of the Prime Minister and Cabinet, Ministry of Foreign Affairs and Trade, Ministry of Health and New Zealand Trade and Enterprise. MPI's Acting Director-General initially chaired the RSL, after which he delegated the responsibility to the then Deputy Director-General Compliance and Response.

b. The Response Management Team ("RMT") ran the operational response. The RMT advised the RSL, implemented RSL decisions and provided co-ordinated advice to the Response Manager. MPI's Director of Animal and Animal Products acted as Response Manager and chaired the RMT. The RMT comprised operational and policy officials from MPI and the Ministry of Foreign Affairs and Trade. Please note that the Ministry of Health decided that it could best assist by being part of the overall response process, but not the RMT. MPI's response liaison manager co-ordinated with the Ministry of Health.

12. Fonterra's initial notification to MPI on 2 August 2013 stated clearly that the company had received positive tests for *Clostridium botulinum* and outlined the possible effects of *Clostridium botulinum* (that is, it is a highly potent neurotoxin with potentially deadly effects). Further, Fonterra's communications to MPI stated that the contaminated WPC was included in infant formula. Fonterra's written communication indicated that as a next step its customers would need to be notified, although it emerged that Fonterra had already contacted some of its customers. In light of this notification, MPI took a precautionary approach in its response, the first priority of which was protecting consumers' health. This critically important aim continued while the Ministry moved to confirm the accuracy of the information provided by Fonterra through the Ministry's own series of tests on the contaminated WPC.

13. The first RSL meeting occurred at 3.30pm on 2 August 2013, that is two hours after Fonterra informed MPI of the test results. The RSL set the objectives of the response, which were:

1. Protect consumer health

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2. *Protect New Zealand's reputation for safe product and maintain market access in dairy products*

3. *Keep Ministers/SLT and RSL fully informed*

4. *Effective stakeholder liaison*

5. *Document system, process, records and reports.*

6. *Investigate circumstances and any liability*

7. *Learning and preventing any recurrence*

14. The RSL confirmed at its first meeting that, in addition to MPI officials, the group would also include officials from other interested agencies, namely the Department of the Prime Minister and Cabinet, the Ministry of Foreign Affairs and Trade, the Ministry of Health, and New Zealand Trade and Enterprise. Between 60 and 110 officials from across the New Zealand Government worked on the contamination incident response, although only a small proportion of these officials were involved with decision making at the RSL and RMT levels. Key officials involved with the response are identified in the Response Structure diagram included with this submission. MPI would be glad to facilitate the participation of any of these officials in the Inquiry's processes. These officials were involved in a wide range of concurrent and highly coordinated activities including public communications, close liaison with affected businesses, tracing and containment of affected product, technical analysis, liaison with overseas markets, and commissioning of further test results.

15. MPI's two-tier food safety response model quickly established a flexible, but consistent, work pattern (or "daily rhythm") of meetings and reports. On 2 August 2013 both the RMT and RSL group met twice to establish the focus of the response. Further, at midnight on the first day of the response, the RMT produced its first Situation Report to the RSL. The reports provide a comprehensive summary of activities and the state of MPI's understanding of the immediate situation and the flow of information connected to the response.

16. Throughout the first week of the response, both the RSL group and the RMT met twice daily and, in fact, the RMT continued meeting twice daily until 14 August 2013. The frequency and substance of meetings reflected the tasks at hand. As is apparent from the meeting frequency, once the safety of the public, in particular infants, was better-assured through a clearer understanding of which products contained the affected WPC, the tone and frequency of meetings shifted.

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17. The MPI response team also set about tracing the affected WPC product, both in New Zealand and overseas, to ensure that consumers' health could be protected by determining the extent of the contamination and then eliminating the source of that contamination. The consequential benefit of tracing product would be to prove the effectiveness of New Zealand's food safety system and thereby protecting the country's reputation as a producer of safe food. Tracing of the product involved reconciliation of data provided by Fonterra, Nutricia and other companies, across several production facilities and numerous product lines. There were challenges in obtaining this data and reconciling it, and the work was further complicated by further revelations of additional product that had not been accounted for in the initial notification at various stages during the first few weeks. The daily progress on tracing product is included in the Situation Reports. Nonetheless, MPI officials were able to complete a full and accurate tracing and verification report, which was published on 28 August 2013.

18. As a first step in protecting consumers living overseas, on the evening of 2 August 2013 MPI, via MFAT, sent formal messages to diplomatic posts in Bangkok, Beijing, Canberra, Kuala Lumpur and Riyadh. These were the posts connected to the places where Fonterra originally indicated product had been exported. The messages requested that New Zealand diplomats inform competent authorities in those countries about the contamination incident and provide the competent authorities with a formal notification letter from MPI. At the same time, MPI also contacted directly Australia's Department of Agriculture, Fisheries and Forestry.

19. An important aspect of the response aim of protecting consumers (and MPI's risk management approach more generally) was ensuring that consumers were armed with information that allowed them to understand the risks accurately and take their own steps to minimise their exposure to risks. As we noted in our submission on Parts B and C of the Inquiry, "the nature and urgency of the risk information to be conveyed drives the communication messages and approach." In this case, our approach was informed by the widespread distribution of potentially contaminated product, the vulnerability of intended consumers (infants), and the possible severity of the consequences of botulism poisoning.

20. MPI released its first media statement concerning the contamination incident at midnight on 2 August 2013. The necessarily general statement outlined the botulism risk, the sort of products in which the contaminated WPC was used as an ingredient and the steps MPI was taking to trace exactly which product was affected. We note that Fonterra had already informed its major customers about the contamination incident before the company contacted MPI, so some information about the incident was already in the public domain.

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21. The Ministry subsequently issued privileged statements under the Animal Products Act 1999 and the Food Act 1981 on 3 August 2013, 4 August 2013, 6 August 2013 and 12 August 2013. The Ministry also made media statements about voluntary recalls, potentially affected products, the launch of the compliance investigation and the results of its testing and tracing. MPI has provided a set of the Director-General's statements and media statements with this submission.

22. Further, MPI and the Ministry of Health also undertook a significant online advertising campaign to ensure that consumers had the right sort of information in front of them This campaign included innovative use of social media channels and Internet pop-up ads to target information to parents and caregivers who potentially used the affected product.

23. The combination of affected companies' extensive voluntary recall of WPC product from customers and MPI's targeted use of privileged statements about certain products ensured that most of the affected product was withdrawn from sale in New Zealand. MPI would like to extend its appreciation to Fonterra and Nutricia for assisting with tracing product and making voluntary recalls. These companies assisted MPI in performing its functions as a regulator. Without their willing co-operation MPI's task would have been much harder.

24. The substantive response work ceased at the end of August with the following two events:

    a. The completion of a comprehensive product tracing report, which MPI released on 28 August 2013. The results of tracing the destination of 41 tonnes of WPC which had been used in a wide range of products intended for export to several different markets confirmed the importance of a strong focus on tracing product.

    b. The return of MPI's test results from the United States Centers for Disease Control and the United States Department of Agriculture on the affected product, which indicated that the original results for *Clostridium botulinum* were false positives. MPI released a summary of the test results on 28 August 2013, and the full report the next day.

25. The flexibility of MPI's response model has proved invaluable since the WPC incident. The use of the model for both food safety and biosecurity demonstrates the robustness of the model. Since August 2013, MPI has mounted approximately half a dozen food safety responses and approximately 25 biosecurity responses. These numbers do not include trade-related responses. In particular, the response to the second Queensland fruit fly detection of March and April 2014 demonstrates how quickly MPI can implement its response model to ensure that the Ministry fulfils its statutory duties.

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26. MPI notes there are other food safety incident response models used in Australia. For completeness, MPI's view is that the CIMS model works for both food safety and biosecurity incidents and allows MPI to work closely with other New Zealand Government agencies and harness expertise across portfolios other than food safety. The sheer number of both food safety and biosecurity matters with which MPI is concerned demonstrates the difficulty of separating the two response models. By way of illustration, as at 23 May 2014 MPI had:

    a. 205 food complaints and 18 recalls under investigation and/or response;

    b. in the previous week received 12 new notifications of food compliance investigations;

    c. 113 biosecurity matters under incursion investigation and/or response; and

    d. in the previous week received 30 new notifications of pest, disease or organism of concern.

27. The lessons MPI draws from the incident response to the contamination incident are:

    a. the CIMS response model and the use of a two-tier RSL and RMT decision making structure during responses works well, and has proven itself in MPI's subsequent food safety and biosecurity incident responses;

    b. the combination of voluntary industry product recalls and the use of certain public statements by MPI proved sufficient to secure the recall of contaminated product from the New Zealand market (although powers to enter manufacturers' premises, audit records, inspect stock, and impose mandatory recalls will always be necessary for occasions when manufacturers are not so responsible); and

    c. the combination of MPI's risk communications approach directed at consumers and industry co-operation in this matter assisted greatly in protecting consumers.

MPI's compliance investigation and prosecution

28. MPI is mindful in presenting this submission that its compliance investigation does not fall within Part A of the Inquiry's terms of reference. Nevertheless, the investigation does provide useful factual information relevant to this submission.

29. MPI commenced a separate and independent compliance investigation into Fonterra Limited at the same time it began the regulatory response. MPI publicly announced the compliance investigation on

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12 August 2013. As is often the case, the regulatory responses and compliance investigation ran simultaneously but separately. This separation ensured:

a. no interruption to the priorities of the regulatory response; and

b. that the compliance investigation could focus on dealing with investigating the incident and holding the appropriate people to account, without being distracted by the 'here and now' of the immediate response.

30. A feature in this case was the physical separation of the response and compliance teams, which reflected the number of people working on both and the complexity of the issues. The response team worked from MPI's headquarters at Pastoral House on The Terrace, whereas the compliance investigation worked from MPI's Petone offices.

31. The compliance investigation considered whether Fonterra adhered to the processes in its RMP when re-working batches of WPC at its Hautapu plant in February 2012, and whether the company adhered to its legal obligations (including notifying MPI as regulator) in respect of the subsequently re-worked product.

32. As was reported publicly, the compliance investigation resulted in the successful prosecution of Fonterra Limited on four charges under section 134(1) of the Animal Products Act 1999 for:

a. dairy product not processed in accordance with its RMP;

b. export of dairy product not meeting relevant animal product standards;

c. failure to notify regulator of dairy product not processed in accordance with RMP; and

d. failure to notify regulator of dairy product not fit for intended purpose.

33. MPI laid the above four charges on 13 March 2014, and Fonterra publicly accepted all the charges on the same day. Fonterra indicated that the charges were consistent with the conclusions of company's internal investigations. The company pleaded guilty in the Wellington District Court and was fined $350,000. The Admitted Summary of Facts highlights a number of important points, including:

a. at various times when Fonterra first became aware of irregular testing results associated with the WPC at issue, Fonterra had every opportunity to contact MPI to discuss the matter, but refrained from doing so until 12.35pm on 2 August 2013;

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b. in advance of Fonterra notifying MPI of the issues associated with the WPC at issue, particularly in the 24 hour window leading up to 12.35pm on 2 August 2013, Fonterra contacted a number of its customers and others to discuss the matter; and

c. MPI recognises it must continuously adapt New Zealand's food safety system to meet new challenges and opportunities, both here and overseas.

34. The Reasonable Grounds Paper and the Admitted Summary of Facts included with this submission provide further details of what MPI's compliance investigation revealed.

What the WPC contamination incident revealed

35. In thinking about the accumulated knowledge and information MPI now has before it, including all of the experience we gained by way of the regulatory response, compliance investigation and successful prosecution of Fonterra Limited, MPI has gained a large number of insights into what parts of its compliance model worked and areas where it will pursue and implement further changes. The full extent of the lessons learned, how MPI plans to implement the lessons, and the extent to which MPI has implemented the lessons already, are detailed in the Table of Lessons Learned included with this submission.

36. The table lists a number of high-level and specific lessons learned by MPI through the contamination incident. The high-level lessons learned warrant further attention here. Those lessons are:

a. Incident responses are, by their very nature, unplanned and usually unpredictable. Therefore MPI needs to learn from each such response so that it is capable of meeting the challenges of the next response. The WPC contamination response was not different to other incident responses, except in its scale. Accordingly, and understandably, MPI can probably draw more lessons from the incident than many others.

b. The WPC contamination incident sharpened MPI's risk communications approach. A good example of the Ministry quickly using the same approach occurred on 14 March 2014 when it was alerted to the possibility of a small number of apples being infected with Hepatitis A. On that occasion, MPI implemented lessons learned from the WPC response, and quickly issued a detailed media statement identifying the apples at issue so that consumers could take steps to protect their health. A copy of this media statement is included with this submission.

c. MPI's expectations of the food industry are clearer following the response necessitated through Fonterra allowing non-compliant product to enter the food supply chain. MPI needs to

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make its expectations of the food industry abundantly clear, particularly in respect of prompt notification. For example, industry now understands the importance of notifying MPI of export non-compliances and not allowing non-compliant product to enter the food supply chain.

d. MPI aims to make its expectations of the food industry clearer through proactive work too. This includes the dairy risk register, which MPI is compiling with industry. MPI is also undertaking work on the role of verifiers.

Implementing the Inquiry's Parts B and C recommendations

37. MPI is proactively implementing Parts B and C of the Inquiry's recommendations. MPI has learned numerous lessons since Fonterra first contacted the Ministry about suspected *Clostridium botulinum* contamination on 2 August 2013. These lessons add to MPI's commitment to ensuring appropriate systems are in place to protect food consumers, thus ensuring that consumers can trust New Zealand's excellent food safety reputation. The Inquiry has provided impetus to MPI's ongoing commitment to maintaining a world-leading food safety regime.

38. MPI's active engagement with the Inquiry to date has formed part of the process of continuous improvement. In MPI's formal submission dated 14 October 2013 on regulatory and best practice requirements in relation to the dairy industry, the Ministry identified a number of areas where we can tighten up the food system to give consumers even greater comfort in the safety of our food. These were summarised as follows:

a. taking a stronger leadership role;

b. clarifying regulatory requirements, particularly around RMPs;

c. calibrating the performance of verifiers so that they are all performing at a consistently high level;

d. changing the relationship between food operations and verifiers to remove a perception of conflict of interest;

e. progressing the Food Bill;

f. developing new compliance tools and a framework for using them across the organisation;

g. better monitoring and analysis about how the sector is performing; and

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h. shifting our understanding of risk communications and the importance of consumer expectations here and overseas.

39. The above lessons have been reinforced following MPI's compliance investigation and prosecution of Fonterra Limited.

40. The Inquiry released its report on Parts B and C of its terms of reference in December 2013. The government accepted all of the Inquiry's 29 recommendations. It now falls to MPI and other participants in the food safety system to implement these recommendations. At a high level, MPI is implementing the Inquiry's recommendations by the following means:

a. aligning MPI's management structure around functional responsibilities, which took effect in its entirety on 12 May 2014;

b. implementing governance arrangements to ensure that in the aligned structure, branches emphasise cross organisation engagement as a key component of governance performance;

c. expediting the passage of the Food Bill (now the Food Act 2014);

d. developing proposals for an omnibus food safety bill to implement other recommendations requiring legislation; and

e. implementing practical administrative changes at MPI.

41. Please see the Table of actions to implement the recommendations from Parts B and C of the Inquiry included with this submission for a summary of how MPI is implementing the Inquiry's 29 recommendations.

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Work already underway – supporting the food safety system through MPI's alignment process

42. In addition to the lessons learned from the WPC contamination incident, MPI is also working on other initiatives to improve its capacity as a regulator. Indeed, the formation of MPI itself is part of the process towards better regulatory capacity for the food safety system because the Ministry can now leverage a wide range of skills and capability to support work in the food safety portfolio. Regulatory responsibilities to protect the public under the Animal Products Act and the Food Act mean that MPI has to be:

a. an exceptional regulator,

b. a highly effective and innovative operational agency;

c. an influential organisation;

d. a respected and responsive connector across government and industry; and

e. a disciplined funder.

43. At the time of the contamination incident, MPI already supported the food safety system across all its branches, including through:

a. developing policy advice and legislation

b. developing and implementing food safety and suitability standards that are science-driven and risk-based as appropriate, and communicating them to those who must comply with them in a clear manner;

c. verifying that food produced, processed and consumed in New Zealand meets relevant domestic, import and export standards;

d. providing export markets with assurances that food is safe and suitable through the effective implementation of science-and-risk-based standards;

e. monitoring compliance with relevant standards and investigating food-related incidents;

f. overseeing traceability and recalls of products by industry, and exercising recall powers where necessary;

g. managing non-compliance through a range of compliance tools; and

h. communicating with stakeholders and consumers.

44. In addition, as the competent authority for food safety matters, MPI also continues negotiating equivalence arrangements for food safety with overseas trading partners to ensure that food imported to New Zealand is safe, and to enhance access for our safe food products in overseas markets and, where appropriate, to influence international standards for food in trade so that they reflect New Zealand's science-based approach to food safety and thus continue to protect consumers effectively.

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45. Before the Inquiry released its reports on Parts B and C of its terms of reference, the Ministry was already undertaking an alignment exercise to ensure its unity of purpose around core functions, including food safety.

46. Food safety needs to be considered as an integrated and dynamic system. To this end, the alignment process has created three new governance boards which will ensure cross-ministry engagement on important issues, one of which is Food Safety. The Food Safety Board will govern the food safety system, the purpose of which is to protect consumers of food through an effective regulatory regime that covers food produced and consumed within New Zealand, as well as food imported into and exported from New Zealand. This includes ensuring effective design and transparent operation of the regulatory system across policy advice, standard setting, assurance, certification, response and compliance.

47. Structural alignment of senior leadership team responsibilities has also clarified who leads MPI's core systems. In particular, the new position of Deputy Director-General Regulation and Assurance leads the food safety system. The Regulation and Assurance Branch combines MPI's regulation and assurance functions from across the former Standards, Resource Management and Programmes, and Verification and Systems Branches. The branch provides the requisite confidence, transparency and trust to domestic and overseas consumers, and is better placed to support New Zealand's primary industries. Ultimate accountability for the Food System, its regulation and the required assurances rests with the Deputy Director-General Regulation and Assurance, although the successful delivery of MPI's regulatory functions cannot succeed without the rest of MPI playing their role.

48. A standalone Systems Audit, Assurance and Monitoring Directorate with a new position of director recognises the importance of assurance and that the provision of audit and monitoring of our regulatory systems needs to be more visible. To support this, the Manager Systems Audit will play a key role in auditing verifiers and the regulatory system, and provide direct oversight over industry and the services Verification Services provides.

49. Verification Services is now shifted to the Regulation and Assurance branch. Regulatory and verification functions share a unity of purpose, namely maintaining the safety and integrity of the food system for domestic and overseas markets/consumers. Including verification functions in the same branch as other food safety regulatory functions affords the Regulation and Assurance Branch ownership over a larger part of the food safety system. It provides a stronger platform for system accountability, clarifying and supporting the principle of systems leadership and planning. This is also consistent with the WPC Inquiry recommendations for structural improvements to drive a more integrated focus on food safety generally.

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50. MPI's alignment process includes programmes of work focused on:

    a. leadership strategy and delivery, including work on MPI's vision and strategy;

    b. relationships, including the formation of an external stakeholder reference group and regional leadership;

    c. people, including an internal "touchstone" group, identifying career pathways and establishing a strong training and development culture; and

    d. financial and resource management, in particular allocating resources to frontline assurance, verification, compliance and prosecutions work.

Conclusion

51. As stated at the beginning of this submission, the WPC contamination incident presented New Zealand with its largest ever food safety response. MPI's regulatory response and compliance investigation structures coped with the scale and complexity of the response, ultimately leading to the prosecution of Fonterra. This submission explains in some detail the extent to which MPI is currently implementing these lessons. Implementing these lessons forms part of MPI's continuous process of regulatory improvement which contributes to its aim of being a world-class food safety regulator.

52. MPI stands ready to assist the Inquiry with any further information or points of clarification. In the first instance, please direct all enquiries to Scott Gallacher, Deputy Director-General Regulation and Assurance.

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Yours sincerely

Martyn Dunne CNZM
Director-General

APPENDIX
DOCUMENTS SUPPLIED IN SUPPORT OF MPI'S SUBMISSION TO THE INQUIRY

General background documents

	Document	Description / comment
1.	Chronology of events	Covers the incident response
2.	Response structure	Diagram of MPI's incident response structure and the officials involved with the response
3.	Table of lessons learned from the regulatory response and compliance investigation	Detailed summary of organisational lessons MPI learned from response
4.	Table of actions to implement the recommendations from Parts B and C of the Inquiry	Summary of what MPI has done to date to implement Inquiry's recommendations on Parts B and C of its terms of reference
5.	Admitted Summary of Facts prepared by MPI	Supplied to Wellington District Court as part of prosecution

Media releases and Director-General statements

	Announcement	Description	Date	Time
1.	Media release	MPI exploring food safety issue advised by Fonterra this afternoon	Saturday 3 August 2013	12.12am
2.	Director-General statement	Director-General's statement under Animal Products Act and Food Act	Saturday 3 August 2013	2.45pm
3.	Media release	Details announced of one product potentially affected by WPC contamination – press conference at MPI at 4.30pm	Saturday 3 August 2013	3.30pm
4.	Media release	Update – Infant milk formula – precautionary advice updated	Sunday 4 August 2013	12.45pm
5.	Director-General statement	Director-General's statement under Animal Products Act and Food Act	Sunday 4 August 2013	8.30pm
6.	Media release	Update – Karicare formula – further precautionary advice	Sunday 4 August 2013	9.24pm
7.	Media release	MPI welcomes Nutricia recall of two infant formula products	Monday 5 August 2013	10.13am
8.	Media release	Media advisory – MPI press conference at 11.15am	Monday 5 August 2013	10.17am
9.	Director-General statement	Director-General's statement under Animal Products Act and Food Act	Tuesday 6 August 2013	7.30pm

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	Announcement	Description	Date	Time
10.	Media release	Media advisory – MPI press conference at 3.30pm	Wednesday 7 August 2013	11.50am
11.	Media release	MPI corrects error on Fonterra's advice to AsureQuality	Wednesday 7 August 2013	5.56pm
12.	Director-General statement	Director-General's statement under Animal Products Act and Food Act	Monday 12 August 2013	12.00pm
13.	Media release	MPI commences compliance investigation into WPC contamination incident	Monday 12 August 2013	12.50pm
14.	Media release	Nutricia Karicare product recall applying to specific dates	Monday 12 August 2013	2.22pm
15.	Media release	MPI exploring interim measures for dairy sector	Tuesday 20 August 2013	2.28pm
16.	Media release	Media advisory – MPI	Wednesday 28 August 2013	1.34pm
17.	Media release	Negative WPC tests confirm no risk to public	Wednesday 28 August 2013	4.05pm
18.	Media release	MPI releases WPC tracing and verification report	Wednesday 28 August 2013	4.06pm
19.	Media release	No food safety risk from Karicare product	Thursday 29 August 2013	
20.	Media release	MPI caution – potential Hepatitis A in some fruit [example of MPI risk communications following response]	Friday 14 March 2014	

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Government inquiry

into

Whey Protein Concentrate Contamination Incident

Chronology

2 August 2013 – 3 September 2013

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Ministry for Primary Industries

3 June 2014

Purpose

This paper provides to the Inquiry a chronology of key events in the Whey Protein Concentrate (WPC) contamination incident from the time that Fonterra notified MPI of potential contamination on 2 August through to 3 September, which was the date on which the formal response was completed.

Friday, 2 August 2013

- **12.35pm, 2 August 2013:** MPI informed by Fonterra of a food safety issue relating to the potential bacterial contamination of some batches of WPC produced at Fonterra's Hautapu site in New Zealand, including the following information:
    - "Contamination of WPC with Sulphite Reducing Clostridia at levels ranging from 110 – 950 cfu/g, was confirmed as Clostridium Botulinum."
    - "Testing via Mouse bioassay on a composite of the nutritional powders all using the WPC product confirmed the presence of Clostridium botulinum."
    - "37.9MT of WPC has been used in infant formula (0-3 years), juice/dairy beverage, yoghurt and body building powder."
    - The contamination event occurred in May 2012.
    - Product is circulating in markets.
    - "In market product impacted:
        - High Risk: Based on WPC ingredient used and consumer group
            - Abbott: GUMP , 0-3 years - 260MT
            - Danone: IF &FO, 0 – 12 months - 590.5MT (TBC)"
    - "Customers to be notified".
- **Afternoon of 2 August 2013:**
    - The risks associated with the contaminated products remain unclear. MPI decides on a precautionary approach and places protection of consumers as its highest priority.
    - Other government agencies informed: MFAT, DPMC, NZTE, DPMC
    - Ministers alerted
    - RMT holds its first meeting and agrees operational response structure.
- **3.30pm, 2 August 2013:** RSL Meeting formalises response structure and determines objectives and immediate priorities.
    - Priorities for the response:
        - Protect consumer health (globally)
        - Protect New Zealand's reputation for safe production and trade in dairy products and maintain market access
        - Keep all relevant parties informed in a structured and timely manner
        - Document the incident, and the systems and processes that are used to safeguard against such an incident
        - Investigate the incident and determine any liability
        - Learn from the incident and avoid any reoccurrence.
    - Multiple work streams are established:
        - The **Operations Workstream** is responsible for tracing product in the domestic and international markets, and verifying information provided by Fonterra, Nutricia and other companies.
        - The **Technical Workstream** is responsible for concentrating on identifying the bacterium and strain, establishing the Technical

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Advisory Group, liaising with health authorities on medical advice, and establishing commercial arrangements for any testing requirements that markets might impose.

- The **Liaison Workstream** is responsible for managing interactions with Fonterra, Nutricia, Informant Formula Export Association, Food and Grocery Council, Ministry of Health and other external groups.
- The **Market Access Workstream** is responsible for working with overseas posts and liaising with affected markets. It is also answering queries from markets not directly affected.
- The **Communications Workstream** is responsible for managing media relations, preparing media releases, supporting our 0800 number and website processes, and keeping internal staff informed.
- The **Reporting Workstream** prepares the daily ministerial update, DG Statements, responses to Parliamentary Questions, and provides other Ministerial support.

- **3-4pm, 2 August 2013:** Fonterra supplies Exporter Non-Conformance (ENC) notification to MPI and provides details of exported products: MPI Health Certificate numbers, Cypher numbers, Product Names, Destinations, Importers and Vessel/Voyage details.
- **4.30pm, 2 August 2013:** AsureQuality verifiers review Hautapu line to confirm equipment identified as the cause of the event had been removed and that all affected product had been included in the exception report. Some affected product had not been included in the exception report.
- **Evening, 2 August 2013:** MPI begins providing as much information as possible to consumers and offshore regulators, including by way of:
  - alerting paediatric units via the Ministry of Health;
  - working with the relevant companies on voluntary recalls;
  - seeking to track all potentially affected products through the supply chain as quickly as possible; and
  - directly notifying the Commonwealth Department of Agriculture (DAFF) in Australia of the potential contamination.
- **6pm, 2 August 2013:** Fonterra provides further information about three potentially affected ciphers.
- **6.30pm, 2 August 2013:** RSL Meeting agrees on immediate liaison activities. Receives technical update and communications update.
- **Approx 7.00pm, 2 August 2013:** Fonterra reports that WPC exported to Danone Australia had also been formulated by Nutricia at three New Zealand manufacturing facilities into Follow-On Formula. Fonterra indicates that four batches were exported to China, and one batch was for sale in New Zealand.
- **Evening:** Nutricia informs MPI that none of the five consignments of affected formula destined for New Zealand are in market: three are stored at Mainfreight, one is en route back to Australia and one is still in the factory. MPI continues to work at verifying this information as a priority.
- **9pm, 2 August 2013:** Overseas posts provided with a heads up, including talking points for discussion with regulators in potentially affected countries.
- **Midnight, 2 August 2013:** First Situation Report issued.
  - Almost 38 metric tonnes of the affected WPC has been used as an ingredient in more than 870 tonnes of infant formula, juice/dairy beverage, yoghurt, body building powder and also in stock food. The event occurred when product was re-processed using a disused production line which had not been cleaned appropriately.

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- It has been confirmed that affected WPC has been used in five batches of Nutricia infant formula follow on product. Four of these are in the Chinese market and one in the New Zealand market. (Potentially contaminated product on the New Zealand market is follow-on infant formula 6-12 months. This has been re-imported from Danone and marketed under the Nutricia label).
- Vitaco body building product may also be potentially contaminated but this has not yet been confirmed.
- A response structure has been established with Scott Gallacher, the Acting Director-General of MPI as chair and includes officials from MFAT, MoH, DPMC and NZTE.
- MPI and MFAT have contacted Posts to notify them about the WPC contamination including talking points for discussion with regulatory authorities in countries that have received potentially contaminated product. This will be followed with a formal letter to be given to regulatory authorities in countries receiving suspect product. [redacted] has been contacted directly.

[s.(6)(a)]

- MPI is issuing a public media release in New Zealand.
- The World Health Organisation's International Food Safety Authorities Network (INFOSAN) will be notified shortly before the media release.
- The Ministry of Health is contacting paediatric units to let them know and ask them to use different infant formula brands.
- Fonterra is expected to directly notify the companies to which they sold product and to notify the dairy industry.
- Fonterra is undertaking further urgent tracing to determine if any other product or markets are affected.

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Saturday, 3 August 2013

- **12.12am, 3 August 2013:** MPI issues first press release on WPC, advising that it is exploring a food safety issue that it had been advised by Fonterra.
- **Priorities for 3 August 2013:**
  - Issuing a Director-General statement under the Animal Products Act 1999 and the Food Act 1981 notifying the public of the issue and advising them of the appropriate steps to take
  - Providing medical advice to District Health Boards
  - Setting up the consumer help-lines
  - Proceeding with a product risk assessment
  - Determining the strain of *C botulinum*
  - Continuing to liaise with international markets, Fonterra, Nutricia and Vitaco
  - Sending letters providing further information to markets receiving potentially contaminated products
  - Responding to issues and concerns raised by the media
  - Confirming the scope of contamination, including sending two verifiers recognised under the Animal Products Act 1999 to Hautapu to ascertain that the problem is confined to the three lines already identified, and to seek further consignment information.
- **8am, 3 August 2013:** RMT Meeting receives situation report and updates. Establishes priorities.
- **8am, 3 August 2013:** All Fonterra imports of WPC and milk-based powders to China are suspended, and testing requirements are imposed on other dairy products.

- **9am, 3 August 2013:** RSL Meeting receives situation report and updates. Agrees immediate priorities.
- **10.00am, 3 August 2013:** First industry teleconference.
- **10.30am, 3 August 2013:** Response Team Meeting. Responsibilities allocated. Priorities established. Daily 'Rhythm' established, which involves daily meetings, reports, industry teleconferences, etc.
- **Midday, 3 August 2013:** Second Situation Report issued. MPI is still waiting for confirmation from Fonterra about the strain and toxin identified and the testing methodologies used.
- **2.00pm, 3 August 2013:** RMT Meeting reviews situation report and receives updates.
- **2.30pm, 3 August 2013:** Fonterra issues a press release stating that:
    - "On Wednesday 31 July 2013, tests indicated the potential presence of a strain of Clostridium (Clostridium Botulinum) in a sample, which can cause botulism."
    - The release also states that Fonterra has advised its customers about the incident: "Fonterra today advised eight of its customers of a quality issue involving three batches of a particular type of whey protein concentrate (WPC80) produced at a single New Zealand manufacturing site in May 2012. As a result, these customers are urgently investigating whether any of the affected product, which contains a strain of Clostridium, is in their supply chains. If need be, they will initiate consumer product recalls."
- **2.45pm, 3 August 2013:** MPI Acting Director-General issues first statement under Food Act 1981 and Animal Products Act 1999 advising that Nutricia Karicare Follow-on formula products for children from 6 months old may contain some batches of contaminated whey protein and that alternative products or brands be used.
- **3pm, 3 August 2013: RSL** Meeting receives situation report and agrees actions.
- **4pm, 3 August 2013:** MPI issues a press release concerning the D-G's statement.
- **4.30pm, 3 August 2013:** MPI holds a press conference at Pastoral House.
- **Afternoon, 3 August 2013:** Fonterra notifies MPI of a new line of infant formula base powder produced from contaminated WPC in Australia and supplied to Danone, which was then supplied to Nutricia NZ and potentially used in formula for domestic and export markets. Further information requested from Fonterra. Liaison formally established with Nutricia.
- **4.48pm, 3 August 2013:** MFAT updates posts on the D-G's statement.
- **Evening, 3 August 2013:** Ministers updated by aide memoire.
- **6pm, 3 August 2013:** Third Situation Report issued:
    - MPI still waiting for confirmation from Fonterra of the strain and toxin type of pathogen. However, based on discussions with Fonterra and Vitaco, MPI was able to confirm that the UHT treatment process used to manufacture Vitaco product ensured the product posed no risk to public health.
- **6.30-7pm, 3 August 2013:** Fonterra notified MPI of additional batches of potentially contaminated WPC supplied to Danone/Nutricia. MPI holds a teleconference with Nutricia to convey our urgent need for information to support tracing, recall and market access work.
- **International markets:**
    - All international markets directly affected by the potential contamination have been notified, and also some unaffected markets. The World Health Organisation's International Food Safety Authorities Network (INFOSAN) has been notified.

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- Work is underway to develop a Trade Impact Assessment to assess the impacts of the contamination on trade.

[s.6(a)]

- [redacted]

Next steps:

- MPI to investigate testing the Nutricia product held by Mainfreight for Clostridium. It is likely that the testing will be done at ESR's Christchurch laboratory. The test is relatively insensitive and therefore may return a negative result even if there is Clostridium present.
- Tracing activities will continue. MPI expects to be confident of the location of all potentially affected product within New Zealand by the end of 4 August.
- MPI has asked Fonterra to liaise with the Dairy Companies Association of New Zealand (DCANZ) and the rest of the dairy industry to keep them fully informed of the response. MPI has heard that some dairy companies consider they are not yet adequately informed.
- MPI is determining the appropriate compliance investigation for this event.
- MPI will communicate information for exporters to China.

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Sunday, 4 August 2013

- **Current priorities:**
  - Updating the Director-General statement under the Animal Products Act 1999 and the Food Act 1981
  - Securing supply of domestic infant formula
  - Determining the strain of *C botulinum*
  - Continuing to liaise with international markets, Fonterra, Nutricia and Vitaco
  - Responding to issues and concerns raised by the media
  - Confirming the scope of contamination through forward tracing
  - Determining the scale of potential trade impacts.
- **Public health priorities:**
  - Ensuring supply of infant formula and confidence about its use
  - Providing information to health professionals, including Healthline, PlunketLine, contacting paediatric units and using the GP fax system from tomorrow
  - Undertaking enhanced surveillance for infant botulism via the Paediatric Surveillance Unit
  - Developing a process for obtaining botulinum antitoxin.
- **4 August, 2013:** Fonterra's animal feed subsidiary, NZAgbiz, recalls specified batches of Ancalf calf milk replacer and Brown Bag milk replacer.
- **Morning, 4 August 2013:** Nutricia instigates a "precautionary recall in New Zealand" of:
  - Karicare Infant Formula Stage 1 – batches 3169 and 3170
  - Karicare Gold+ Follow On Formula Stage 2 (6-12 months) – batches D3183.
- **9am, 4 August 2013:** RMT Meeting reviews situation report and receives updates.
- **9am, 4 August:** AsureQuality conducts site visit at Fonterra Waitoa to review tracing information, and identifies discrepancies in records that requires reconciliation of data and stocktake under the supervision of AsureQuality.
- **10am, 4 August 2013: RSL** Meeting receives update and agrees actions.
- **11am, 4 August 2013:** Response Team Meeting.

- **Midday, 4 August 2013:** Fourth Situation Report issued.
    - MPI is still waiting for confirmation from Fonterra of strain and toxin type. MPI has asked Fonterra to release Agresearch staff from obligation of confidence to speed up the process.
    - MPI is in the process of setting up a Technical Advisory Group
- **12.15pm, 4 August 2013:** MPI issues updated precautionary advice.
- **2.30pm, 4 August 2013:** Vitaco issues a media statement indicating that its UHT product is not affected.
- **3pm, 4 August 2013:** RMT Meeting brainstorms key scenarios. Plans resourcing and relief staff.
- **4pm, 4 August 2013: RSL** Meeting receives update and agrees actions.
- **6pm, 4 August 2013:** Fifth Situation Report issued.
    - Initial product tracing report indicates that many hundreds of tonnes of material are affected, but there is incomplete or inaccurate information and some product may never be accounted for.
    - MPI still waiting for Nutricia to reconcile its records and provide further information.
    - Fonterra indicate that there may be a recall of some stockfeed. MPI is working with the NZ Veterinary Association to provide advice to farmers.
- **8.30pm, 4 August 2013:** MPI Acting Director-General issues further precautionary advice and a revised statement under Food Act 1981 and Animal Products Act 1999 advising that:
    - *"I now advise that the following Nutricia Karicare products cannot be ruled out as containing the contaminated batches of whey protein. I therefore recommend that these products are not consumed and alternative brands used. Nutricia Karicare Stage 1 Infant Formula for babies from birth. Nutricia Karicare Stage 2 Follow-on formula products for children from 6 months old."*
    - The revised Statement was issued because Nutricia was unable to identify to MPI all the products that may have been contaminated through incorporation of the affected WPC, and the locations of potentially contaminated products.
- **11pm, 4 August 2013:** Nutricia provides a spreadsheet of information identifying finished product, intended markets and inventory regarding current location.
- **International markets:** MPI and MFAT continue to work with affected markets and respond to inquiries from other markets that are not affected.

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Monday, 5 August 2013

- **Current priorities:**
    - Keeping a watching brief on supply of domestic infant formula;
    - Determining the strain of *C botulinum*;
    - Continuing to liaise with international markets, Fonterra, Nutricia and Vitaco;
    - Responding to issues and concerns raised by the media;
    - Confirming the scope of contamination through forward tracing;
    - Determining the scale of potential trade impacts.
    - Set up a Technical Advisory Group to provide specialist advice across the response.
- [redacted]
- **7.15am**: Fonterra notifies MPI of an additional 17 x 25kg bags of affected WPC, produced at Fonterra Darnum and supplied to Danone.

Withheld under 6(a)

- 15 of these bags were used in the manufacture of two batches of Follow-On formula. One batch is already on the list of affected product. The other batch is new to the list and was destined for New Zealand and Thailand.
- MPI is determining whether this broadens the range of Nutricia products known to be affected and / or the markets receiving potentially contaminated Nutricia products.
- MPI sends verification staff to Fonterra's data centres in Auckland and Melbourne.
- MPI considers a new D-G's Statement and/or a product recall.
- MPI considers plans to ensure supply of infant formula in the event of a Nutricia product recall.

- **8.30am, 5 August 2013:** RMT Meeting reviews situation report and receives updates.
- **10.30am, 5 August 2013: RSL** Meeting receives update and agrees actions.
- **11am, 5 August 2013:** Teleconference between Fonterra, MPI and AgResearch to discuss laboratory diagnostics, identification and toxin typing.
- **11.15am, 5 August 2013:** MPI holds a media briefing. Local and international interest in the issue.
- **3pm, 5 August 2013:** Sixth Situation Report issued.
  - MPI systems auditors are going to Fonterra HQ to verify product reconciliation and to Fonterra Darnum to work alongside DFSV in product reconciliation.
  - MPI cannot see the link from Fonterra information through to Nutricia recall decisions in order to have sufficient confidence that all product has been captured.
  - *[s.6(a)]* [redacted]
  - MPI is working on a testing and sampling regime to provide support to overseas markets. Detailed information requested from Fonterra to support market access work.
- **4pm, 5 August 2013:** RMT Meeting receives updates, discusses scenarios and plans resourcing of the response.
- **4.45pm, 5 August 2013: RSL** Meeting receives update and agrees actions.
- **Evening, 5 August 2013:** Nutricia expands its recall to cover all batches of Stage 1 New Baby Infant Formula and Stage Gold+ 2 Follow-on Formula.
  10.15pm, 5 August 2013: MPI issues a media statement welcoming Nutricia's expanded recall.

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Tuesday, 6 August 2013

- **Current priorities:**
  - Protecting domestic and overseas consumer health
  - Ensuring a secure domestic supply
  - Tracing and confirming contaminated product
  - Ensuring ongoing market access and assurance
  - Rebuilding confidence in New Zealand's diagnostic and scientific capabilities
  - Determining the appropriate time for Ministers to reengage with overseas markets
- **Next steps**
  - Keeping a watching brief on supply of domestic infant formula
  - Determining the strain of *C botulinum*

- Continuing to liaise with international markets, Fonterra, Nutricia and Vitaco
- Responding to issues and concerns raised by the media
- Confirming the scope of contamination through forward tracing
- Determining the scale of potential trade impacts
- Using the Technical Advisory Group to provide specialist advice across the response.

- **Overnight:**
  - Following discussions with the Director-General of MPI, Nutricia agrees to extend its product recall to include all batches of:
    - Karicare Stage 1 New baby Infant Formula (From Birth)
    - Karicare Gold+Stage 2 Follow On Formula (From 6 Months)
- **8.30am, 6 August 2013:** RMT Meeting reviews situation report and receives updates.
- **9.30am, 6 August 2013: RSL** Meeting receives update and agrees actions.
- **3.00pm, 6 August 2013:** MPI Acting Director-General issues statement under Food Act 1981 and Animal Products Act 1999 advising that all batches of Karicare Stage 1 and 2 infant formula should be returned to retailers and alternative brands used.
- **3pm, 6 August 2013:** Seventh Situation Report issued.
  - There are three audits of data reconciliation processes underway at Fonterra sites. Site verification continues at four related sites. Until this work is completed, MPI cannot have confidence that all contamination has been identified.
  - MPI still waiting for testing details from Fonterra and AgResearch, but information provided to date indicates that further work is required to validate the identification of the Clostridium strain and determine whether a toxin is present. Comparison between US FDA methodology and AgResearch methodology identifies several differences in approach.
  - Bacterial isolates are shipped from AgResearch in Palmerston North to IDC at Wallaceville.
  - Negotiations for testing and DNA sequencing with CDC and FDA in USA, and with ESR in Christchurch.
  - MPI working with Food and Grocery Council to ensure security of supply of infant formula to New Zealand consumers.
- **4pm, 6 August 2013:** RMT Meeting reviews situation report and receives updates. Plans resourcing and relief staffing.
- **4-5pm, 6 August 2013:** Samples for testing arrive at ESR and IDC.
- **5pm, 6 August 2013: RSL** Meeting receives update and agrees actions.
- **Progress on tracing:**

  <u>Fonterra</u>

  Hautapu processing plant:
  - Reconciliations completed for human consumption material (including how much they produced and where it went);
  - Reconciliations in progress for "Loss stream" products (products of insufficient quality for human consumption) that has been downgraded to animal feed

  Waitoa processing plant:
  - Currently awaiting written confirmation on the status of reconciliation. MPI staff are actively pursuing this information.

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Darnum (Victoria, AUS) processing plant:

- A MPI safety auditor is visiting the Darnum plant and working with two auditors (from Dairy Food Safety Victoria) to verify records for products received from Hautapu and dispatched from Darnum back to NZ.

Auckland – Head office:

- MPI have a team working closely with Fonterra staff to verify all records of affected product. We are awaiting those results.

Nutricia

- MPI Staff are confirming information records of all affected materials received from Fonterra.
- In terms of incoming product records and the flow through of product that is being sent to other processors (e.g. Dairy Goat, Unitec, etc). MPI officials are coordinating with these companies to locate any product in stores.
- MPI staff are overseeing the return of containers from the ports.
- MPI has been working to confirm all exports of affected product and to notify our trading partners (back over the last 6 months).

Wednesday 7 August 2013

- **8.30am, 7 August 2013:** RMT Meeting reviews situation report and receives updates.
- **9.30am, 7 August 2013: RSL** Meeting receives update and agrees actions.
- **3pm, 7 August 2013:** Eighth Situation Report issued.
  - Number of 0800 calls has declined.
  - Verifiers have been on-site at Fonterra Headquarters and other properties in New Zealand and Australia to confirm reconciliation and tracing data.
  - Draft laboratory testing plan considered by MPI.
- **4pm, 7 August 2013:** RMT Meeting reviews situation report and receives updates.
- **5pm, 7 August 2013: RSL** Meeting receives update and agrees actions.
- **Communications progress:**
  - The MPI website is being promoted as the best source of up-to-date information
  - Communications targeting Maori and Pacific Island parents and caregivers are being progressed through radio and community networks
  - MPI is making a YouTube video providing advice to parents about infant formula
  - MPI is implementing an online and print advertising campaign with Nutricia.
  - There was a press conference today by the Directors-General of Primary Industries and Health
  - A clarifying media statement was subsequently released with respect to the Fonterra notification to AsureQuality of this issue
  - Calls to MPI Helpline are down to about 50 from about 250 per day.
- **Compliance investigation**
  - MPI has commenced a formal compliance investigation into the incident. It is critical that the investigation does not impede the operational response. At this stage, the focus is on planning, including:
    - reviewing the regulatory requirements;
    - identifying the information pertaining to the decisions of different parties; and

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- reviewing relevant legislation, particularly sections that relate to powers and offences.

- **International markets:**
  - **Australia:** Australia has released a media statement that it has a: "high level of confidence in the quality and safety of Australian-made dairy products and has not been formally notified of any changes to our export arrangements with any trading partner."
  - **Thailand:** Dumex has initiated a product recall of five affected product lines.
  - **International Food Safety Authorities Network:** MPI has received information requests from the World Health Organisation, [redacted]

[s.6(a)]

Thursday 8 August 2013

- **8.30am, 8 August 2013**: RMT Meeting reviews situation report and receives updates.
- **9.30am, 8 August 2013: RSL** Meeting receives update and agrees actions.
- **11.15am:** Nutricia advise that all Nutricia product has been put on hold at MPI's request. Investigation confirms that there is no instruction to hold all product and this is advised to Nutricia at 2.10pm.
- **3pm, 8 August 2013:** Ninth Situation Report issued.
  - Public information campaign underway, including newspaper advertisements, parenting websites, other sites likely to be visited by parents and caregivers, as well as mainstream websites.
- **4pm, 8 August 2013:** RMT Meeting reviews situation report and receives updates.
- **5pm, 8 August 2013: RSL** Meeting receives update and agrees actions.
- **Tracing progress:**
  - Based on information from Fonterra and Nutricia, MPI understands that 67,878 affected cans entered the New Zealand market from the beginning of May. About 40,000 of those cans have been detained by MPI in the supply chain, [redacted].

[s.6(a)]

  - The remainder are subject to recall, and are either being held by retailers or have been sold. MPI is currently seeking information on the number of cans being held by and returned to retailers.
  - MPI is now close to having full confidence of where certified affected product has gone to. This information has been provided to relevant regulators in the countries concerned, and each market is putting in place appropriate measures.
  - Product has also been parallel exported to countries that do not require official certification. MPI does not hold information about the volume or destination of these exports. MPI is working with the exporters and importing countries to trace these as far as possible.
  - [redacted]

[s.6(a)]

  - The Acting Director-General of MPI has issued Notices of Direction under the Animal Products Act 1999 to all known parallel exporters instructing that the affected Nutricia products may not be exported until further notice.
- **8 August 2013:** Fonterra issues a press release "welcoming the New Zealand Government's confirmation that the quality issue involving whey protein concentrate is confined to the products made from three batches of WPC80 and no other New Zealand dairy products are affected." The press release also states that "Our

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customers have worked quickly to locate and secure products that were not in the market and, where they had already reached retail shelves, initiate recalls. Their fast response has meant that almost all products are now back or on their way back".

- **Technical Advisory Group**
    - MPI is setting up a Technical Advisory Group (TAG) to provide the Government with independent technical advice on matters relating to the WPC response. MPI is planning to hold the first TAG meeting early next week. The TAG will be asked to provide advice on a range of issues including:
        - Advice on the biology of *C botulinum;*
        - The diagnostic procedures being used by MPI to confirm the identity of the bacteria;
        - The risk analyses that may inform any further recall decisions;
        - Technical recommendations on proposed response actions.
- **Carry-over contamination**
    - The production of infant formula involves processing and blending a number of base ingredients, one of which is whey protein concentrate. During processing, small amounts of material from the previous batch can remain in parts of the processing equipment and be present in the subsequent batch.
    - Any contamination present, such as *C botulinum* bacteria, is progressively diluted in the subsequent product. MPI is assessing at what point infant formula processed after batches using contaminated WPC is safe.
    - At the appropriate time, this information may help the Acting Director-General to consider narrowing the current advisory Statement. It may also be used to inform Nutricia's decision to release additional batches and blends of infant formula product currently secured in Auckland.

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Friday 9 August 2013

- **Overnight and throughout the day:**
    - Late Thursday evening, Fonterra advised that one 25kg bag of contaminated WPC was provided to the Fonterra Research and Development Centre, Palmerston North and distributed to staff for use in product development trials. 12kg was distributed to a student at an unspecified school. Fonterra says it was aware of this situation on Tuesday 6 August.
    - On Friday morning, Fonterra advises that the WPC was provided to Palmerston North Girls' High School for a science project involving development of a sports drink that was provided to approximately 50 pupils.
    - On Friday, Fonterra, MPI and the local Medical Officer of Health were on site at the school talking with the Principal.
    - Fonterra and the Ministers of Health and Food Safety issued media releases today after students and parents had been notified.
    - MPI's technical team carried out an urgent safety assessment, taking into account last exposure and residual risk. MPI concluded that there are no current risks associated with the exposure.
- **8.30am, 9 August 2013:** RMT Meeting reviews updates.
- **9.30am, 9 August 2013: RSL** Meeting receives update and agrees actions.
- **1.30pm, 9 August 2013: RSL** Meeting receives update and agrees actions.
- **3pm, 9 August 2013:** Tenth Situation Report issued.
    - Terms of reference for Technical Advisory Group finalised.
- **4pm, 9 August 2013:** RMT Meeting reviews updates.

- **Scope of recall**
  - Nutricia and the Food & Grocery Council are pushing for the scope of the recall to be narrowed.
  - MPI has developed a plan to support a decision on whether, and to what extent, the recall can be narrowed. The Acting Director-General is expected to be in a position to make this decision by mid-late next week.
- **International markets**
  - [redacted]
  - [redacted]

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Saturday, 10 August 2013

- **10am, 10 August 2013:** RMT Meeting reviews updates.
- **1.30pm, 10 August 2013: RSL** Meeting receives update and agrees actions.
- **3pm, 10 August 2013:** Eleventh Situation Report issued.

Sunday, 11 August 2013

- **10am, 11 August 2013:** RMT Meeting reviews updates.
- **1.30pm, 11 August 2013: RSL** Meeting receives update and agrees actions.
- **3pm, 11 August 2013:** Twelfth Situation Report issued.
  - Reconciliation nearly complete for Nutricia and Dairy Goat products.
  - Planning for a two-step approach to narrow the scope of the recall.
- **4pm, 11 August 2013:** RMT Meeting reviews situation report and receives updates.
- **Scope of recall**
  - The Director-General of MPI is considering issuing a revised statement under the Animal Products and Food Acts.
  - Nutricia plans to announce a narrowing of its voluntary recall at a media conference at midday on Monday 12 August.
  - MPI is working to gain assurance that the scope of the infant formula recall could be safely narrowed.
  - An implementation package is being prepared (subject to final decision) and includes:
    - Revised Director-General statement to be published on MPI's website
    - MPI media release
    - Supporting website information and information for consumer phone lines - both MPI and MoH
    - Informing overseas regulators.

Monday, 12 August 2013

- **9am, 12 August 2013:** RMT Meeting reviews updates.

- **12.00pm, 12 August 2013:** MPI Acting Director-General issues statement under Food Act 1981 and Animal Products Act 1999 advising that the production dates that Karicare infant formula may have been affected have been identified. Consequently only Karicare Stage 1 and 2 infant formula produced between 21 May 2013 and 2 August inclusive should be returned to retailers.
- **1-4pm, 12 August 2013:** Technical Advisory Group meets for the first time.
- **1.30pm, 12 August 2013: RSL** Meeting receives update and agrees actions.
- **12 August 2013:** Nutricia reduces product recall of Karicare infant formula to that with a production date of 21 May 2013 to 2 August 2013 inclusive.
- **3pm, 12 August 2013:** Thirteenth Situation Report issued.
    - Focus of the response shifting as a result of the narrower recall.
    - Difficulties reconciling data from Waitoa/CanPac because Fonterra are struggling to provide accurate information.
    - Approximately 58 potential 'grey trade' exporters have been identified and contacted by email over the weekend.
- **4pm, 12 August 2013:** RMT Meeting reviews situation report and receives updates.
- **Compliance investigation:**
    - MPI issues a press release announcing that it has commenced a compliance investigation. Its purpose, amongst other things, is to identify whether Fonterra and other participants in the risk management process have complied with their regulatory obligations, or may have committed any breaches or offences.
    - The compliance investigation is being led by the Director of Compliance and has at least 20 staff currently assigned to it, operating out of MPI's Petone office.

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Tuesday 13 August 2013

- **8.30am, 13 August 2013:** RMT Meeting reviews situation report and receives updates.
- **11.15am, 13 August 2013:** Fonterra advises that some contaminated stockfeed had been reimported to New Zealand from Maxum Stockfeed. On the basis of low risk and low volume, no recall was initiated. However, 99.7 tonnes of unsold product was held as a precautionary measure while MPI and Fonterra considered its suitability for sale.
- **1.30pm, 13 August 2013: RSL** Meeting receives update and agrees actions.
- **3pm, 13 August 2013:** Fourteenth Situation Report issued.
    - Final data reconciliation for Waitoa/CanPac is being hampered by discrepancies in information provided.
    - Samples for testing are awaiting clearance at US border and MPI is attempting to expedite clearance.
- **4pm, 13 August 2013:** RMT Meeting reviews situation report and receives updates.
- **International markets**
    - [redacted]

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Wednesday 14 August 2013

- **14 August 2013:** Samples clear US Customs for sending to CDC laboratory.
- **9am, 14 August 2013:** RMT Meeting reviews situation report and receives updates.

- **3pm, 14 August 2013:** Fifteenth Situation Report issued.
    - Waitoa/CanPac product now all accounted for.
    - Professor Eric Johnson confirms that AgResearch test was inconclusive due to its methodology.
    - A risk assessment confirms that Abbott products were not affected by the contamination incident.
- **4pm, 14 August 2013:** RMT Meeting reviews situation report and receives updates.
- **14 August 2013:** Fonterra informs MPI informed about 14 additional pallets of WPC that are potentially contaminated that were sent from Australia to China and Malaysia. MPI liaises with DAFF in Australia and with Nutricia to verify the source of the pallets. Fonterra also informed MPI about customer samples of a nougat bar that were sent to the USA.

Thursday 15 August 2013

- **9am, 15 August 2013:** RMT Meeting reviews updates.
- **3pm, 15 August 2013:** Sixteenth Situation Report issued.
    - Confirmation that the AgResearch mouse bioassay did not conform with FDA protocol.
    - Risk assessment of Maxum stockfeed completed: no food safety recall as there is no food safety risk to humans and the risk to stock is very low.
- **Afternoon, 15 August 2013:** Fonterra advises MPI and Nutricia of a correction to data concerning 14 pallets of affected powder sent from Darnum to Nutricia. Product is rapidly traced and all was used within the batches already deemed affected. Nutricia ceased selling product to customers until MPI verified their data.
- **Liaison with industry**
    - MPI begins to scale back the frequency of liaison with industry. There is still daily contact with Fonterra, and Fonterra staff are still located at MPI offices in Wellington. There was no teleconference with DCANZ today.

Friday 16 August 2013

- **9am, 16 August 2013:** RMT Meeting reviews updates.
- **1.30pm, 16 August 2013: RSL** Meeting receives update and agrees actions.
- **3pm, 16 August 2013:** Seventeenth Situation Report issued.
- **Current priorities**
    - Protecting domestic and overseas health, as well as consumer confidence
    - Completing the tracing and verification final report
    - Finalising a plan to restore full market access in key markets
    - Ensuring ongoing market access and assurance, by liaising with international markets and key exporters
    - Determining the strain of Clostridium
    - Progressing the MPI compliance investigation and the Government inquiry
    - Establishing the process for the lessons learnt review.

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Saturday 17 August 2013

- **8.45am, 17 August 2013:**
  - Fonterra provides a spreadsheet showing new lines of base WPC powder sent from Fonterra Darnum to Nutricia NZ and Dumex Thailand. MPI starts tracing the product to ensure it is locked down in New Zealand and Thailand.
  - Throughout the day MPI works with Nutricia to verify that the newly identified product is under control. However, there is some discrepancy between Fonterra's and Nutricia's data.
- **1pm, 17 August 2013:** RMT Meeting reviews updates.
- **4pm, 17 August 2013:** RMT Meeting reviews updates.

Sunday 18 August 2013

- **18 August 2013:** MPI informed about 28 new pallets sent from Fonterra Australia to Danone China that may contain potentially contaminated WPC.
- **4pm, 18 August 2013:** RMT Meeting reviews updates. Considers a possible media release on all current dairy issues and possible legal action.

Monday 19 August 2013

- **9am, 19 August 2013:** RMT Meeting reviews situation report and receives updates.
- **3pm, 19 August 2013:** Eighteenth Situation Report issued.

Tuesday 20 August 2013

- **Morning:** Notification of a [redacted] is the likely diagnosis, rather than polio or botulism.

[s.9(2)(a)]

- **9am, 20 August 2013:** RMT Meeting reviews situation report and receives updates.
- **20 August 2013:** MPI announces that it is exploring interim measures to strengthen consumer assurances around New Zealand's dairy production.
- **1.30pm, 20 August 2013: RSL** Meeting receives update and agrees actions.
- **3pm, 20 August 2013:** Nineteenth Situation Report issued.
- **Interim measures**
  - MPI is aware that there has been public and trading partner concern about aspects of our food safety system as the result of this and other events over the last six months. In response, today MPI announced that it will:
    - Increase the regulatory presence in manufacturing premises;
    - Increase the level of and nature of testing across dairy production to improve the identification of non-compliance issues;
    - Run tracing simulations to test the capability of the industry to rapidly track and trace product through their supply chains; and
    - Increase reviews of the risk management plans dairy producers have for manufacturing facilities.
- **Investigations and inquiries**
  - The Government has agreed in principle to establish an Inquiry.

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- The MPI compliance investigation continues.
- Fonterra's management has initiated an inquiry into this incident and the Fonterra Board has also established an independent Inquiry Committee, chaired by Sir Ralph Norris.
- The Financial Markets Authority has indicated it may also investigate whether Fonterra met the relevant securities legislation requirements.

Wednesday 21 August 2013

- **9am, 21 August 2013:** RMT Meeting reviews updates.
- **3pm, 21 August 2013:** Twentieth Situation Report issued.

Thursday 22 August 2013

- **9am, 22 August 2013:** RMT Meeting reviews updates.
- **Australian product exported to Asia**
  - The additional pallets of potentially contaminated WPC that Fonterra notified over the weekend had been used to manufacture products in, and exported from, Australia. [redacted]

[s.6(a)]

  - Danone is confident that the recently identified additional product in Malaysia and Thailand falls within these countries' existing product recalls. Danone has advised that the product to China (Follow On Formula) has been distributed to the market since July. It does not fall within the scope of Danone's recalls in China. Danone considers that the product is of low risk and no concern.
  - MPI has been liaising with DAFF on these issues.
- **Testing**
  - Provisional results indicate an increasing likelihood that the contamination is not *C. botulinum*. MPI is planning for this scenario and the sequence of decisions and communications should it arise. However, we will be making no change to the response until we have confirmed information from the full suite of tests.
  - A number of our trading partners are beginning or considering enhanced testing of our dairy products for *C. botulinum* using a mouse bioassay. If these tests are not done to the prescribed standard, there is a reasonable likelihood of false positive results. We have set up a team to work through how we can respond to such a situation to minimise the trade impacts, and will provide further updates on this work.
- **Impacts of the response on New Zealand businesses**
  - MPI and New Zealand Trade and Enterprise (NZTE) have been liaising with affected exporters throughout the response, ranging from food processing companies to health supplement firms. [redacted]

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- Some companies reported product is not being cleared, new exports are not being sent, and customers are slowing down on new orders and job losses are likely to follow. Many of these companies reported being hit heavily in their cash flow and some of the smaller firms face financial challenges as a result. [redacted]
- Details remain patchy, due to the companies' reluctance to share commercially sensitive information.
- NZTE and MPI have asked NZTE customer companies to provide a regular weekly update of what products are entering or being refused entry into what markets and in what volumes.
- NZTE will continue to work with MPI to update companies on a regular basis. We are drawing on the insights from the companies to inform the ongoing market access efforts.

- **Communications**
  - MPI is working with supermarkets on deciding when point of sale notices can be scaled back. MPI is currently proposing that notices are removed by the end of August. MPI will line up its website notifications with what is decided.

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Friday 23 August 2013

- **9am, 23 August 2013:** RMT Meeting reviews updates.
- **1.30pm, 23 August 2013: RSL** Meeting receives update and agrees actions.
- **3pm, 23 August 2013:** Twenty-First Situation Report issued.
  - Preliminary mouse testing shows no evidence of a botulinum-toxin-producing *Clostridium sp*.

Monday 26 August 2013

- **9am, 26 August 2013:** RMT Meeting reviews updates.
- **26 August 2013:** Tracing and verification report completed and approved by Acting Director-General. MPI is preparing for its publication over 27 and 28 August.
- **3pm, 26 August 2013:** Twenty-Second Situation Report issued.

Tuesday 27 August 2013

- **9am, 27 August 2013:** RMT Meeting reviews updates.
- **1.30pm, 27 August 2013: RSL** Meeting receives update and agrees actions. Agrees to release of Tracing and Verification Report.
- **4.30pm, 27 August 2013:** Fonterra advises of more 'possibly' potentially affected product under their control.
- **Tracing report:** MPI releases Tracing and Verification report under embargo to DAFF, Fonterra, Nutricia, Abbott, DCANZ and the Dairy Product Safety Advisory Council.
- **Testing:** MPI is developing a report summarising the full suite of tests and results that MPI has initiated and undertaken on the back of Fonterra notifying the potential contamination on 2 August. At this stage, it is looking likely that this report could be released this coming Friday if MPI receives the final results from the United States in the next day or so.

Wednesday 28 August 2013

- **28 August 2013:** MPI receives results confirming that the bacteria found in the WPC is not *Clostridium botulinum*. Full testing report is available at the MPI website from 31 August 2013.
- **3pm, 28 August 2013:** Twenty-Third Situation Report issued.
- **4.00pm, 28 August 2013:**
  - The Acting Director General issues a further Statement under the Food Act 1981 and Animal Products Act 1999 stating that there has been no *C. botulinum* contamination of products. He also revokes his earlier Statements.
  - MPI is in the process of removing the other regulatory controls as quickly as possible.
  - MPI also issues a media statement in English and Chinese.
  - Once all regulatory controls are removed, Fonterra and Nutricia will need to decide whether to release the product to market.
- **28 August 2013:** MPI releases Whey Protein Concentrate Incident Tracing and Verification Report.

Thursday 29 August 2013

- **9am, 29 August 2013:** RMT Meeting reviews situation report and receives updates.
- **1.30pm, 29 August 2013: RSL** Meeting receives update and agrees actions.
- **International markets**
  - [redacted]
  - MPI will continue to liaise with affected exporters to determine how quickly markets return to normal following the release of the diagnostic testing and Tracing and Verification reports.
  - [redacted] MPI is also drafting letters that companies can use to assure their overseas customers that the potential contamination issue has been confirmed as *C. sporogenes* and there has been no unsafe contamination of their products.
- **Diagnostic testing**
  - MPI is developing a report on the full suite of tests (just under 200) and results that MPI has initiated and undertaken. As soon as it is ready, the report will be made available to overseas authorities, who are keen to receive comprehensive information on the diagnostic testing as soon as possible. MPI also intends to put a more easily digestible report on our website for the public.

Friday 30 August 2013

- **9am, 30 August 2013:** RMT Meeting reviews situation report and receives updates.
- **3pm, 30 August 2013:** Twenty-Fourth Situation Report issued.

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Saturday 31 August 2013

- **31 August 2013:** MPI publishes diagnostic report on its website.

Monday 2 September 2013

- **9am, 2 September 2013:** RMT Meeting reviews updates.

Tuesday 3 September 2013

- **9am, 3 September 2013:** RMT Meeting reviews updates.
- **Midday, 3 September 2013:** RSL Meeting receives update and agrees actions.

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WPC 2013 Response

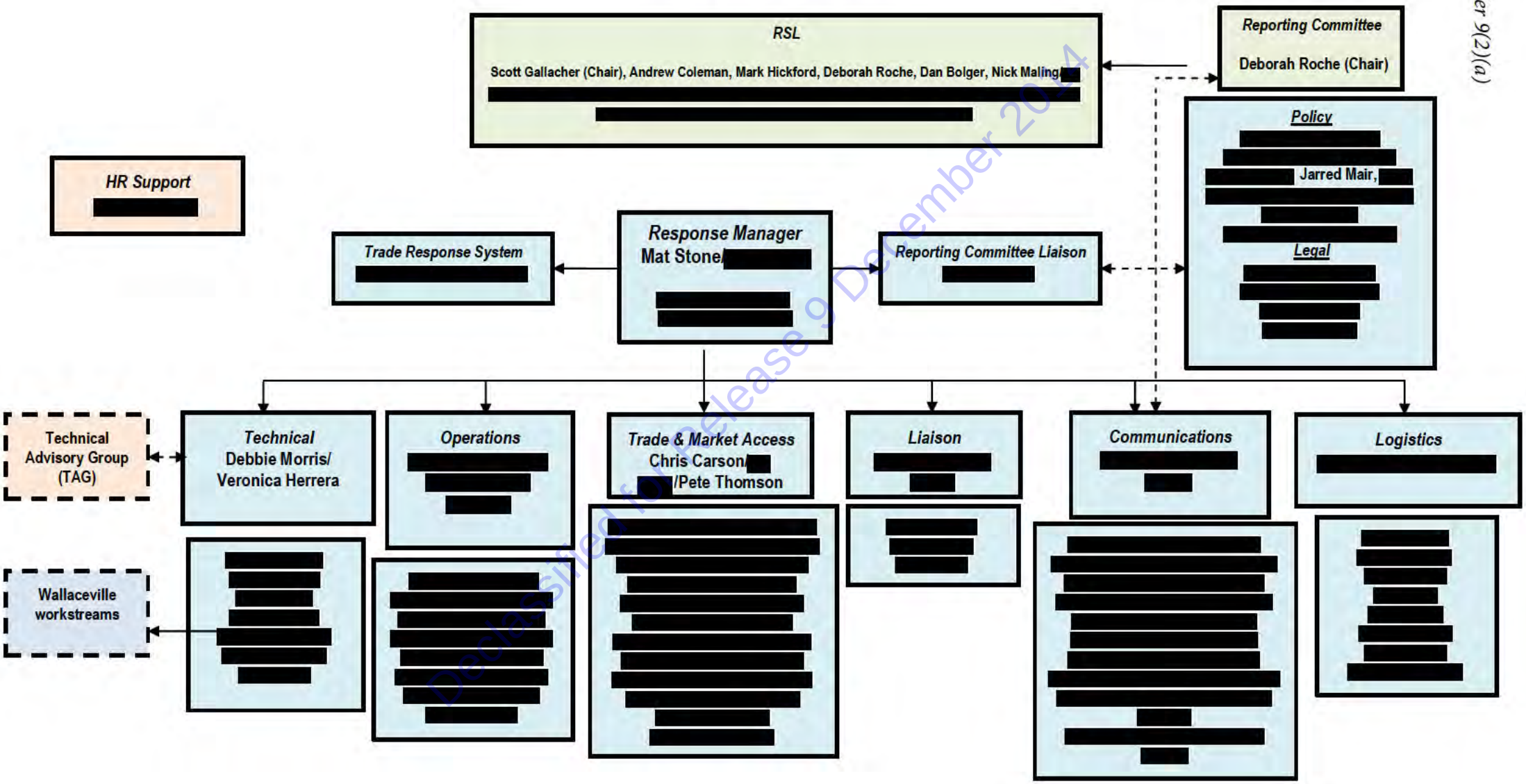

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TABLE OF LESSONS LEARNED BY MPI

	Lesson learned	Proposed action	Actions taken
1.	Incident responses are generally unplanned and typically unpredictable. What made the WPC contamination incident different was its scale.	Build organisational capacity by exposing MPI staff to experience of a range of responses.	Continuing to build organisational capacity in, and experience of, responses.
2.	MPI needs to make its expectations of the food industry abundantly clear, particularly in respect of early notification to MPI of export non-compliances and not allowing non-compliant product to enter the food supply chain.	MPI will use both proactive and reactive means to establish its expectations of industry.	Fonterra Ltd prosecuted (reactive). MPI working with industry to create a dairy risk register.
3.	MPI's Co-ordinated Incident Management System response model with its two-tier decision making structure – Response Strategic Leadership group and Response Management Team – met the demands of responding to the country's largest food safety incident. MPI's response model proved its flexibility and scalability.	MPI will continue to use the Response Strategic Leadership group and Response Management Team as its template for food safety responses (and, for completeness, biosecurity responses).	No actions required.
4.	The combination of voluntary industry product recall and the use of certain public statements by MPI proved sufficient to secure the recall of contaminated product from the New Zealand market. The use of mandatory recall powers was unnecessary.	MPI would consider using Director-General statements in any future food safety response to encourage voluntary recalls. Mandatory recall provisions should remain in statutes.	Certain enforcement powers in the new Food Act 2014 have been strengthened and will commence early.
5.	Whilst SRCs themselves are not a significant risk to the general population, they can provide an indicator of the performance of hygienic processing controls.	MPI has incorporated an expanded programme of testing into monitoring programmes for nutritional powders intended for infant consumption. Companies have also themselves incorporated greater routine testing. [redacted]	Independent Verification Programme reviewed to incorporate SRC testing (completed, ongoing). China Overseas Market Access Requirement updated, and testing and verification programme implemented (completed, ongoing)

[Withheld under s.6(a)]

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	Lesson learned	Proposed action	Actions taken
6.	The current format for documenting RMPs is complex. As was discovered in this case, RMPs contained many documents running to thousands of pages. This complexity makes it difficult for the RMP operator to maintain awareness of the requirements of the RMP and its many parts.	MPI is reviewing the RMP process to address how RMPs are created, approved, maintained and stored. [redacted] At the same time, we are considering how to give effect to this in the context of the existing regulatory environment.	MPI officials are undertaking the background policy work [redacted]
7.	The current RMP approval process includes significant changes that must be notified to MPI, and insignificant changes that the RMP operator can make without advising MPI. Consequently, many versions of RMPs were created and the RMP operator and MPI held and referred to different outline versions creating confusion and making compliance difficult.	MPI is reviewing the RMP process to address how RMPs are created, approved, maintained and stored. [redacted] At the same time, we are considering how to give effect to this in the context of the existing regulatory environment.	MPI officials are undertaking the background policy work [redacted]
8.	No specifications exist for dairy manufacturers in regards to listing of dairy maintenance compounds, as provided for under the Animal Products (Dairy) Regulations 2005, although specifications do exist for farm dairies (milking sheds).	MPI is considering developing specifications for dairy manufacturers.	Awaiting policy consideration.
9.	Currently section 51(c) of the Animal Products Act requires an exporter to advise MPI of any non-conformance when the exporter "knows" that animal product/material exported is unfit for intended purpose. As occurred in this case, Fonterra had strong suspicions, but the word "know" set a high threshold meaning that the company was not required to report the suspected non-conformance.	MPI will review how well the existing threshold in section 51(c) of the Animal Products Act meets the purposes of the Act as part of the.	MPI officials are undertaking the background policy work [redacted]

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[Withheld under 9(2)(f)(iv)]

	Lesson learned	Proposed action	Actions taken
10.	The current practice by a Recognised Agency, AsureQuality, of providing 48 hours' notice for "unannounced audits" nullifies the intent and impact of these audits and those being audited sufficient time to prepare.	MPI is reviewing this practice, and the Animal Products Export Verification Programme.	Notice of Direction issued ensuring Verifiers will undertake unannounced audits of RMP holders producing nutritional powders for infant consumption (completed and ongoing).
11.	A review of Fonterra's compliance with reporting requirements in regards to Critical Event Reports and Export Non-Conformances has shown significant non-compliance that was not followed up or acted on by MPI.	MPI's processes are being reviewed with a view to ensuring the role of the regulator is understood and affirmative action plans put in place to achieve and maintain compliance.	Systems to receive, review and respond to exception reports and export non-conformances reviewed. (completed and ongoing)
12.	The performance of a Recognised Agency, AsureQuality, in regards to notifying MPI within 72 hours of CERs has shown that there is ongoing lateness and thus non-compliance.	MPI's processes are being reviewed with a view to ensuring the role of the regulator is understood and affirmative action plans put in place to achieve and maintain compliance.	Enhanced systems of communication and direction between MPI and verifiers developed. This includes Notices of Direction and twice annual "Verifier Summit" meetings, (Completed and ongoing)
13.	The boundary between entry and examination and other powers under the Animal Products Act is unclear. For example, auditors may be using examination powers while officers from MPI are simultaneously using coercive powers as part of an investigation. This is a fine line that needs careful consideration on a case by case basis.	MPI is reviewing all aspects of its entry and examination powers.	A Compliance Liaison position is now parts of MPI's Co-ordinated Incident Management System to ensure that audit and investigation activity is carefully co-ordinated and does not undermine the activity of the other or to confuse the subject of the activity as to what powers are being exercised.

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	Lesson learned	Proposed action	Actions taken
14.	MPI needs to consider whether the Acts it administers have adequate offence provisions relating to supply of unsafe ingredients and supply of unsafe food, which may happen long after the event that caused a food safety problem. The Animal Products Act currently allows a two-year time limit after the date on which the offence was committed for charges to be laid. In some circumstances this period can be insufficient to allow for a thorough investigation process to be followed. In this instance, MPI's investigation was afforded only six to eight months to investigate and lay charges as the product in question had been produced 18 months prior to MPI being alerted about the *clostridium botulinum* test result.	[redacted]	MPI officials are undertaking the background policy work [redacted] The new Food Act 2014 contains a four-year time limit after commission of the offence for the filing of charging documents.
15.	Further clarity is needed on the use of the terms "non-conformance" and "non-compliance". These terms form part of everyday verification/audit terminology but, in MPI's experience, represent a level of subjectivity in the process that poses a risk. Current guidance for the dairy sector requires all critical "non-compliances" to be reported and anything else is captured in audit report to the operator. There are concerns that systematic and ongoing "non-conformances" are maybe not being escalated. In the food sector the terms have been defined as follows, however it is unclear if this is widely accepted across all sectors: i. 'non-conformance' is where an operator is not conforming to requirements of their Food Control Plan. ii. 'non-compliance' is where the operator's actions or omissions contravene a substantive offence provision of the Food Act 1981 or its regulations. (Food Audit (Verification) Guide 2011)	[redacted]	MPI officials are undertaking the background policy work [redacted]

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[Withheld under 9(2)(f)(iv)]

	Lesson learned	Proposed action	Actions taken
16.	The potentially conflicting motivations for third party auditors to work directly with the operators who contract those same auditors need to be considered with clear guidance set.	Potential changes require further policy consideration. [redacted]	Awaiting policy consideration.
17.	Knowledge of roles and responsibilities across MPI. A better understanding of what people do across the organisation would assist in streamlining response and investigation processes so that input is fed in to the right places, the right people are involved and activity that is core to each group can progress unhindered.	MPI undertook its management alignment to improve accountability and knowledge flow within the Ministry.	Alignment implemented.
18.	Risk communications comprise an essential part of incident responses by, amongst other things, providing consumers sufficient information to safeguard their own wellbeing.	Ensure that food safety responses take a transparent risk communications approach to empower consumers.	Implemented. For example, see media release dated 14 March 2014 concerning apples and Hepatitis A.

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May 2014 update on recommendations of the Report on New Zealand's Dairy Food Safety Regulatory System

Cabinet has accepted all 29 recommendations of the WPC Inquiry.

	Inquiry recommendations (verbatim)	Lead Minister	Cabinet / Ministerial decisions	MPI / agency implementation
	The wider view			
1	The Ministry, in consultation with the industry and other relevant government agencies, should focus on emerging risks and prepare a high-level risk register identifying such risks to dairy food safety and supply.	Food Safety	MPI work programme.	MPI is implementing a system for identifying and managing future strategic risks in partnership with the dairy industry.
2	The Ministry should convene a working group to develop a strategic plan to build up sector-wide dairy processing and regulatory capability.	Primary Industries	Complete.	On track for establishment of the working group, with the potential Chair and nominating organisations for members approached.
3	A centre of food safety science and research, which could be a virtual centre, should be established to ensure New Zealand remains a leader in the food safety field.	Science and Innovation Food Safety	In progress. (Ministers to set criteria for assessment of proposals to host the Centre)	Ministers have announced a call for expressions of interest have been released for a Food Safety Science and Research Centre. The Centre is expected to be up and running by the end of 2014.
4	In collaboration with other government agencies, the Ministry should step up its role and resources, both here and abroad, to allow more effective interaction with New Zealand's most important, and emerging, export markets, particularly China.	Primary Industries	Complete.	The Government has committed an additional $4.430 million in 2014/15 rising to $8.295 million in 2017/18 and out-years to increase the Ministry for Primary Industries (MPI) presence overseas. The implementation of this capability is in progress. In particular MPI have posted additional personnel, including a senior official, to China to boost capability in the region.
5	All organisations in the sector should endeavour to increase collaboration, whether among regulators, the Ministry and the industry, or within the wider dairy industry.	Food Safety Primary Industries	MPI work programme.	An MPI-led review of existing forums and work programmesis underway to enable greater ongoing collaboration.
	Regulatory design			
6	The Ministry should accelerate the standards integration programme, using specialist drafters, technical industry experts and recognised agencies from the start of the process. In particular: o Risk management programme requirements should be elevated to regulations, along with the requirements for the notification and reporting of food safety events. o There should be a new requirement that risk management programmes be limited to food safety and related regulatory matters. o The Ministry, verifiers, laboratories and industry should jointly work on drafting and publishing escalation guidelines for food safety incidents.	Food Safety	In progress (Ministerial/Cabinet decisions required for legislative proposals.)	This is underway and recommendations requiring legislative change are being progressed through a new omnibus Food Safety Law Reform Bill.
7	Following the rewrite of the requirements for risk management programmes, the Ministry should receive and maintain records of full and up-to-date programmes.	Food Safety	MPI work programme.	Awaiting changes to legislation through a new omnibus Food Safety Law Reform Bill.
8	It is important that risk management programmes be periodically re-evaluated.	Food Safety	In progress. (Ministerial/Cabinet decisions required for legislative proposals.)	Ministers have agreed that this will occur as a part of the process of examining legislative changes required as part of a new omnibus Food Safety Law Reform Bill

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	Inquiry recommendations (verbatim)	Lead Minister	Cabinet / Ministerial decisions	MPI / agency implementation
	Role of the regulator			
9	A Food Safety and Assurance Advisory Council should be established to provide the Ministry with high-level independent strategic advice and risk analysis and report annually to the Director-General on the performance of the system.	Food Safety	Complete.	Minister for Food Safety has announced that the Council will be established to provide independent advice to the government on issues relating to food safety. The Council will be set up by, and report to, MPI's Director-General. It will consider operational, policy, and regulatory issues across New Zealand's entire food safety and assurance regime. Cabinet has allocated $250,000 per year for the Food Safety Assurance Advisory Council.
10	The Ministry should consider the following aspects of its operations: o Structure: ensure a more integrated focus on the dairy sector and food safety generally. o Roles: ensure greater clarification of multiple, and sometimes conflicting, roles. o Capacity and capability: ensure additional skilled staff in food safety generally and specifically in the dairy sector. o Visibility: ensure greater prominence of the Ministry's food safety role. o Risk communication: ensure greater resourcing of, and priority for, this role. o Engagement: hold regular workshops and participate fully in overseas forums.	Primary Industries and Food Safety	MPI work programme.	The Director-General, in consultation with employees of MPI, has put in place a plan to align MPI's structure and governance to provide for greater visibility and focus on food safety. The alignment will become effective from mid-May 2014
11	Additional funding should be allocated as appropriate to Vote Primary Industries and Vote Food Safety, targeted at food safety and dairy-related capability; China and new markets capability; the redrafting of regulations; and the Food Safety and Assurance Advisory Council.	Food Safety Primary Industries	Complete.	The Government allocated an additional $8-12 million per year when it accepted the WPC Inquiry recommendations.
	Role of verifiers			
12	The independent verification system should be strengthened in the following ways: o Provider greater clarity of the verifier's role as agent of the Ministry to make clear the true client is the regulator, not the industry. o Subject dairy processing operators using template risk management programmes to more rigorous scrutiny. o Encourage verifiers and the industry (with Ministry approval) to consider how the regular auditing processes can provide more evaluation without straying into consultancy, o Involve verifiers in product dispositions featuring novel or improvised working. o Provide verifiers' accreditation reports directly to the Ministry to ensure full and transparent reporting.	Food Safety	In progress. (Ministerial/Cabinet decisions required for legislative proposals.)	In process of examining legislative changes required as part of a new omnibus Food Safety Law Reform Bill. Early policy work has begun for those changes that do not require any legislative changes.
13	The Ministry should carry out more analysis of audit information to identify areas of particular concern, emerging issues or risks and compliance trends.	Food Safety	MPI work programme.	MPI is reviewing system changes to better extract and analyse data holdings to get better information to government and industry.
14	Accreditors and verifiers should endeavour to consult and collaborate as appropriate to ensure continued improvements to the accreditation and verification systems.	Food Safety	MPI work programme.	Project underway, led by accreditation bodies with MPI providing feedback and consultation to ensure that there is continual improvement.
	Testing: quality and integrity			
15	Sulphite Reducing Clostridia (SRC) testing should not be mandatory for all dairy products.	Food Safety	MPI work programme.	No further action required.

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	Inquiry recommendations (verbatim)	Lead Minister	Cabinet / Ministerial decisions	MPI / agency implementation
16	The Ministry should compile and maintain a list of accredited laboratories for non-standard or novel tests.	Food Safety	MPI work programme.	A laboratory capability plan will be finalised in the coming months.
17	The Ministry should give priority and resources to better analysis of existing data to identify trends, including extending its surveillance programmes where appropriate.	Food Safety	MPI work programme.	MPI is reviewing system changes to better extract and analyse data holdings to get better information for government and industry.
	Implementation of food safety standards			
18	The Ministry, recognised agencies and industry should work to foster a positive food safety culture, and identify mechanisms to evaluate the food safety culture within companies.	Food Safety	MPI work programme.	The MPI alignment changes will enable greater relationships between industry and MPI on issues of food safety culture. MPI has also committed to implementing industry forums as a mechanism to improve food safety culture within companies.
19	The Ministry should promptly inform industry of new overseas market access requirements and where practicable consult industry about such requirements.	Food Safety	MPI work programme.	This is already a core function of MPI, and takes place on a daily basis across the full range of industries producing food and animal material for export.
20	The compliance and enforcement tools in the Animal Products Act 1999 should be aligned with those in the Food Bill, which is currently before Parliament, and should include a full range of tools.	Food Safety	In progress. (Ministerial/Cabinet decisions required for regulatory proposals.)	In process of examining legislative changes required as part of a new omnibus Food Safety Law Reform Bill.
21	The Ministry should prioritise analysis of food safety compliance data.	Food Safety	MPI work programme.	MPI is reviewing system changes to better extract and analyse data holdings to get better information government and industry.
	Traceability, recall and contingency planning			
22	The Ministry should convene a working group to consider first, the most appropriate regulatory provisions for traceability of dairy products, and secondly, a code of practice or similar to guide industry in implementing such provisions.	Food Safety	In progress. (Ministerial/Cabinet decisions required for regulatory proposals.)	The Traceability Working Group has been established, comprising members from the dairy and grocery industry. The group has held its first meeting, and reports to the Director-General of MPI.
23	Recall provisions should be revised, in particular: o Mandatory recall provisions in food legislation should be aligned. o Voluntary recall obligations should be set out in regulations rather than in risk management programmes. o Regulations should require industry to simulate recalls, audited by verifiers. o Circumstances in which privileged statements can be made should be clarified.	Food Safety	In progress. (Ministerial/Cabinet decisions required for regulatory proposals.)	Changes to mandatory recall powers are included in the Food Bill due to be reported back from the Primary Production Select Committee. In process of examining other legislative changes required as part of a new omnibus Food Safety Law Reform Bill.
24	The Ministry should be given statutory responsibility for food safety contingency planning. Industry and regulators should simulate tracing, recall and general food safety incidents from time to time as part of such contingency planning.	Food Safety	In progress. (Ministerial/Cabinet decisions required for regulatory proposals.)	In process of examining legislative changes required as part of a new omnibus Food Safety Law Reform Bill.

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	Inquiry recommendations (verbatim)	Lead Minister	Cabinet / Ministerial decisions	MPI / agency implementation
	Infant formula			
25	The Ministry should prioritise its infant formula work programme, and complete the revision of food safety-related regulatory requirements for the manufacture of infant formula (and, if appropriate, ingredients for infant formula) within six months.	Food Safety	In progress. (Ministerial/Cabinet decisions required for regulatory proposals.)	MPI has a dedicated infant formula team, and regulatory requirements are being examined as a priority.
26	The Ministry, with input from the relevant working groups, should resolve whether infant formula and other high-risk products should routinely undergo Sulphite Reducing Clostridia (SRC) testing, based on scientific, risk-based and cost-benefit analysis.	Food Safety	MPI work programme.	Analysis has shown that no further action is required.
27	The Ministry should strengthen requirements for exporters of infant formula to ensure traceability.	Food Safety	In progress (Ministerial/Cabinet decisions required for regulatory proposals.)	Relevant requirements are currently being prepared by MPI.
28	Regulatory requirements under both the Animal Products Act 1999 and the Food Act 1981 should be aligned.	Food Safety	In progress (Ministerial/Cabinet decisions required for regulatory proposals.)	In process of assessing the need for regulatory or administrative changes.
29	The Ministry, in consultation with the industry, should develop options to provide foreign markets with the assurance of authenticity of New Zealand-manufactured infant formula products.	Food Safety	In progress.	This work will be informed by the Traceability Working Group in consultation with MPI.

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CAPTION SHEET

MINISTRY FOR PRIMARY INDUSTRIES	**v**	**FONTERRA LIMITED** 9 Princes Street AUCKLAND

CHARGES

CRN: 14085500849

Dairy product not processed in accordance with Risk Management Programme
Section 134(1)(a) and section 16(1)(a) Animal Products Act 1999
Penalty: $100,000 - Section 134(2)(b)(i) Animal Products Act 1999

CRN: 14085500847

Export of dairy product not meeting relevant animal product standards
Section 134(1)(d) and section 51(b)(i) Animal Products Act 1999
Penalty: $200,000 - Sections 134(2)(a)(i) and 134(3)(c) Animal Products Act 1999

CRN: 14085500848

Failure to notify regulator of dairy product not processed in accordance with Risk Management Programme
Section 134(1)(a) and section 16(1)(a) Animal Products Act 1999
Penalty: $100,000 - Section 134(2)(b)(i) Animal Products Act 1999

CRN: 14085500846

Failure to notify regulator of dairy product not fit for intended purpose
Section 134(1)(d) and section 51(c) Animal Products Act 1999
Penalty: $100,000 - Section 134(2)(b)(i) Animal Products Act 1999

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ADMITTED SUMMARY OF FACTS

The Defendant

1. The defendant, Fonterra Limited (Fonterra) is one of a number of subsidiary companies of Fonterra Co-operative Group Limited. Fonterra Co-operative Group Limited holds a 99.01% shareholding.

2. Fonterra Co-operative Group Limited is a New Zealand multi-national dairy cooperative owned by more than 10,000 New Zealand dairy farmers with more than 17,000 employees. Fonterra Co-operative Group Limited is New Zealand's largest company. Fonterra Co-operative Group Limited is the world's largest global milk processor and dairy exporter, being responsible for approximately 30% of the world's dairy exports and with total revenues of NZ$18.6 billion. In 2013, dairy exports of nearly $13.5 billion made up around 45% of New Zealand's total export earnings. A New Zealand Institute of Economic Research report published December 2010 estimated that the dairy industry, including downstream activities such as marketing, wholesaling and transport, contributed around 2.8% to New Zealand's GDP.

3. Fonterra operates more than 30 manufacturing sites throughout New Zealand. Fonterra is registered with the Ministry for Primary Industries (MPI) as the operator of the Risk Management Programme for these sites.

4. Approximately 97 percent of milk produced in New Zealand is processed into dairy products, with the balance sold on the domestic liquid milk market.

5. New Zealand dairy exports go to over 100 countries with key markets being China, the United States, Japan and the European Union.

6. In the 2011 season Fonterra collected approximately 16 billion litres of milk in New Zealand, representing around 90% of the country's milk production. This was complemented by 1.8 billion litres of milk sourced in Australia and 2.6 billion litres sourced in Latin America.

7. The total dairy ingredient sales volume for Fonterra in the 2013 season was 2.8 million metric tonnes, of which approximately 2.4 million metric tonnes was processed in New Zealand. The company has an extensive global sales network servicing customers in over one hundred countries.

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8. One of the manufacturing sites operated by Fonterra is situated at Hautapu in the Waikato region.

9. The Hautapu site was first established in 1866 and currently has 300 staff on site. The site processes 151 tankers of milk per day and when operating at peak capacity will process 4.1 million litres of milk per day with a storage capacity for 6,500 tonnes of powders, 16,000 tonnes of cheese and 3,500 tonnes of whey protein concentrate.

10. The site has a number of factories which specialise in the manufacture of high-value products including cheese, casein, whey protein concentrate, hydrolysate, lactoferrin, milk protein concentrate and lactose – bound for the domestic market, as well as international markets in Asia, Europe and the USA.

11. Located within one building on the site are the Whey Protein Concentrate (WPC) factory and the Scale Up Facility (SCUF) factory. These factories are coded 1239 and 1282 respectively.

12. These are the two factories that gave rise to the events leading to the charges now before the Court.

13. The Whey Protein Concentrate factory takes Whey, the liquid remaining after milk has been curdled and strained during the cheese making process, and uses it to manufacture Whey Protein Concentrate which is a milk powder.

14. The Hautapu site processes 3,500 tonnes per year of Whey Protein Concentrate (1,900 tonnes of cheese Whey Protein Concentrate & 1,600 tonnes of rennet Whey Protein Concentrate) in the Whey Protein Concentrate factory (1239).

15. Different protein concentrations of Whey Protein Concentrate can be manufactured to customer specification and the product is labelled accordingly e.g. Whey Protein Concentrate WPC80, WPC35. The numerical (e.g.80) refers to the protein concentrate level (80%).

16. WPC80 is used in a variety of products such as yoghurts, beverages and dairy desserts. It also provides a source of protein fortification for nutritional products and infant food.

17. The SCUF factory is routinely used to manufacture whey protein hydrolysates which are predominantly used for sports nutrition.

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18. With regard to the matter now before the Court, the SCUF (1282) factory was used to convert processed WPC powder back to a liquid form so that it could then be re-processed in the WPC factory.

Regulatory Environment

19. New Zealand is a major exporter of dairy products to over 100 countries and its dairy industry operates in accordance with best international practice.

20. The Ministry for Primary Industries (MPI) operates integrated regulatory controls from the farm through to export which provide a high level of assurance to both New Zealand domestic consumers and New Zealand's export markets.

21. New Zealand's regulatory and industry controls meet or exceed best international practice. These controls ensure that importing country competent authorities can be assured of the safety and identity of dairy products certified by MPI.

22. All exporters of dairy products are required to be registered and operate in accordance with New Zealand laws as well as meet the market access requirements of any market they export to.

23. All dairy businesses must meet legal requirements, which ensure their dairy products are safe and suitable for human consumption. Legislation that sets out the requirements for dairy manufacturers includes:
    - Food Act 1981
    - Animal Products Act 1999
    - Animal Products (Dairy) Regulations 2005
    - Animal Products (Dairy Processing Specifications) Notice 2011

24. Food-related legislation in New Zealand has two main purposes:
    - to protect public health and safety
    - to facilitate access to domestic and export markets.

25. The intent of New Zealand's regulatory environment is to ensure that the food New Zealand produces, imports and exports is safe and suitable for domestic and international consumers.

26. The provision of safe and suitable food is critical to the New Zealand economy. New Zealand has a reputation as a trusted supplier of food, which is protected by

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quarantine laws, border controls and a regulatory framework to ensure the safety and suitability of food and food-related products.

27. The Animal Products Act 1999 (the Act) requires most food businesses to operate under a Risk Management Programme (RMP).

Risk Management Programme

28. In general, all primary processors of animal material and products for human or animal consumption are required to operate under a RMP that is registered with MPI.

29. Part 2 of the Act sets out who must operate a RMP. This includes all primary processors of animal material. Part 2 also identifies duties required of operators such as ensuring that the operations of the animal product business do not contravene the relevant requirements of and under the Act, including the requirements set out in the operators' RMP.

30. A RMP is a written programme designed to manage the hazards, wholesomeness and labelling of animal material and products. Hazards may be biological, chemical or physical. It sets out how the manufacturer will identify and control, manage, eliminate or minimise food safety hazards and other risk factors in relation to their processing. All animal products traded and used must be 'fit for intended purpose' and meet the requirements of the Act and associated legislation.

31. Once registered with MPI, the RMP is a legally binding document that must be developed and implemented in accordance with the Act and other relevant New Zealand legislation.

32. The Fonterra Hautapu site operates pursuant to a MPI registered RMP (identification number R007) that was first registered on the 15th of August 2006. The operator of this RMP is Fonterra Limited.

Hazard Analysis and Critical Control Point (HACCP)

33. Dairy manufacturers are required to have, as part of their RMP, systems in place for monitoring the manufacturing environment, the process and the dairy material or product to confirm that pathogens are controlled.

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34. A key element of this is a HACCP plan which is a systematic identification of hazards and the measures for their control to ensure the safety of food. It focuses on prevention rather than end-product testing.

35. A HACCP plan is a documented system to ensure control of significant food safety hazards in a food manufacturing process.

Reporting Requirements

36. The Act, various regulations, specifications and notices, and RMPs create notification obligations upon dairy processors to report to Recognised Agencies and/or MPI in cases where the regulatory requirements of the RMP are not met. In cases where the requirement is to report to the Recognised Agency, the Agency is required to then notify MPI.

37. A Recognised Agency is an individual or body accredited by MPI.

38. A Recognised Agency engages recognised persons (accredited individuals) to carry out specific functions and activities to check that food businesses are meeting requirements. These functions and activities include:
- evaluating and/or verifying food businesses operating under a RMP
- verifying that food businesses meet certain export requirements
- laboratory testing, analysis and calibration of animal material or products
- sampling for monitoring and surveillance purposes
- other functions or activities required under the Act.

39. In the case of Fonterra Limited, the Recognised Agency is AsureQuality.

Summary of Events

40. On 2 and 3 February 2012, WPC80 was manufactured and packed in the Fonterra Hautapu WPC factory.

41. All products manufactured at the Hautapu site are manufactured in accordance with a documented Product Specification which details data relevant to the product such as type of product, composition (e.g. moisture content), constraints (e.g. dietary statements such as halal), ingredients (e.g. Cheese Whey) and testing parameters including chemical, microbiological, physical, sensory, trace element, mineral composition and parameters that the product must meet.

42. WPC80 is manufactured in accordance with the following product specifications;

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- Product Specification document dated 27 June 2004 Product Number 104579 Whey Protein Concentrate (WPC80) Cheese
- Product Specification document dated 27 June 2004 Product Number 104578 Whey Protein Concentrate (WPC80) Cheese
- Product Specification document dated 27 June 2004 Product Number 104589 Whey Protein Concentrate (WPC80) Rennet

43. All products manufactured in the WPC factory are assigned a unique identification code known as a cipher which is derived from the month, year and day of packaging.

Code	Month	Code	Year	Day of Month
K	June	U	2010	02
L	July	V	2011	03
A	August	W	2012	04
B	September	X	2013	
C	October			
D	November			
E	December			
F	January			
G	February			
H	March			
I	April			
J	May			

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44. Thus G references the month, W references the year and the numeric references the day the product was packaged. GW03 therefore can be translated to show that the packing took place on 3 February 2012.

45. During the manufacturing process of WPC80 on 2 February 2012, an unusually high pressure reading in the plant caused an engineer to examine the plant machinery. In conducting this examination the engineer shone a torch up an air intake to check for a blockage. In doing so, the air pressure sucked the torch into the inlet pipe with sufficient force to break the hard plastic torch lens against a damper.

46. The plant was immediately stopped and a number of large pieces of the broken lens were recovered. At this stage approximately 1 tonne of WPC80 had been manufactured.

47. In assessing the incident, factory staff believed that the plant fan clearance, radiator and static fluid bed would prevent any missing pieces getting into the product and the plant was restarted and the manufacture of WPC80 continued with a further 41 tonnes of WPC80 then being manufactured.

48. This action resulted in the possible contamination of a further 41 tonnes of WPC80 in addition to the 1 tonne already possibly contaminated by the broken torch lens.

49. In total 42.050 tonnes of WPC80 was manufactured and was allocated cipher numbers GW02 and GW03

50. In accordance with standard practice, retention samples were taken and ultimately analysed. The WPC80 met all regulatory product specification requirements.

51. The following day, 3 February 2012, the incident was reviewed by factory staff and it was determined that there were two pieces still missing from the broken torch lens. It was considered possible that the missing pieces had ended up in the powder although this was deemed to be unlikely.

52. The plant was stopped and an inspection conducted. Small pieces, equivalent to one of the two missing pieces were found on the radiator within the plant. The rest of the plant was checked and no other pieces were found. Reconstruction of the broken lens determined that the missing piece was wedge shaped and approximately 15x25mm.

53. Because of the possible contamination, the factory staff planned to pack the product and place it on hold, which prevented it from being released to customers and check the plant again at the end of run to try and locate the missing pieces of torch lens.

54. That same day the incident was reported internally in the Fonterra Product Safety Risk Management Programme as an exception report, number 562 and the incident was categorised as a foreign matter, Category 'B'. The Fonterra RMP categorises two levels of incident;

- Category A – low risk issue dealt with internally by Fonterra
- Category B – referred to the Recognised Agency, in this case AsureQuality, for review and to authorise disposition options for the product.

AsureQuality act on behalf of MPI.

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55. An investigation into this incident by Fonterra considered that the supervisor made a poor product safety judgement by continuing to manufacture product after the incident by potentially contaminating a further 41 tonnes needlessly. If production had been halted at the time of the incident the amount of product implicated would have been limited to 1 tonne.

56. Five days later, on 8 February 2012, Fonterra reported the incident to AsureQuality by way of Exception Report. On 9 February 2012 AsureQuality submitted the Exception Report to MPI who allocated the incident an identification number (CER6266).

57. On 20 February 2012, Fonterra submitted a Product Disposition request (PD2550v1) for Ciphers GW02 and GW03 to AsureQuality seeking approval to release the affected product to 'Restricted Markets'. This option was not supported by AsureQuality who considered release for further processing and filtration as more appropriate. This is referred to by MPI as a re-process and by Fonterra as a rework process.

58. On 13 March 2012 AsureQuality sent the Product Disposition request PD2550v1 to MPI. They did not recommend it be approved because reclassification to 'Restricted Markets' implied Fonterra were not confident that there was no foreign matter in the product.

59. On 16 March 2012 MPI declined Product Disposition PD2550v1.

60. On 11 April 2012, AsureQuality advised Fonterra that Fonterra's amended Product Disposition request PD2550v2 was approved. This amended request was to re-process the potentially contaminated product with the inclusion of a filtration step, or release it to the local market for stock food on the proviso that Fonterra accepted any commercial risk.

61. On 12 April 2012, AsureQuality advised MPI that it had approved the amended Product Disposition request.

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<u>Dairy Product Not Processed In Accordance With Risk Management Programme</u>

62. On 2 May 2012, prior to reworking the GW02 and GW03 ciphers, the Hautapu Plant Manager responsible for the WPC factory and the SCUF factory designed a process by which the two ciphers could be reprocessed using both factories, to ensure that any residual foreign object contamination could be removed by filtration. A wet rework of this nature had not been undertaken previously and was unique. The rework instruction was titled '*WPC Recon through SCUF Wet*'.

63. The rework instruction documented the fitting of flexi hoses to bypass unnecessary steps in the process and identified that reconstitution of powder via the SCUF factory reconstitution room would be required. Reconstitution basically meant that the powder was turned back into a liquid form in the SCUF factory so that it could then be run through the WPC factory, filtered and then dried into powder form again. With no previous reworks of WPC having taken place there was no facility for the reconstitution of powder other than in the SCUF factory.

64. When the product was re-worked it was not necessary for it to go through the standard WPC manufacturing process. Three sections of the usual manufacturing process were bypassed. Temporary flexi-hoses were used to do this. There was also one 25m long fixed stainless steel pipe that was incorporated into the process. This piece of pipe is a permanent part of the WPC factory but is seldom used and in fact had not been used in manufacture for approximately two years.

65. The rework plan did not address the fact that the stainless steel pipe had not been used for at least two years prior to the WPC80 rework. It also did not address the necessary cleaning procedures.

66. The temporary flexi hoses and the 25m long fixed stainless steel pipe were subject to Clean In Place (CIP) cycles. CIP is a dairy term used to describe an automated cycle where, for example, a caustic wash is flushed through the pipes before and after each product run, using a chemical solution greater than PH7, usually Sodium Hydroxide.

67. The Caustic CIP process used was the ordinary, day-to-day process for cleaning pipes, including pipes not used for extended periods. It is best practice to require acid cleaning on any equipment unused for over 24 hours. Where possible, use of plastic flexi hoses should be avoided in dairy processing. Stainless steel can be cleaned better than plastic hoses at appropriate temperatures.

68. Fonterra conducted a hydrolysate manufacturing process using the SCUF factory immediately before the first rework process of WPC80 was undertaken. No flexi-hoses were used and the standard processes were followed. The first two batches of WPC80 re-work were then run through the SCUF factory and then into the WPC factory with the flexi-hoses in place. Following that, four standard hydrolysate batches were manufactured, then a further WPC80 re-work batch and finally a standard batch of hydrolysate.

69. The following schedule outlines the sequence of Hydrolysate and WPC80 re-processing:

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Date	Production Type
16 May 2012	Protein Hydrolysate manufactured
17 May 2012	Manufacture of JW17 104579 using rework from 104578 GW02
18 May 2012	Manufacture of JW18 104579 using rework from 104578 GW02, units C1093-C1099
19 May 2012	Protein Hydrolysate manufactured
20 May 2012	Protein Hydrolysate manufactured
21 May 2012	Protein Hydrolysate manufactured
22 May 2012	Protein Hydrolysate manufactured
22 May 2012	Manufacture of JW22 104589 Rennet Casein Whey using rework from 104578 GW03, units R0865 – R0877
23 May 2012	Protein Hydrolysate manufactured

70. A Caustic Clean In Place cycle was undertaken after every standard hydrolysate and every rework run.

71. Both plants were then shut down for the season.

72. After completing the rework of WPC80 ciphers GW02 and GW03, the reworked product was packed out on 17, 18 and 22 May 2012 respectively as ciphers JW17, JW18, and JW22 and transferred to the Hautapu warehouse

73. Regulatory specification testing was completed for the re-processed WPC80 and ciphers JW17, JW18 and JW22 were found to meet those testing requirements.

74. The rework of JW17, JW18, and JW22 was not within the scope of the Hautapu site RMP, had not been approved through the change control process required under the RMP, and should not have proceeded.

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Export Of Dairy Product Not Processed In Accordance With Risk Management Programme

75. Ciphers JW17, JW18 and JW22 were subsequently shipped to Australia, China or within New Zealand. Cipher JW17 went to Fonterra Australia as did the majority of cipher JW18. The residual amount of cipher JW18 remaining in New Zealand went to the Fonterra Research and Development Centre and NZAgbiz. Cipher JW22 went to the Wahaha Group in China as well as NZAgbiz and Vitaco Health in New Zealand.

76. On 22 October 2012, 13,475kgs of the WPC80 from ciphers JW17 and JW18 re-processed at Hautapu was received by the Fonterra Altona warehouse in Melbourne, Australia. This facility stores ingredient used to manufacture products as well as finished products, for Fonterra Australia. This includes

products for use by the Darnum Park site as macro ingredients in manufacturing nutritional powders.

77. The Darnum Park site produces whole, skim and specialty nutritional milk powders for domestic and export markets. The majority of the site's production (91%) is nutritional milk powders supplied to customers for their use as a macro ingredient in the production of various infant milk formulas.

78. 99% of Darnum nutritional powder is supplied to the Danone Group, a French multinational corporation based in Paris. Danone produces a range of dairy products including infant milk formula. In New Zealand these are manufactured and marketed under the Nutricia brand.

79. WPC80 is used by the Darnum plant as a macro ingredient in their manufacture of nutritional milk powders. Ciphers JW17 and JW18 were delivered from the Altona warehouse to the Darnum site in varying quantities between 27 February 2013 and 14 March 2013 to meet manufacturing schedules. WPC80 ciphers JW17 and JW18 were used as macro ingredients in 39 mixes (19 batches) of nutritional powders, all destined for Danone which was manufactured between 1 and 21 March 2013.

80. Retention samples taken at the time of packing the nutritional powders were sent to an independent and accredited dairy laboratory in accordance with Australian Dairy criteria where they were then tested to ensure they met Australian regulatory requirements.

81. If there is a customer specification, testing is also undertaken to determine whether the product also meets those requirements. Darnum nutritional products destined for Danone are tested for Sulphite Reducing Clostridia as a customer specification rather than a regulatory specification. In New Zealand, there is no regulatory specification requiring the testing of WPC for Sulphite Reducing Clostridia and, until June 2013, Fonterra New Zealand customer specifications did include the testing of WPC for Sulphite Reducing Clostridia.

82. On 21 March 2013, the independent laboratory advised Darnum of positive test results for Sulphite Reducing Clostridia exceeding Danone specifications in 7 of the 19 batches submitted for testing.

83. Darnum commenced an investigation to determine the source of the Sulphite Reducing Clostridia contamination. They concluded that the common denominator across all batches that had tested positive for Sulphite Reducing Clostridia was the WPC80 from ciphers JW17 and JW18 manufactured at Hautapu.

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84. On 22 March 2013, the Technical Manager of Powders and Nutritionals at Darnum made arrangements for a sample of the infant base powder with the elevated Sulphite Reducing Clostridia levels to be forwarded to the Fonterra Research and Development Centre for testing. He also arranged for testing of Hautapu retention samples of ciphers JW17 and JW18 for the presence of Sulphite Reducing Clostridia. The test results subsequently identified Sulphite Reducing Clostridia levels in the retention samples ranging between 400cfu/g and 8,200cfu/gm.

85. The Technical Manager of Powders and Nutritionals at Darnum then requested that the Fonterra Research and Development Centre test the Darnum infant base powder for *Clostridium perfringens* (*C. perfringens*) which is the form of clostridia that commonly causes food poisoning.

86. On 8 May, the Fonterra Research and Development Centre advised the Technical Manager of Powders and Nutritionals at Darnum that further testing of Hautapu retention samples of ciphers JW17 and JW18 indicated several variants of *Clostridium sporogenes (C. sporogenes)* with similar typing patterns to the contaminated Darnum product. They noted the MALDI-TOF mass spectrometer was reporting unidentified strains that clustered close to *C. perfringens*. The further tests returned Sulphite Reducing Clostridia levels of 14,000cfu/g for cipher JW17 and 900cfu/g for cipher JW18. The Fonterra Research and Development Centre indicated that there was little doubt that there was a strong link between the ingredient (ciphers JW17 and JW18) and the contaminant in the nutritional powder.

87. The Fonterra Research and Development Centre also alerted the Technical Manager of Powders and Nutritionals at Darnum that *Clostridium botulinum* (*C. botulinum*) is simply a *C. sporogenes* with the toxin gene and that they were going to determine whether AgResearch at Massey University could assay for the presence of the toxin gene.

88. The Fonterra Research and Development Centre believed that it was extremely unlikely that the organisms identified by the MALDI-TOF as *C. sporogenes*, were carriers of the toxin gene but that they would be derelict in their duty if they did not consider the possibility.

89. The Fonterra Research and Development Centre concluded that regardless of the nature of the organism within the WPC80, it had been found to contain very high levels of clostridia which certainly indicated a lost process control and/or failure to maintain good hygienic practice.

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90. On 9 May 2013, the Technical Manager of Powders and Nutritionals at Darnum advised the Site Manager, Hautapu, and the Hautapu Plant Manager, that their WPC80 product was unfit for purpose because it contained high Sulphite Reducing Clostridia levels.

91. He prepared a document referred to as the "*SRC Complaint Background Document V01 2013 05 10*" and provided it to the Hautapu Managers in which he stated that a total of 468 tonnes of nutritional powder had been affected with Sulphite Reducing Clostridia levels up to 360cfu/g. The reduced levels in the finished product as compared with those found in the WPC80 ingredient, reflect the dilution of the WPC80 when it is used during the manufacture of infant base formula, for Danone, at Darnum.

92. WPC80 is used at a concentration of between 1% and 3% in nutritional powders manufactured at Darnum.

93. The Technical Manager of Powders and Nutritionals at Darnum concluded by saying that the Sulphite Reducing Clostridia levels in ciphers JW17 and JW18 demonstrated a significant good manufacturing process failure and rendered the product unfit for the purpose for which it was supplied.

94. On 10 May 2013, Fonterra commenced an investigation into the cause of the elevated Sulphite Reducing Clostridia levels in ciphers JW17 and JW18.

95. On 20 May 2013, the Fonterra Research and Development Centre forwarded their final report to Darnum which stated that the dominant Clostridium species identified in all samples tested was *C. sporogenes*. The presence of large numbers of *C. sporogenes* raised the question as to whether they might pose a health risk to infant consumers i.e. has *C. sporogenes* the potential to be pathogenic. Strains of the pathogen *C. botulinum* Group1, which are unable to produce toxin, are referred to as *C. sporogenes*.

96. The Fonterra Research and Development Centre recommended that representative isolates of the *C. sporogenes* from the nutritional powder blend should be screened for the ability to produce the *C. botulinum* toxin at AgResearch in Palmerston North.

97. The Fonterra Research and Development Centre also stated that the alternative was to withdraw the product in question from the infant food chain.

98. On 25 May 2013, the Technical Manager of Powders and Nutritionals at Darnum advised the Fonterra Research and Development Centre that all product affected by the incident had been rejected by Danone and had been withdrawn for sale as

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either stock food or edible disposal for general populations. That is, all product had been withdrawn from the infant food chain. Based on that, proceeding with the screening work to confirm that the *C. sporogenes* are non toxin-producing could not be justified.

Failure To Notify Regulator Of Dairy Product Not Processed In Accordance With Risk Management Programme

99. On 31 May 2013, the Director Operations and Supply Chain, Fonterra-Australia again made contact with the Director New Zealand Milk Product Operations and the General Manager Operations, Central North Island, raising additional concerns that the WPC80 ciphers JW17 and JW18 were manufactured from 100% rework. He indicated the 100% rework could be significant because it was a non-standard manufacturing process and there was the possibility that the Sulphite Reducing Clostridia may have come from the flexi hoses or demineralised water used to reconstitute the WPC80.

100. The Director New Zealand Milk Product Operations forwarded this information to the General Manager Quality and Technical, who tasked a staff member with resolving a number of questions including who authorised the 100% rework and whether it followed the change control process as is required and set out in the approved RMP.

101. On 4 June 2013, the Director Operations and Supply Chain, Fonterra-Australia advised the Director New Zealand Milk Product Operations that the contamination can only have occurred if there was growth of Sulphite Reducing Clostridia in the plant because typical Sulphite Reducing Clostridia results in WPC80 are less than 1cfu/g. The recorded levels from ciphers JW17 and JW18 were 1,000 to 10,000 times higher than typical levels, indicating that a significant deviation from normal hygiene conditions or process had occurred. The Director Operations and Supply Chain, Fonterra-Australia also stated that affected batches of WPC80 were manufactured by 100% wet reconstitution of previously downgraded product and that a 100% reconstitution is not considered to be standard practice and increases the risk of quality issues arising.

102. The Regional Technical Manager, NZ Operations, then established a serious event team to investigate the matter. He reiterated that the 100% rework was a non-standard manufacturing process and expressed concern that there appeared to be no process in place to look at the risk around the rework. He also queried whether the product disposition should have stated a percent of rework and whether there should have been a level of decision analysis applied to the decision.

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103. On 12 June 2013, a Fonterra internal commercial decision saw the implementation of Sulphite Reducing Clostridia testing into product specifications for WPC80 with a maximum limit of 100cfu/g imposed.

104. On 18 June 2013, the Fonterra Research and Development Centre reported that under normal manufacturing conditions (ie, compliance with HACCP, good manufacturing process and the Risk Management Programme) elevated levels of Sulphite Reducing Clostridia should not be a concern. However, given the manufacturing process of concentrated whey products, if product does become contaminated, spore forming bacteria will survive and be present in the final nutritional product.

105. On 20 June 2013, Fonterra became aware that affected WPC80 from cipher JW17 was also used in the production of infant powder nutritionals at their Waitoa plant.

106. The Fonterra Research and Development Centre indicated that developments in the microbiology of the clostridia suggest that Fonterra should be very careful when it sees such levels of clostridia and *C. sporogenes* specifically. They stated that it was important to be confident that the organisms are actually *C. sporogenes* and not *C. botulinum* which would pose a serious risk to infants (infant botulism).

107. The Fonterra Research and Development Centre recommended that they initiate further testing to determine whether the organisms in the affected WPC80 were in fact *C. sporogenes* and not *C. botulinum* as such testing would rule out a food safety issue relating to *C. botulinum* leaving only the process hygiene or product quality issue.

108. On 20 June 2013, the Fonterra Nutritionals Technical team prepared a review paper on the WPC80 contamination issue which recommended, among other things, that Sulphite Reducing Clostridia and *C. perfringens* testing be implemented on identified nutritionals products made at Waitoa in January and March 2013, which used affected WPC80 from Hautapu. If Sulphite Reducing Clostridia levels were high, then toxin testing would be appropriate in accordance with the Fonterra Research and Development Centre report of 20 May 2013.

109. Between 20 and 28 June 2013, Fonterra approved further testing of the Waitoa product for Sulphite Reducing Clostridia, *C. perfringens* and toxin testing by AgResearch.

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110. On 28 June, AgResearch provided a draft contract relating to Polymerase Chain Reaction (PCR) and mouse bioassay testing to the Fonterra Research and Development Centre. The purpose of these tests was to determine whether the detected *C. sporogenes* were in fact *C. botulinum*.

111. On 28 June, a Fonterra serious event internal inquiry review included the following conclusions:
- Whilst the complaint from Fonterra Australia was unsubstantiated (Sulphite Reducing Clostridia is not included in the WPC80 specification), the cost of the complaint was split between Fonterra Australia and Fonterra New Zealand.
- Ciphers JW17, JW18 and JW22 were made from 100% rework and were manufactured with an atypically high Sulphite Reducing Clostridia profile
- Outstanding action points which would be dealt with as business as usual were identified including:
    - Review of plant set-up for 100% rework
    - Add 100% rework procedures to SOPs
    - Identify potential hot-spots for Sulphite Reducing Clostridia in the process
    - Develop testing protocol for next time 100% rework process is required

112. On 3 July 2013, the Sulphite Reducing Clostridia and *C. perfringens* test results from the Fonterra laboratory for the product manufactured at Waitoa indicated high Sulphite Reducing Clostridia levels.

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<u>Failure To Notify Regulator Of Dairy Product Not Fit For Intended Purpose</u>

113. On 8 July 2013, samples of the Waitoa product Sulphite Reducing Clostridia were taken to AgResearch for testing for toxin genes. Fonterra Research and Development Centre advised, if toxin genes are found "then we have an answer. If no toxin genes then next week the representative material will go to Hamilton for mouse bioassays - if dead mice then we have an answer - If no dead mice then we have an answer". Fonterra Research and Development Centre confirmed that they may receive a positive, but not a negative, toxin result later that week.

114. On 12 July 2013, Fonterra staff prepared the final Sulphite Reducing Clostridia contamination review report. Recommendations included the completion of the clostridium toxin investigation to determine food safety risk on three affected batches of nutritional products made at Waitoa. Fonterra management were advised that in relation to the toxin testing, that there was "*no serious risk here, purely precautionary*".

115. On the evening of 18 July 2013, a Fonterra Research and Development Centre staff member met with AgResearch and was told that the colony morphology of the product isolates was more comparable with *C. botulinum* than with *C. sporogenes*. He was also told that AgResearch had difficulty extracting DNA from the product isolates which is a phenomenon more often experienced with *C. botulinum* than *C. sporogenes* isolates.

116. AgResearch's recommendation was that Fonterra should not read too much into the findings at that stage and that AgResearch would continue their analysis over the weekend with the hope that the results would be available towards the end of the weekend.

117. On 19 July 2013, the Fonterra Research and Development Centre queried whether Fonterra had tracked all the WPC80, irrespective of whether it had been used as an ingredient in infant formula (0-6mths) or growing up milk product (12mths^{+}), or whether it was still in the form of WPC80.

118. On 20 July 2013, the preliminary results of the clostridia testing were escalated to senior Fonterra managers and the decision to escalate the event to "critical" would be made once organism species and counts were known.

119. On 22 July, Fonterra Research and Development Centre provided an update from AgResearch stating that the product isolates had tested negative for botulinum neurotoxin genes A, B, E and F (which strains are known to be fatal to humans).

120. Later that day, Fonterra initiated the formation of a Critical Event Team to manage the WPC80 issue. Fonterra believed that there was a very low risk with a "*95% chance it's not botulinum*".

121. On 23 July 2013, the General Manager Quality and Technical emailed other Fonterra managers advising that testing of the WPC80 indicated it was suspicious for a pathogenic strain but that it would not be before the 5 August that they would get confirmation of toxin production. The prevailing advice until then was that it was a non-pathogenic strain. The General Manager Quality and Technical advised that Fonterra needed to establish the whereabouts of product, identify a recall process, determine the decision criteria and provide a heads up to the corporate communications staff. He said that if the tests were positive for toxins, then it would be escalated to a NZ Milk Products or Fonterra Crisis on the basis of reputation, media and possible financial impacts. He did not mention food safety as criteria for escalation. If the tests were negative for toxins then the matter would be de-escalated.

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122. At 4:30pm on 23 July, the matter was formally escalated to a Critical Event.

123. On 24 July, four key work streams were identified for the Critical Event team, one of which included communicating with Fonterra stakeholders. This did not include MPI or AsureQuality.

124. Another work stream was the investigation of the rework process at Hautapu. This work stream established and subsequently reported back to management that the rework undertaken at Hautapu of ciphers GW02 and GW03 was not standard work for the WPC factory. The report also established that the rework process was not documented in the plant Rennet Whey or Cheese WPC HACCP plans and was not within the scope of the Hautapu site RMP. The report concluded that the rework should not have proceeded.

125. On 26 July 2013, the Fonterra Critical Event Team decided, for a number of reasons including the fact that the overall risk for botulinum in dairy powders in New Zealand was considered very low, to put product in Fonterra's control on hold and that customers would not be contacted until test results were confirmed on 5 August 2013. That decision was to be reviewed on the 31st of July 2013.

126. On 28 July 2013, AgResearch commenced the mouse bio assay testing and on 30 July, preliminary results were relayed to Fonterra, indicating some type of toxin, that may or may not be *C. botulinum*, was present and that further testing was necessary to confirm the presence of *C. botulinum*.

127. On 30 July 2013, AgResearch advised Fonterra that one isolate tested had some toxic effect on a mouse but wanted to confirm the results. Further results were expected on 1 August 2013.

128. On 31 July 2013, Fonterra received advice from AgResearch that the mouse bioassay testing had confirmed the presence of *C. botulinum* in the WPC80 ciphers from Hautapu.

129. Fonterra escalated their response with the formation of a Crisis Management Team. A teleconference call took place at 5:15pm that day during which it was suggested that MPI should be advised. It was agreed that because of the seriousness of the issue it should be reported directly to MPI as opposed to the Recognised Agency, AsureQuality.

130. On 1 August 2013, Fonterra began preparation of an Export Non Conformance document for the purposes of reporting to MPI.

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131. At 2:08pm that day, Fonterra emailed key MPI managers requesting a teleconference at 4:30pm that day and were advised that they were unavailable at that time and sought to reschedule for the following day. A MPI manager sought clarification from Fonterra as to the purpose of the teleconference but received no reply.

132. At a meeting of Fonterra senior managers later that day, the issue of reporting the *C. botulinum* contamination to MPI was raised again. The Managing Director, New Zealand Milk Products asked what would happen once it was reported to MPI. He was advised that it would go to Ministers and would then go public. Discussion then took place regarding notifying customers of the issue prior to notifying MPI. The Managing Director, New Zealand Milk Products directed that the key affected clients, Abbott and Danone were to be advised overnight.

133. After the meeting, Fonterra emailed a MPI manager seeking a teleconference at 11:00am the following day. The Managing Director, New Zealand Milk Products contacted the Fonterra Chief Executive, informing him of the issue and the need for a recall. Fonterra then began contacting their major customers.

134. From 12:00am on 2 August 2013, Fonterra began contacting the eight customers they had identified as having received product directly affected by contaminated WPC80 batches, including two infant nutritional customers, three beverage companies and three stock feed companies.

135. On 2 August 2013, Fonterra requested a teleconference meeting with MPI officials for 11:00am to discuss "*SRC*". A MPI official queried as to what was meant by "*SRC*", to which Fonterra replied, "*Sulphite Reducing Clostridia*".

136. In all of the interchanges with MPI, Fonterra neither identified to MPI the specific nature of the issue nor the seriousness.

137. At 10:00am on 2 August, Fonterra convened an internal conference call. The conference call was headed by the Managing Director, New Zealand Milk Products. There was discussion about the feedback received overnight as a result of the affected customers being advised. Instructions were given not to report the issue to MPI until approval was given by the Managing Director, New Zealand Milk Products.

138. After the Fonterra internal conference call, Fonterra was contacted by a MPI official asking why the requested teleconference call had been delayed. The Fonterra representative told him that he was unable to talk until the Managing Director, New Zealand Milk Products had briefed the Chief Executive of Fonterra.

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139. At 10:59am Fonterra advised MPI that the meeting would be delayed once again until midday that day and at 11:30am, the Chair and three members of the Fonterra Board were briefed by the Chief Executive and the Managing Director, New Zealand Milk Products about the issue.

140. At 11:54am, the Managing Director, New Zealand Milk Products gave the approval for his staff to inform MPI of the issue.

141. At 12:00pm the meeting between MPI and Fonterra went ahead and Fonterra informed MPI of the positive result for *C. botulinum* in three batches of WPC80.

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SUMMARY OF OFFENDING

CRN: 14085500849

DAIRY PRODUCT NOT PROCESSED IN ACCORDANCE WITH RISK MANAGEMENT PROGRAMME

142. The defendant is the operator of a RMP registered with MPI, recorded as R007, for the Hautapu site where they manufacture dairy product.

143. The defendant's RMP includes an instruction document entitled "*SYSM19, FTO Change Control, version 4, dated 22 July 2011*".

144. This document must be used for any change that has the potential to introduce a new, or increase an existing, health and safety hazard, or could affect the quality of product manufactured by Fonterra.

145. The document also identifies examples of changes that would require the procedures within to be followed.

146. Some of those examples are:
- Any activity outside of Standard Operating Procedures
- Changes to plant alignment
- Non-standard equipment replacement
- Changes to processing such as a modified process step

147. On 2 and 3 February 2012, WPC80 was manufactured at Hautapu.

148. This product was assigned the cipher references GW02 and GW03.

149. Foreign object contamination occurred during the manufacturing process and approval was sought from MPI to rework the product.

150. Approval was granted with the requirement for a filtration step to be included, so as to remove any foreign object contamination.

151. In order to achieve the approved rework, the defendant determined that they would need to link the SCUF and WPC factories using non-standard equipment. They also identified the need to bypass elements of the standard manufacturing process and planned to use temporary flexi hoses to achieve this.

152. Linking these two plants and the use of non-standard equipment was outside of Standard Operating Procedures.

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153. The defendant was therefore required to follow the procedures contained within "*SYSM19, FTO Change Control, version 4, dated 22 July 2011*".

154. A rework process was developed but was not submitted and approved in accordance with the procedures set out within "*SYSM19, FTO Change Control, version 4, dated 22 July 2011*".

155. The product was reworked between 16 and 23 May 2012 at Hautapu and assigned the cipher references JW17, JW18 and JW22.

156. The use of non-standard equipment, such as temporary flexi-hoses and the seldom used stainless steel pipe, to modify the manufacturing process, likely resulted in increased levels of bacteria known as Sulphite Reducing Clostridia.

157. The increased levels of bacteria indicated a loss of process control and failure to maintain good hygiene practice.

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CRN: 14085500847

EXPORT OF DAIRY PRODUCT NOT MEETING RELEVANT ANIMAL PRODUCT STANDARDS

158. In addition to the facts outlined for CRN 1, the defendant is registered as an exporter of dairy product with MPI.

159. Pursuant to section 51(b)(i) of the Act, it is the duty of every exporter of animal products to export only animal products that meet relevant standards and specifications.

160. Pursuant to Regulation 9 of the Animal Products (Dairy) Regulations 2005, Fonterra is required to ensure that the premises, places, facilities, equipment, and essential services, for which they are responsible, in relation to the processing of dairy product, are operated in a manner that minimises and manages the exposure of dairy product to risk factors.

161. As a consequence of the flawed rework process, ciphers JW17, JW18 and JW22 were exposed to risk factors, as evidenced by the contamination with Sulphite Reducing Clostridia.

162. On or about 26 July 2012, a quantity of cipher JW22 was exported from New Zealand to China through the Port of Auckland.

163. Ciphers JW17 (4,750kgs) and JW18 (8,775kgs) were exported from New Zealand to Australia on 3 October 2012 through the Port of Auckland.

164. A further quantity of JW22 was exported to China on or about 13 November 2012 through the Port of Auckland.

165. In total, 14,475kgs of JW22 were exported to China.

CRN: 14085500848

FAILURE TO NOTIFY REGULATOR OF DAIRY PRODUCT NOT PROCESSED IN ACCORDANCE WITH RISK MANAGEMENT PROGRAMME

166. In addition to the facts outlined for CRN 1, the defendant's RMP document entitled "*Fonterra New Zealand PSRMP Manual*" required that significant concerns about the fitness for intended purpose of dairy product be notified as an exception to the Recognised Agency, AsureQuality, as soon as practicable, but no later than 24 hours.

167. The purpose of the defendant's RMP document entitled "*EXNC11:Managing Product Safety Events*" is to ensure that product safety events are managed in accordance with the approved Product Safety RMP with appropriate reporting to relevant Fonterra personnel and that reports submitted to the Recognised Agency are in a consistent format with all relevant data being included.

168. The document records that if dairy product intended for export has been processed outside a Risk Management Programme or outside the boundaries of the Act, it is a Category B exception and is required to be reported to the Recognised Agency.

169. The WPC80 reworked at Hautapu was principally intended for export. Whilst much of the product was exported to Australia and China in 2012, a quantity of cipher JW17 was used at the Fonterra Waitoa site to manufacture nutritional powder.

170. Between 23 July 2013 and 31 July 2013, in the course of investigating the elevated Sulphite Reducing Clostridia issue associated with ciphers JW17, JW18 and JW22, the defendant developed significant concerns that these ciphers had been processed outside its RMP because the change control process had not been followed. In particular, Fonterra held these significant concerns from 24 July 2013 when Fonterra's Critical Event team established a work-stream to investigate the rework process at Hautapu.

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171. During this period, the defendant did not notify AsureQuality of these concerns, in contravention of its RMP.

CRN: 14085500846

FAILURE TO NOTIFY REGULATOR OF DAIRY PRODUCT NOT FIT FOR INTENDED PURPOSE

172. As a registered exporter of dairy product with MPI, the defendant is under a duty to notify the Director-General of MPI as soon as possible, and in any case not later than 24 hours after the event or first knowledge of the event, in any case where animal products exported by the exporter are not fit, or are no longer fit, for intended purpose.

173. Under section 5 of the Act, animal product will not be fit for intended purpose if, amongst other reasons, it did not have the relevant risk factors managed in accordance with the RMP or it did not meet the relevant animal products standards.

174. Regulation 6 of the Animal Products (Dairy) Regulations 2005 is a relevant animal products standard and provides that dairy product must not contain biological hazards at a level that may be directly or indirectly harmful to humans.

175. The term "Hazard" is defined under the Act to include a biological agent that either "is in or has the potential to be in animal… product" that "leads or could lead to an adverse health effect…".

176. At 12:07pm on 31 July 2013, AgResearch advised Fonterra of positive confirmation of the presence of *C. botulinum* through Mouse Bio-Assay tests.

177. Fonterra was required to notify the Director-General as soon as possible but avoided doing so until midday on 2 August, 48 hours later.

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Impact of offending

178. New Zealand promotes itself as a producer of food that is both fit for purpose and safe, to global markets.

179. New Zealand's reputation and image for quality and safe dairy products in key foreign markets was damaged by the Fonterra WPC80 *C. botulinum* incident. The confidence of those markets in the effectiveness of New Zealand's overall food safety regulatory system was also shaken.

180. Access to a number of foreign markets was impacted and restrictive measures were imposed on dairy imports by a number of New Zealand's trading partners.

181. New Zealand government officials in collaboration with affected New Zealand companies have had to commit time, money and resource to highlight the effectiveness of our food safety regulatory system and to rebuild the trust of foreign markets in New Zealand food exports, in particular dairy.

182. Whilst New Zealand has been able to provide assurance to foreign market regulatory authorities around the effectiveness of our food safety regulatory system and the quality of New Zealand dairy exports, the impact of the Fonterra WPC80 *C. botulinum* incident and consumer fears regarding health risks, means that it might take some time to repair consumer trust to its former levels in New Zealand dairy products.

183. The New Zealand government and many New Zealand companies associated with the manufacture and/or export of dairy products have incurred additional expense in managing the fallout from the Fonterra WPC80 *C. botulinum* incident.

184. It is not possible to estimate the cost to the New Zealand economy and it is even more difficult to put a figure on the financial losses incurred by a number of New Zealand and foreign companies as a consequence of this matter.

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MPI FROM AUGUST13

MPI exploring food safety issue advised by Fonterra this afternoon

Send this release to more contacts

Media release

SENT 03 Aug 2013 12:12 AM (New Zealand Standard Time)

FROM [redacted] *[s.9(2)(a)]*

SUBJECT **MPI exploring food safety issue advised by Fonterra Friday afternoon**

EMAIL BODY

MPI exploring food safety issue advised by Fonterra this afternoon

The Ministry for Primary Industries is working closely with Fonterra on a food safety issue with a range of products manufactured from whey protein concentrate produced at a single New Zealand manufacturing site in May 2012.

The whey concentrate appears to contain a strain of *Clostridium botulinum*, which can cause botulism.

"Our focus is on ensuring that there are no contaminated products on the New Zealand market. We are working with Fonterra and its customers, to identify if there are any products posing a risk," MPI Acting Director General Scott Gallacher said.

"At present, we are continuing to verify information provided to us, and we will update further if any products are identified. Products on the market will be recalled if they are found to contain the contaminated protein."

Mr Gallacher said the government had advised the appropriate regulatory authorities in overseas markets of the situation.

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"We are also working with Fonterra to establish what has happened, how it happened, and what can be done to ensure it does not happen again."

Fonterra informed MPI of the contamination Friday afternoon.

Fonterra has advised the whey concentrate is used in a range of products including infant formula, growing up milk powder and sports drinks. Dairy products such as fresh milk, yoghurt, cheese, spreads and UHT milk products are not affected.

For further information please contact: MPI media phone 029 894 0328.

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Ministry for Primary Industries
Manatū Ahu Matua

DIRECTOR-GENERAL STATEMENT UNDER THE ANIMAL PRODUCTS ACT 1999 AND THE FOOD ACT 1981

Issued at 2.45pm 3 August 2013

At 12.35pm on Friday 2 August 2013, Fonterra notified the Ministry for Primary Industries of a food safety issue involving three batches of whey protein concentrate (WPC80) produced at a single New Zealand manufacturing site in May 2012.

At approximately 7.00pm, we were advised that products manufactured by Nutricia contained these batches of whey protein and were present in New Zealand.

The safety issue relates to contamination of some batches of whey protein with bacteria known as Clostridium botulinum which can cause illness.

The Acting Director-General, Scott Gallacher, for the purpose of section 37 of the Food Act 1981 and section 84 of the Animal Products Act 1999, advises that the following products may contain these batches of protein.

Nutricia Karicare Follow-on formula products for children from 6 months old.

These are the only products we have been advised of that may contain the whey protein concentrate and have food safety concerns.

I have been informed that the specific batches of follow-on formula that may contain this whey protein are not currently in any New Zealand retail store. We are still in the process of verifying the location of all products that may contain these batches of whey protein. I am taking a cautionary approach and, until this verification process has been completed, I advise parents and caregivers with infants consuming Nutricia Karicare Follow-on formula products, which is specifically marketed for infants over 6 months, to use infant formula for children aged 0-6 months, ready-made liquid infant formulas, or alternative brands.

I will provide further updates as soon as more information becomes available.

If you have any concerns about the consumption of these products, please call the following numbers.
If your concern is for health reasons, please call Healthline on 0800 611 116 or Plunketline 0800 933 922 for advice.
If your concern is about other aspects of these products, please call the Ministry for Primary Industries' consumer helpline on 0800 693 721.

Nutricia Karicare Follow-on formula products are sold through retail outlets such as supermarkets mainly in 900g tins.

Scott Gallacher
Acting Director-General
Ministry for Primary Industries

Declassified for release 6 December 2014

Pastoral House, 25 The Terrace, PO Box 2526
Wellington 6140, New Zealand
Telephone: 0800 00 83 33, Facsimile: +64-4-894 0300
www.mpi.govt.nz

MPI FROM AUGUST13

Details announced of one product potentially affected by whey protein contamination - Press conference at MPI at 4.30pm

Send this release to more contacts

Media release

SENT **03 Aug 2013 3:30 PM (New Zealand Standard Time)**

FROM **Ministry for Primary Industries <mmrelease@isentia.com> on behalf of media.enquiries@mpi.govt.nz**

SUBJECT **Details announced of one product potentially affected by whey protein contamination - Press conference at MPI at 4.30pm**

ATTACHMENTS DGStatement.pdf (432.51kb)

EMAIL BODY

Declassified for Release 9 December 2014

Details announced of one product potentially affected by whey protein contamination - Press conference at MPI at 4.30pm

Details announced of one product potentially affected by whey protein contamination

The Ministry for Primary Industries today announced the details of one product in New Zealand potentially containing contaminated whey protein from Fonterra's Hautapu manufacturing facility.

"Since we were informed by Fonterra yesterday afternoon that three batches of concentrated whey protein contain *Clostridium botulinum,* MPI has been working intensively to identify what, if any, products on the New Zealand market may be contaminated," Acting Director General Scott Gallacher said.

"The batches of whey product have been on sold and mixed with other ingredients to form 870 tonnes of consumer products sold in a variety of markets. I am now publishing a statement under the Animal Products Act 1999 and Food Act 1981 identifying the following products in New Zealand:

Nutricia Karicare follow-on formula products for children from 6 months old.

"MPI has been advised that in the case of the Nutricia Karicare, five batches of follow-on formula were manufactured using the contaminated whey protein," Mr Gallacher said.

"Nutricia has advised that three of those batches are in a warehouse in Auckland, one is on a ship, and the other is in storage in Australia. Nutricia has advised it has locked down those batches, and they will not be sold on the market.

"MPI is still in the process of verifying this information, and today sent a team to Nutricia's Auckland warehouses," Mr Gallacher said.

"Until this process is completed, I advise parents and caregivers with infants consuming Nutricia Karicare follow on formula products from 6 months, to use infant formula for children aged 0-6 months, ready-made formulas or alternative brands."

Mr Gallacher said the government had last night advised regulatory authorities in markets where affected product had gone.

"MPI and the Ministry of Foreign Affairs and Trade are continuing to work with overseas regulators to provide information as it becomes available. Clearly, a number of markets are very concerned about this situation."

Formal statement from the Director-General attached

MPI advisory
MPI will hold a media conference at its Pastoral House, 25 The Terrace, today at 4.30pm.
Media contact: MPI media phone 029 894 0328

Consumer support

If you have any health concerns, please call Healthline on 0800 611 116 or Plunketline for advice.

If you have questions about a product, please call MPI's consumer helpline on 0800 693 721.

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Follow MPI on Twitter **@MPI_NZ**

For noting: The Ministry of Health and the Ministry for Primary Industries support and encourage parents to breastfeed their infants until a year of age, and supplement their diet with appropriate solids from around 6 months of age. Infants under the age of one year who are not breastfed should be fed with an appropriate infant formula, and should not be fed with regular cow's milk.

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MPI FROM AUGUST13

UPDATE – Infant milk formula - precautionary advice updated

Send this release to more contacts

Media release

SENT 04 Aug 2013 12:45 PM (New Zealand Standard Time)

FROM [redacted] *[s.9(2)(a)]*

SUBJECT UPDATE – Infant milk formula - precautionary advice updated

EMAIL BODY

UPDATE – Infant milk formula - precautionary advice updated

The Ministry for Primary Industries has received further information from Fonterra relating to batches of infant formula base powder containing whey protein that may have been contaminated with Clostridium botulinum.

The infant formula base was supplied to Nutricia from Fonterra and it is likely to have been manufactured into infant formulas, some of which may be on sale.
As a result Nutricia has instigated a precautionary recall in New Zealand of the following products:

Karicare Infant Formula Stage 1 (0–6 months) in NEW ZEALAND ONLY with batch numbers 3169 and 3170 (use by 17 06 2016 and 18 06 2016). The batch number and use by date can be found on the base of the tin.

Karicare Gold+ Follow On Formula Stage 2 (6–12 months) in NEW ZEALAND ONLY with batch number D3183 (use by 31 12 2014). The batch number and use by date can be found on the base of the tin.

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For more information, see
http://www.nutriciababy.co.nz/main/aboutus/news.html.

Please note, in view of additional advice from Nutricia this morning, the earlier formal advice from the Director-General of MPI will be updated today.

MPI is working to establish whether any other specific products and batches may contain the whey protein, and the location of any affected batches. MPI and the Ministry of Foreign Affairs and Trade are working with regulatory authorities in the relevant international markets to provide them with new information in relation to this development as soon as possible.

Media contact: MPI media phone 029 894 0328.

More information will be published on the MPI website www.mpi.govt.co.nz as soon as it becomes available.

Anyone with any health concerns is urged to contact their local health professional or call Healthline on 0800 611 116 or Plunketline on 0800 933 922 for advice.

Consumer support

If you have any health concerns, please call Healthline on 0800 611 116 or Plunketline on 0800 933 922 for advice.

If you have questions about a product, please call MPI's consumer helpline on 0800 693 721.

Follow MPI on Twitter **@MPI_NZ**

For noting: The Ministry of Health and the Ministry for Primary Industries support and encourage parents to breastfeed their infants until a year of age, and supplement their diet with appropriate solids from around 6 months of age. Infants under the age of one year who are not breastfed should be fed with an appropriate infant formula, and should not be fed with regular cow's milk.

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REVISED DIRECTOR-GENERAL STATEMENT UNDER THE ANIMAL PRODUCTS ACT 1999 AND THE FOOD ACT 1981

4 August 2013 8.30pm – Statement 2
This statement replaces the Director-General statement issued at 2.45pm 3 August 2013

Further to my statement issued at 2.45pm yesterday afternoon (Saturday, 3 August 2013), at 6.00pm yesterday evening Fonterra notified the Ministry for Primary Industries of new information relating to batches of infant formula base powder manufactured from whey protein concentrate (WPC80) contaminated with the bacteria known as Clostridium botulinum, which can cause illness.

The infant formula base powder was supplied to Nutricia and is likely to have been manufactured into infant formulas.

On 4 August 2013 Nutricia issued a product recall notice, available at http://www.nutriciababy.co.nz/main/aboutus/news.html That notice advised that Nutricia has instigated a "precautionary recall in New Zealand" of the following products:

Karicare Infant Formula Stage 1 (0-6 months) in NEW ZEALAND ONLY with batch numbers 3169 and 3170 (use by 17.06.2016 and 18.06.2016). The batch number and use-by date can be found on the base of the tin.

Karicare Gold+ Follow On Formula Stage 2 (6–12 months) in NEW ZEALAND ONLY with batch number D3183 (use by 31.12.2014). The batch number and use by date can be found on the base of the tin

As of today, Nutricia has been unable to identify to the Ministry for Primary Industries all the products that may have been contaminated through incorporation of this ingredient, and the locations of potentially contaminated products. We are still in the process of verifying which products and which batches contain the whey protein, and their location. As a result of this, I have decided to expand my precautionary advice.

As Acting Director-General, I, Scott Gallacher, for the purpose of section 37 of the Food Act 1981 and section 84 of the Animal Products Act 1999, advise that my statement of 3 August 2013 issued at 2.45pm is superseded by this statement.

I now advise that the following Nutricia Karicare products cannot be ruled out as containing the contaminated batches of whey protein. I therefore recommend that these products are not consumed and alternative brands used.

Nutricia Karicare Stage 1 Infant Formula for babies from birth
Nutricia Karicare Stage 2 Follow-on formula products for children from 6 months old

In addition to the particular information made available by Nutricia at http://www.nutriciababy.co.nz/main/aboutus/news.html to which consumers should refer, I have not been able to establish which specific batches of these products may contain this whey protein, or whether affected batches are currently in any New Zealand retail stores.

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Pastoral House, 25 The Terrace, PO Box 2526
Wellington 6140, New Zealand
Telephone: 0800 00 83 33, Facsimile: +64-4-894 0300
www.mpi.govt.nz

I will provide further updates as soon as more information becomes available.

If you have any concerns about the consumption of these products, please call the following numbers.

If your concern is for health reasons, please call Healthline on 0800 611 116 or Plunketline 0800 933 922 for advice.

If your concern is about other aspects of these products, please call the Ministry for Primary Industries' consumer helpline on 0800 693 721.

Nutricia Karicare products are sold through retail outlets such as supermarkets, mainly in 900g tins.

Scott Gallacher
Acting Director-General
Ministry for Primary Industries

Declassified for Release 9 December 2014

MPI FROM AUGUST13

UPDATE – Karicare formula – further precautionary advice

Send this release to more contacts

Media release

SENT 04 Aug 2013 9:24 PM (New Zealand Standard Time)

FROM [redacted] *[s.9(2)(a)]*

SUBJECT UPDATE – Karicare formula – further precautionary advice

ATTACHMENTS Director General Statement 2 Aug 4.pdf (664.57kb)

EMAIL BODY

Declassified for Release 9 December 2014

UPDATE – Karicare formula – further precautionary advice

The Ministry for Primary Industries has further expanded its precautionary advice about Karicare infant formula products.

Acting Director-General Scott Gallacher says the Ministry now recommends parents and caregivers avoid feeding two products from the Karicare range to their infants until freedom from contamination with the bacterium *Clostridium botulinum* can be confirmed.

"As of this evening, MPI has not been able to fully trace through Nutricia's supply chain which specific batches of its products may contain contaminated whey protein, and which don't, and whether affected batches are in New Zealand stores.

"It may be over the coming days, the company can provide this information which would allow me to be assured of the safety of these products.

"But in the meantime, I have decided to expand my precautionary advice and have issued another formal Director-General Statement under the Animal Products Act 1999 and the Food Act 1981," Mr Gallacher says.

In this statement, MPI now advises that it cannot rule out the following Nutricia Karicare products as potentially contaminated and recommends they are not fed to children until further notice.

Nutricia Karicare Infant Formula Stage 1 for babies from birth

Nutricia Karicare Stage 2 Follow-on formula for children from six months old

MPI now recommends parents and caregivers use alternative products until further notice.

Please note, this evening's Director-General Statement supersedes earlier advice from MPI at 12.30pm today. Advice may change again, once further information is available.

"Until we get more certainty around those Karicare products outlined above, I am asking parents not to use them and use an alternative product in the meantime," Mr Gallacher said.

"MPI is working closely with industry and the Ministry of Health to ensure there are sufficient alternative infant formula products on the market, and we will be closely monitoring supply until this matter is resolved."

Further information on the wider issue
Currently, there is no information to suggest any other infant formula products on the market in New Zealand are affected.

MPI and the Ministry of Foreign Affairs and Trade are working with regulatory authorities in the relevant international markets to provide them with new information in relation to this development as soon as possible.

Media contact: MPI media phone 029 894 0328.

More information will be published on the MPI website www.mpi.govt.co.nz as soon as it becomes available.

Consumer support

If you have any health concerns, please call Healthline on 0800 611 116 or Plunketline on 0800 933 922 for advice.

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If you have questions about a product, please call MPI's consumer helpline on 0800 693 721.

Follow MPI on Twitter **@MPI_NZ**

Note: The Ministry of Health and the Ministry for Primary Industries support and encourage parents to breastfeed their infants until a year of age, and supplement their diet with appropriate solids from around 6 months of age. Infants under the age of one year who are not breastfed should be fed with an appropriate infant formula, and should not be fed with regular cow's milk.

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MPI FROM AUGUST13

MPI welcomes Nutricia recall of two infant formula products

Send this release to more contacts

Media release

SENT **05 Aug 2013 10:13 PM (New Zealand Standard Time)**

FROM **Ministry for Primary Industries <mmrelease@isentia.com> on behalf of media.enquiries@mpi.govt.nz**

SUBJECT **MPI welcomes Nutricia recall of two infant formula products**

EMAIL BODY

MPI welcomes Nutricia recall of two infant formula products

The Ministry for Primary Industries (MPI) welcomes Nutricia's recall of two lines of infant formula that may have been contaminated and is encouraging consumers to return any product they have or dispose of it.

MPI Acting Director-General Scott Gallacher says the health of consumers is of the utmost importance and it's critical that these products are recalled until contamination by *Clostridium botulinum* can be ruled out.

The recalled products are:

- Karicare Stage 1 New Baby Infant Formula (from birth) – all batches
- Karicare Gold+ Stage 2 Follow On Formula (from six months) – all batches

The recall does not affect any other Nutricia Karicare products.

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Clostridium botulinum is a food poisoning bacteria that can cause infant botulism. Contamination potentially occurred when whey protein concentrate was processed in a dirty pipe at a Fonterra plant.

Yesterday MPI issued precautionary advice not to use some of Nutricia's products because all potentially contaminated products made from the whey protein concentrate had not yet been traced.

Following further information from Fonterra today, Nutricia has decided to conduct a precautionary recall of two of its products until all potentially affected batches have been traced.

Scott Gallacher says Nutricia's approach is consistent with MPI's precautionary advice.

"It's critical that any products that are a potential risk to public health are removed until we can be assured they are safe. At this time we don't know which products are potentially contaminated and because of that uncertainty a recall is prudent.

"It is important that people do not consume any of the recalled products they may have purchased. We are urging people to check their cupboards and if people do have any of the recalled products they should return them to where they bought them from for a full refund or dispose of them via their normal household rubbish."

Mr Gallacher says that MPI is working closely with Fonterra and Nutricia to trace all potentially contaminated products as quickly as possible.

"We are continuing to review all of the information as it comes to hand and if anything changes, we will provide an update as soon as one becomes available."

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Media contact:
MPI media phone 029 894 0328 or media.enquiries@mpi.govt.nz

Consumer support
If people have health concerns, they can ring Healthline on 0800 611 116 or Plunketline on 0800 933922 for advice.

People can telephone MPI's consumer helpline on 0800 693 721 if they have questions about a product.

Note: The Ministry of Health and the Ministry for Primary Industries support and encourage parents to breastfeed their infants until a year of age, and supplement their diet with appropriate solids from around six months of age. Infants under the age of one year who are not breastfed should be fed with an

appropriate infant formula, and should not be fed with regular cow's milk.

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MPI FROM AUGUST13

MEDIA ADVISORY – MPI PRESS CONFERENCE AT 11-15 AM

Send this release to more contacts

Media release

SENT 05 Aug 2013 10:17 AM (New Zealand Standard Time)

FROM [redacted] *[s.9(2)(a)]*

SUBJECT MEDIA ADVISORY – MPI PRESS CONFERENCE AT 11-15 AM TODAY

EMAIL BODY

MEDIA ADVISORY – MPI PRESS CONFERENCE AT 11-15 AM

The Ministry for Primary Industries Acting Director General, Scott Gallacher will be holding a press conference today at 11.15am to discuss the food safety implications around the current whey protein contamination issue.

The press conference is to be held at Pastoral House, 25 The Terrace.

Please RSVP by calling the MPI media phone on 029 894 0328 or by email to enquiries@mpi.govt.nz

ENDS

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Ministry for Primary Industries
Manatū Ahu Matua

REVISED DIRECTOR-GENERAL STATEMENT UNDER THE ANIMAL PRODUCTS ACT 1999 AND THE FOOD ACT 1981

6 August 2013 3pm – Statement 3
This statement updates the Director-General statement issued at 7.30pm 4 August 2013

Further to my statement issued at 7.30pm on Sunday 4 August 2013, Nutricia has now issued a recall for **all** batches of its Karicare Stage 1 Infant Formula 1 (0-6 months) and Karicare Gold+ Stage 2 Follow On Formula (6-12 months) products. Information about this recall may be found at http://www.nutriciababy.co.nz/main/aboutus/news.html

The possibility of these products having been manufactured with whey protein concentrate (WPC80) contaminated with the bacteria known as Clostridium botulinum, which can cause illness, cannot be ruled out.

As Acting Director-General, I, Scott Gallacher, for the purpose of section 37 of the Food Act 1981 and section 84 of the Animal Products Act 1999, advise that:

- **my statement of 4 August 2013 issued at 7.30pm is updated by this statement; and**
- **the following Nutricia products should not be consumed**

Nutricia Karicare Stage 1 Infant Formula (0-6 months), all batches

Nutricia Karicare Gold+ Stage 2 Follow on formula products for children from 6 months old, all batches

Consumers should return these products to their retailer, and use alternative brands.

We are still in the process of verifying which products and which batches contain the whey protein, and their location. Until this process is complete, consumers are advised to stop using the above products.

I will provide further updates as soon as more information becomes available.

If you have any concerns about the consumption of these products, please call the following numbers.

If your concern is for health reasons, please call Healthline on 0800 611 116 or Plunketline 0800 933 922 for advice.

If your concern is about other aspects of these products, please call the Ministry for Primary Industries' consumer helpline on 0800 693 721.

Nutricia Karicare products are sold through retail outlets such as supermarkets, in 900g tins and single-serve sachets.

Scott Gallacher
Acting Director-General
Ministry for Primary Industries

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Pastoral House, 25 The Terrace, PO Box 2526
Wellington 6140, New Zealand
Telephone: 0800 00 83 33, Facsimile: +64-4-894 0300
www.mpi.govt.nz

MPI FROM AUGUST13

MEDIA ADVISORY – MPI PRESS CONFERENCE AT 3.30PM

Send this release to more contacts

Media release

SENT **07 Aug 2013 11:50 AM (New Zealand Standard Time)**

FROM **Ministry for Primary Industries <mmrelease@isentia.com> on behalf of media.enquiries@mpi.govt.nz**

SUBJECT **MEDIA ADVISORY – MPI PRESS CONFERENCE AT 3.30PM**

EMAIL BODY

MEDIA ADVISORY – MPI PRESS CONFERENCE AT 3.30PM

Good morning

The Ministry for Primary Industries Acting Director General, Scott Gallacher will be holding a press conference today at 3.30pm to discuss the current whey protein contamination issue.

The press conference is to be held at Pastoral House, 25 The Terrace.

Please RSVP by calling the MPI media phone on 029 894 0328 or by email to: media.enquiries@mpi.govt.nz

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MPI FROM AUGUST13

MPI corrects error on Fonterra's advice to AsureQuality

Send this release to more contacts

Media release

SENT 07 Aug 2013 5:56 PM (New Zealand Standard Time)

FROM [redacted] *[s.9(2)(a)]*

SUBJECT MPI corrects error on Fonterra's advice to AsureQuality

EMAIL BODY

MPI corrects error on Fonterra's advice to AsureQuality

AsureQuality was not informed of the contamination of Fonterra's whey protein concentrate on Thursday 1 August, as stated this afternoon by the Ministry for Primary Industries.

"I have now confirmed with AsureQuality and Fonterra that AsureQuality was informed after MPI was informed of the issue on Friday 2 August. I am concerned that the statement I made this afternoon, saying AsureQuality were informed on Thursday, was incorrect and I wish to correct it," MPI acting director general Scott Gallacher said.

"The error was because I misinterpreted information provided to me about what should have occurred, as opposed to what did occur. Under Fonterra's Risk Management Plan, it is required to inform AsureQuality and MPI within 24 hours of test results showing a potential food safety issue.

"I am advised that this didn't occur in this case. Fonterra notified us on Friday 2 August before any contact with AsureQuality," Mr Gallacher said.

"My misunderstanding resulted in the wrong information being provided to the Minister for Food Safety and subsequently to the Prime Minister. I apologise for the confusion this may have caused."

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Media Contact:
MPI media phone 029 894 0328

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Ministry for Primary Industries
Manatū Ahu Matua

REVISED DIRECTOR-GENERAL STATEMENT UNDER THE

ANIMAL PRODUCTS ACT 1999 AND THE FOOD ACT 1981

12 August 2013, 12:00 pm - Statement 4
This statement updates the Director-General statement issued at 3pm 6 August 2013.

Further to my statement issued at 3pm on Tuesday 6 August 2013, Nutricia has now issued a recall for Karicare Stage 1 Infant Formula (0-6 months) and Karicare Gold+ Stage 2 Follow-on Formula (from 6 months) products produced between 21 May 2013 and 2 August 2013 inclusive. Information about this recall may be found at http://www.nutriciababy.co.nz/main/aboutus/news.html

There is a possibility that these products have been produced with whey protein concentrate (WPC80) potentially contaminated with the bacteria known as Clostridium botulinum, which can cause illness. Nutricia has now identified, and the Ministry for Primary Industries has verified to my satisfaction, the production dates between which Karicare Stage 1 Infant Formula (0-6 months) and Karicare Gold+ Stage 2 Follow-on Formula (from 6 months) products may have been affected.

As Acting Director-General, I, Scott Gallacher, for the purpose of section 37 of the Food Act 1981 and section 84 of the Animal Products Act 1999, advise that:

- **my statement of 6 August 2013 issued at 3pm is updated by this statement; and**
- **the following Nutricia products should not be consumed:**

  Nutricia Karicare Stage 1 Infant Formula (0-6 months), produced between 21 May 2013 and 2 August 2013 inclusive.

  Nutricia Karicare Gold+ Stage 2 Follow-on Formula (from 6 months) produced between 21 May 2013 and 2 August 2013 inclusive.

Consumers should return these products to their retailer.

Explanation

This statement updates the one issued by me on 6 August 2013.

Nutricia has now issued a recall for Karicare Stage 1 Infant Formula (0-6 months) 900g cans and Karicare Gold+ Stage 2 Follow-on Formula (from 6 months) 900g cans produced between 21 May 2013 and 2 August 2013 inclusive. That formula may have been produced with whey protein concentrate potentially contaminated with the bacteria Clostridium botulinum, which can cause illness. Information about this recall may be found at http://www.nutriciababy.co.nz/main/aboutus/news.html.

Karicare Infant Stage 1 Formula (0-6 months) and Karicare Gold+ Stage 2 Follow-on Formula (from 6 months) products produced before 21 May 2013 are unaffected by the potential contamination.

Karicare Infant Stage 1 Formula (0-6 months) and Karicare Gold+ Stage 2 Follow-on Formula (from 6 months) products produced after 2 August 2013 are unaffected by the potential contamination.

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If you have any concerns about the consumption of these products, please call the following numbers.

If your concern is for health reasons, please call Healthline on 0800 611 116 or Plunketline 0800 933 922 for advice.

If your concern is about other aspects of these products, please call the Ministry for Primary Industries' consumer helpline on 0800 693 721.

Scott Gallacher
Acting Director-General

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MPI FROM AUGUST13

MPI commences compliance investigation into whey contamination incident

Send this release to more contacts

Media release

SENT **12 Aug 2013 12:50 PM (New Zealand Standard Time)**

FROM **Ministry for Primary Industries <mmrelease@isentia.com> on behalf of media.enquiries@mpi.govt.nz**

SUBJECT **MPI commences compliance investigation into whey contamination incident**

EMAIL BODY

MPI commences compliance investigation into whey contamination incident

The Ministry for Primary Industries (MPI) has commenced a compliance investigation into the potential contamination of three batches of Fonterra's whey protein concentrate.

"I have said a number of times since MPI was first notified on Friday August 2 of this issue, that we have a number of questions about it, including when relevant parties were informed, and when they should have been informed," MPI acting Director-General Scott Gallacher said.

"This compliance investigation will determine whether regulatory requirements under the Food Act and the Animal Products Act were met by all parties involved, or whether any parties may have committed any breaches or offences.

"The investigation will include decisions made by all parties and their response, including during production of the whey protein concentrate, and from when anomalies in testing initially arose. It will be led by MPI's Director of Compliance, and will involve upwards of 20 people," Mr Gallacher said.

"MPI will continue to provide operational updates on other matters relating to

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the potential contamination of whey protein concentrate, but it cannot comment any further on the compliance investigation until it is completed. It is likely to take three to six months," Mr Gallacher said.

Maximum penalties for breaching regulations under the Food and Animal Products Acts range from $100,000 to $500,000, and/or up to 12 months imprisonment, depending on the nature of the offence.

MPI will also undertake a formal debrief process on its own response to the incident, to identify any lessons learned.

Media Contact: Call MPI's media phone on 029 894 0328 or email media.enquiries@mpi.govt.nz

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MPI FROM AUGUST13

Nutricia Karicare product recall applying to specific dates

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Media release

SENT 12 Aug 2013 2:22 PM (New Zealand Standard Time)

FROM [redacted] *[s.9(2)(a)]*

SUBJECT **Nutricia Karicare product recall applying to specific dates**

ATTACHMENTS Production date image.docx (20.38kb)
img-812114523-0001.pdf (548.34kb)

EMAIL BODY

Nutricia Karicare product recall applying to specific dates

Media Release
12 August 2013

Nutricia Karicare product recall applying to specific dates

The Acting Director-General of the Ministry for Primary Industries (MPI) has today issued a revised Statement under the Food and Animal Products Acts regarding the precautionary recall in New Zealand of two Nutricia Karicare infant formulas.

The revised statement shows that the precautionary recall now only applies to 900g cans of Nutricia Karicare Stage 1 Infant Formula (0-6 months) and Nutricia Karicare Gold+ Stage 2 Follow-on Formula (from 6 months) produced between **21 May 2013 and 2 August 2013 inclusive.**

Acting Director-General Scott Gallacher says this means batches of those products manufactured outside of those dates are now not affected by the precautionary recall.

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"If people still have 900g cans of Nutricia Karicare Stage 1 Infant Formula (0-6 months) and Nutricia Karicare Gold+ Stage 2 Follow-on Formula (from 6 months) at home, they need to check the production date on the base of the tin." (Image is attached to this press release)

"If the production date is between 21.05.2013 and 02.08.2013, that infant formula is still subject to a precautionary recall within New Zealand and has the potential of being contaminated by the bacteria *Clostridium botulinum*. It should not be consumed and we recommend it be returned to the place you purchased it from," Mr Gallacher says.

"Please note this only applies to the two products listed above. No other Nutricia Karicare products are being recalled. All 29.6g sachets and 32.8g sticks of Karicare infant and follow on formulas, regardless of production date, are now also excluded from the precautionary recall, and can be consumed."

Mr Gallacher says working closely with its government and industry partners, MPI has been able to identify and trace all potentially affected Nutricia products and narrow down the scope of the potentially affected Karicare formulas. MPI continues to notify and work with all markets identified as having received any potentially affected product.

"As always, the health and wellbeing of consumers is our top priority. We now know, on the basis of information from Fonterra and Nutricia, which we have now verified, which Nutricia products were manufactured using the potentially contaminated whey protein concentrate. Batches of the two affected Karicare infant formulas not manufactured within those specific dates can now go back on the shelves.

"Nutricia has given us full confidence that the only products going back on supermarket shelves from today are manufactured outside of those dates," Mr Gallacher says.

Anyone wanting more information on which products are subject to recall and how to check production dates should call Nutricia's Customer Careline on 0800 258 268.

Anyone with health concerns related to this issue should contact **Healthline on 0800 611 116** or **Plunketline on 0800 933 922.**

For more information, please contact the MPI Mediaphone on 029 894 0328.

The Acting Director-General's statement is attached.

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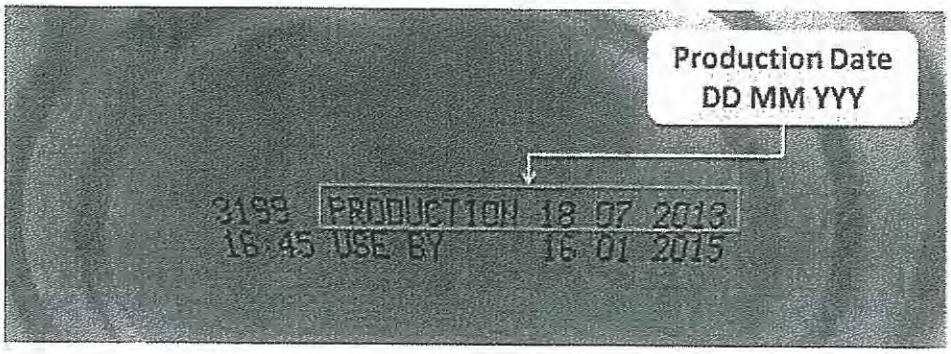

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MPI FROM AUGUST13

MPI exploring interim measures for dairy sector

Send this release to more contacts

Media release

SENT 20 Aug 2013 2:28 PM (New Zealand Standard Time)

FROM [redacted] *[s.9(2)(a)]*

SUBJECT MPI exploring interim measures for dairy sector

EMAIL BODY

Declassified for Release 9 December 2014

MPI exploring interim measures for dairy sector

The Ministry for Primary Industries (MPI) is exploring interim measures to strengthen consumer assurances around New Zealand's dairy production.

"Our dairy sector trades on New Zealand's reputation, and that reputation is built on the strong assurances our regulatory system provides, and the quality of New Zealand's products," MPI acting director-general Scott Gallacher said.

"The reality is the convergence of events over the last six months has sparked debate about some elements of our food system. We need to respond to that."

"Ministers have established an inquiry process that will yield long term recommendations for how our food safety system in relation to dairy can be further improved. In the meantime, MPI is considering interim measures."

MPI will:

- Lift the regulatory presence in manufacturing premises;
- Lift the level of and nature of testing across dairy production to improve the identification of non-compliance issues;

Run tracing simulations to test the capability of the industry to rapidly track and trace product through their supply chains;

Increase reviews of the risk management plans dairy producers have for manufacturing facilities.

"At the same time, MPI is also increasing the level of analysis it routinely undertakes of regulatory non-compliance across the dairy sector. We will be looking for trends that will help us identify whether there are any further interim measures that may be required," Mr Gallacher said.

"In any food system, there are issues that arise from time to time. New Zealand's food system is no different. Our testing regimes are thorough and robust when compared with the world's leading dairy producing nations. And when issues do arise, we deal with them promptly and openly with our trading partners. If there is a food safety risk, we notify the public, and from time-to-time we also notify about broader non-compliance issues, such as the nitrate issue.

"Nevertheless, there is always room for improvement. I am confident these interim measures will help to reinforce consumer trust and confidence in our dairy products," Mr Gallacher said.

Media Contact: 029 894 0328

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MPI FROM AUGUST13

Media Advisory - Ministry for Primary Industries

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Media release

SENT **28 Aug 2013 1:34 PM (New Zealand Standard Time)**

FROM [redacted] *[s.9(2)(a)]*

SUBJECT **Media Advisory - Ministry for Primary Industries**

EMAIL BODY

Media Advisory - Ministry for Primary Industries

The Ministry for Primary Industries will be holding a media briefing today at 4PM to release a report which traces the status of whey protein affected by recent recalls. Results of tests of whey protein will also be made available.

The briefing will be held at Pastoral House, 25 The Terrace, in Wellington.

Please RSVP by calling the MPI media phone on 029 894 0328, or by email to media.enquires@mpi.govt.nz

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MPI FROM AUGUST13

Negative WPC tests confirm no risk to public

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Media release

SENT **28 Aug 2013 4:05 PM (New Zealand Standard Time)**

FROM **Ministry for Primary Industries <mmrelease@isentia.com> on behalf of media.enquiries@mpi.govt.nz**

SUBJECT **Negative WPC tests confirm no risk to public**

EMAIL BODY

Negative WPC tests confirm no risk to public

The Ministry for Primary Industries has received results confirming that the bacteria found in the whey protein concentrate (WPC) manufactured by Fonterra is not *Clostridium botulinum*. The organism is confirmed as *Clostridium sporogenes*. It is therefore not capable of producing botulism causing toxins.

There are no known food safety issues associated with *Clostridium sporogenes*, although at elevated levels certain strains may be associated with food spoilage.

"When MPI received information from Fonterra on 2 August that it had detected *Clostridium botulinum* in some of its products, I immediately adopted a precautionary approach to protect consumers both here and overseas," acting director-general Scott Gallacher said today.
"We needed to act on what we knew at that time. The information we had then said there was a food safety risk to consumers and we moved quickly to address it."

At the same time, MPI commissioned a further array of tests to validate the initial results Fonterra reported. A total of 195 tests using a range of technologies have been conducted in laboratories here and in the USA. Results from the most definitive of these tests arrived over night, and were assessed with appropriate technical advice on hand today.

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"We sought additional testing at both local and international laboratories, seeking the most robust results we could get. Scientists used a range of methods – all came back negative for *Clostridium botulinum*," said Mr. Gallacher.

"MPI has today informed overseas regulators of these results, and we will be providing them with a full diagnostic report shortly. I will also be revoking my Director-General's statement, issued under the Food and Animal Products Acts, about this issue."

A failure of hygiene during processing remains a concern for customers incorporating WPC into their products. However, the concern primarily relates to quality and the potential for spoilage when used in foods that support growth of *Clostridium sporogenes* from spores.

For media inquiries please call:
MPI media line on 029 894 0328
Or by email on media.enquiries@mpi.govt.nz
Follow MPI on Twitter **@MPI_NZ**

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MPI FROM AUGUST13

Ministry for Primary Industries releases WPC Tracing and Verification report

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Media release

SENT **28 Aug 2013 4:06 PM (New Zealand Standard Time)**

FROM **Ministry for Primary Industries <mmrelease@isentia.com> on behalf of media.enquiries@mpi.govt.nz**

SUBJECT **Ministry for Primary Industries releases WPC Tracing and Verification report**

EMAIL BODY

Ministry for Primary Industries releases WPC Tracing and Verification report

The Ministry for Primary Industries (MPI) has released a report detailing the tracing and verification of potentially contaminated whey protein concentrate (WPC).

The report details the approach MPI, along with its partners, has adopted to locate all potentially affected WPC. All potentially affected product has been accounted for.

Fonterra advised MPI on 2 August that batches of its whey protein concentrate may have been potentially contaminated with the bacterium *Clostridium botulinum*.

"In conducting and releasing the report, we have taken an open and transparent approach. The report shows the tracing process undertaken." said MPI Acting Director-General Scott Gallacher. "This means companies are named, transactions between them are identified, and some information about their processes and equipment is included."

"The health and wellbeing of consumers is our priority and warrants this level of disclosure and our cautionary approach," Mr Gallacher said.

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The tracing and verification report outlines:

- The initiating event at Fonterra Hautapu
- The distribution of potentially contaminated WPC to specific sites and processors
- The incorporation of potentially contaminated WPC into other products, and their distribution
- The methods MPI used to verify information on the distribution and location of the potentially affected product
- The recalls initiated and their management
- The tracing of exports, and notification of overseas authorities

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The report addresses the full range of information MPI received from Fonterra over the course of the last few weeks, including where Fonterra had identified additional potentially affected product MPI is satisfied that all product affected by the potential contamination incident has either been recalled, assessed as being of low risk and/or is under detention in various countries.

Further investigations are underway to help MPI understand how the situation came about, and what lessons can be learned from it.

There have been no confirmed reports of illness of any kind related to these batches of whey protein concentrate, anywhere in the world.

"This report is an important step in reassuring consumers and markets," said Mr Gallacher.

"We appreciate the cooperation of affected companies who have worked with MPI throughout this incident," said Mr Gallacher.

MPI also announced on 20 August that interim measures will be implemented – ahead of the outcome of the reviews into this matter:

MPI will:

Lift the regulatory presence in manufacturing premises

Lift the level of and nature of testing across dairy production to improve the identification of non-compliance issues

Run tracing simulations to test the capability of the industry to rapidly track and trace product through their supply chains

Increase reviews of the risk management plans dairy producers have for manufacturing facilities.

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Or by email on media.enquiries@mpi.govt.nz
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29 August 2013

Media Release

No food safety risk from Karicare products

The Ministry for Primary Industries (MPI) has confirmed that, on the basis of information to hand, there was never a food safety risk associated with any Karicare products made with whey protein concentrate (WPC).

This includes all of Nutricia NZ Limited's Karicare Infant Formula.

MPI has received results confirming that products containing WPC manufactured by Fonterra, including all Nutricia Karicare Infant Formula Stage 1 and Karicare Gold + Follow-On Formula Stage 2 products, are not and never were contaminated with *Clostridium botulinum* and pose no risk to consumers of contracting botulism.

The organism detected is confirmed as *Clostridium sporogenes*. It is therefore not capable of producing botulism causing toxins.

There are no known food safety issues associated with *Clostridium sporogenes,* although at elevated levels certain strains may be associated with food spoilage.

"Yesterday, I revoked my Director-General's statement, issued under the Food and Animal Products Acts, about this issue," said MPI Acting Director General, Scott Gallacher. "That covers the precautionary advisory for the two above-mentioned Nutricia Karicare products."

"We sought additional testing at both local and international laboratories, seeking the most robust results we could get. Scientists used a range of methods – all came back negative for *Clostridium botulinum*," said Mr. Gallacher.

"The WPC had been used to manufacture a range of products, including Nutricia's."

For media inquiries please call:
MPI media line on 029 894 0328
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Ministry for Primary Industries
Manatū Ahu Matua

MPI caution - potential Hepatitis A in some fruit

Contact MPI

The Ministry for Primary Industries (MPI) is cautioning New Zealand consumers of a small quantity of fresh fruit sold in late February and early March that there is a relatively low risk that this fruit had been contaminated with Hepatitis A virus.

MPI Deputy Director General Scott Gallacher says it is important that consumers understand the risk of transmission of the virus is relatively low, but MPI is issuing this information as a precaution so that people with any related concerns about their health can contact their doctor.

"As always, MPI is placing the health and wellbeing of all consumers first.

"We have been advised that a person packing some varieties of apples and peaches in a Hawke's Bay packhouse has been diagnosed with Hepatitis A.

"This worker handled Royal Gala and New Zealand Beauty apples and Golden Queen peaches over a four day period while they would have been infectious. Hepatitis A virus can remain infectious on the surface of fruit for some months and transmit infection to other handlers and consumers.

Mr Gallacher says while some potentially affected fruit has been traced and withdrawn from sale, it is expected that approximately 1400 cartons have been sold, with fruit either consumed or still in some people's homes.

Mr Gallacher says all fruit involved in this case was for domestic New Zealand supply and has not been exported.

The fruit concerned was on sale between 27 February and 13 March 2014 at the following outlets.

Royal Gala apples from:
All Countdown supermarkets in the North Island.
The following Christchurch retailers - G Morris and Son, Fresh Connection, United Fresh, Edgeware Supervalue.

Golden Queen peaches from:
All Countdown supermarkets in the North Island.
Pak n Save, New World and Four Square supermarkets from Taupo to Kaitaia.

The following Auckland retailers – Dahua Supermarket (Albany), Lim Chour (K-Road), Fruit World Pioneer Plaza (Henderson), Manukau Fresh Fruit and Vege, Fresh for Less (Henderson), Save Fruit and Vege Shop (Manukau), Green Field Fruit and Vege (Green Bay), New Lynn Fresh.

Also Fresh World in Hawera.

New Zealand Beauty apples from:
All Countdown, Fresh Choice and Super Value supermarkets in the South Island.

The Ministry recommends people who bought potentially affected fruit between 27 February and 13 March 2014 to either cook the fruit well before eating, or if in doubt, throw it out.

"The possibility of infection is relatively low, but along with the Ministry of Health, we advise anyone who becomes ill with the following symptoms contact their doctor. Look out for skin jaundice (yellowish tinge), yellowing of the whites of eyes, dark coloured urine and pale bowel motions. Early signs of Hepatitis A are fever, loss of appetite, stomach pains and nausea.

More information

MPI Hepatitis A pathogen data sheet (PDF)
Hepatitis A (Ministry of Health website)

If you are concerned about your health or the health of others, seek advice from your medical practitioner, or you can call the Healthline (0800 611 116) or PlunketLine (0800 933 922).

Key points:

Some Royal Gala and New Zealand Beauty apples and Golden Queen peaches sold in New Zealand between 27 February and 13 March may have been contaminated with the Hepatitis A virus.
The fruit concerned was on sale between **27 February and 13 March 2014**.
Royal Gala apples from: All Countdown, Fresh Choice and Super Value and supermarkets in the North Island.
Golden Queen peaches from: All Countdown, Fresh Choice, Super Value and supermarkets in the North Island. Pak n Save, New World and Four Square supermarkets from to Taupo to Kaitaia
New Zealand Beauty apples from: All Countdown, Fresh Choice and Super Value supermarkets in the South Island.
Risk of infection as a result of handling or eating this fruit is very low.
Symptoms to look out for are: skin jaundice (yellowish tinge), yellowing of the whites of eyes, dark coloured urine and pale bowel motions. Early signs of Hepatitis A are fever, loss of appetite, stomach pains and nausea.
Contact your doctor if you have these symptoms – particularly jaundice.
This fruit has only been sold in New Zealand. It has not been exported.

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