Reply Submission to the Government Inquiry into the WPC Contamination Incident on Part A of the Inquiry's Terms of Reference (25 June 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;
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- 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

REPLY SUBMISSION FROM THE MINISTRY FOR PRIMARY INDUSTRIES TO THE GOVERMNENT INQUIRY INTO THE WHEY PROTEIN CONCENTRATE CONTAMINATION INCIDENT

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7. Notification to customers and the regulator

7.1 What was the timeline leading to the company's notification of the incident to the regulator, and to customers?

7.1.1 Please see the Admitted Summary of Facts included as part of MPI's submission dated 3 June 2014.

7.1.2 MPI notes an inconsistency in Fonterra's submission concerning when the company first informed its customers about the contamination. Fonterra's submission at paragraph 7.2.9 says the company contacted affected customers on Thursday 1 August 2013, whereas the submission at paragraph 9.1.1 and the chronology of events (page 49) indicate that the company began contacting affected customers by telephone after midnight on Friday 2 August 2013 (that is, early on Friday morning). For completeness, the Admitted Summary of Facts (at paragraph 134) also records that Fonterra began contacting customers from midnight on 2 August 2013 (that is, early on Friday morning). In either event, Fonterra began contacting customers about the incident approximately 12 hours before the company notified MPI.

7.2 What information was given to the regulator and to customers?

7.2.1 The information provided to MPI by Fonterra at this time of the incident notification on 2 August 2014 was included with the Ministry's submission dated 3 June 2014.

7.3 What information was provided to, or obtained by, AsureQuality regarding this incident in 2013, and when?

7.4 Was the notification of the incident to the regulator and to customers adequate?

7.4.1 Fonterra's notification to MPI suffered from a number of inadequacies, but in particular the timing delay. This formed one of the charges MPI brought against Fonterra Limited, to which the company pleaded guilty.

Response to Fonterra's submission

7.4.2 Fonterra's submission identifies a number of inadequacies in its notifications, with which MPI agrees.

7.5 What lessons can be learned?

7.5.1 As noted below, prompt notification of the regulator is essential (as well as being a legal requirement).

8. The response of the regulator during the post-notification phase

8.1 What was the timeline of events from initial notification of the incident to the regulator?

8.1.1 Please see the Chronology included as part of MPI's submission dated 3 June 2014.

8.1.2 Appendix C of Danone's submission dated 3 June 2014 provides a timeline about some of the interactions between MPI and Danone. This timeline needs to be read in the context of the other information provided to MPI by Fonterra, on which aspects of MPI's and Danone's responses rested. For example, MPI's request to broaden Danone's product recall on Monday 5 August 2013 was motivated by new information received from Fonterra at 7.15am that day that a further 17 bags of affected product had been found. For completeness, Danone received this information from Fonterra at 4.29pm on Sunday 4 August 2013 (see Appendix D, p 30, of Danone's submission).

8.2 What systems and processes did the regulator have in place to deal with incidents of this sort?

8.2.1 Please see paragraph 11 of MPI's submission dated 3 June 2014.

8.2.2 MPI uses its Food Incident Response Protocol ("**Protocol**") in incidents of this sort, along with the Trade Response Guide (if appropriate). MPI ran the WPC incident response as a combined Food Safety and Trade Response so that the Ministry could provide information to overseas authorities. In turn, this allowed overseas governments to protect consumers, just as MPI was doing in New Zealand. Considering the wide distribution of the affected product in overseas markets, failing to run a joint food safety and trade response could have damaged New Zealand's international relationships and credibility.

8.2.3 For completeness, MPI also has documented structures for biosecurity structures.

8.2.4 The Protocol was developed by the New Zealand Food Safety Authority (NZFSA) in 2007. The Protocol is based on the Coordinated Incident Management System ("**CIMS**") which is best practice across the New Zealand government. Whilst being generally based on CIMS, specific adaptations to meet the requirements of NZFSA and food safety responses were developed. The Protocol reflects the Australian Food Incident Response Protocol, as developed for, and adopted by, the Implementation Subcommittee for Food Regulation.

8.2.5 The use of CIMS enables inter-operability between agencies when incidents of size of and complexity require more than one or two agencies to work together. CIMS provides universal language and enables people to operate within a common framework. An updated version of CIMS has recently (May 2014) been endorsed by the New Zealand Government. As a result of the experience gained from the WPC incident response, MPI has been actively involved in the development of the CIMS update. MPI will be adopting the updated version of CIMS for all response types (adverse events, business continuity, biosecurity, food and trade) as part of the Ministry's single scalable response model (SSRM).

8.2.6 The key purpose of the Australian Food Incident Response Protocol is to coordinate the activities and communications of multiple Commonwealth and State food regulators within the Australian food regulatory system. Although similar in nature the NZ protocol is more focused on ensuing coordination within an agency.

8.2.7 MPI's Trade Response Guide is benchmarked off the Food Incident Response Protocol and mirrors its structures, function process and templates, with some additions.

8.2.8 As is addressed in MPI's submission dated 3 June 2014 at paragraph 11, Ministers, the Ministry of Foreign Affairs and Trade (MFAT), and Ministry of Health and New Zealand Trade and Enterprise were familiar with MPI processes for food responses, having either participated in, or been briefed on, food responses on many occasions. Further, DPMC and the Ministry of Health, along with other agencies, participated in Exercise "Teamwork" before the Rugby World Cup 2011. MPI provided briefings on the response structure to other relevant agencies, such as NZTE, at the time of the response.

8.3 Had those systems and processes been tested and reviewed prior to the incident?

8.3.1 Please see paragraph 26 of MPI's submission dated 3 June 2014, which provides a sense of the constant food safety and biosecurity responses in which MPI engages. Specifically, as at 23 May 2014 MPI had:

8.3.1.1 205 food complaints and 18 recalls under investigation and/or response;

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

8.3.1.3 113 biosecurity matters under incursion investigation and/or response; and

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

8.3.2 MPI also conducted an exercise Exercise "Teamwork" in 2011 in advance of the Rugby World Cup hosted in New Zealand ("Teamwork") to ensure the response protocols were was understood by, and applicable to, stakeholders and other agencies. Exercise Teamwork saw MPI work together with DPMC, the then Ministry of Economic Development, the Ministry of Health, ESR and District Health Boards prepare for New Zealand hosting the international tournament. MPI's role in the exercise related to its border biosecurity and food safety functions.

8.3.3 In 2012, MPI's trade response interoperability with other agencies was tested in Exercise "Taurus".

8.3.4 Please note that MPI will this year lead a further Exercise "Teamwork" which is planned as part of the National Exercise Programme. DPMC and the Ministry of Health will likely participate in this exercise. MPI also routinely conducts exercises that test the biosecurity response system and the trade response protocol.

8.3.5 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. 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.

8.3.6 The Protocol was last reviewed in September 2010 to reflect the merger between the NZFSA and the Ministry of Agriculture and Forestry to create MPI. Based on the recently updated version of CIMS, MPI is currently developing a single, scalable response model (SSRM) that will work across the span of MPI responsibilities (for example, food safety, biosecurity, animal welfare, adverse events and events that challenge business continuity). Prior to 2010, the Protocol was reviewed following its activation to ensure it remained fit for purpose.

8.3.7 Supplementing the Food Incident Response Protocol, as noted above, are MPI response systems for other incidents. The systems for biosecurity responses were refined and codified during 2005-8 and culminated in the 2008 Policy for Responses to Risk Organisms and the processes set out in the Biosecurity Response Knowledge Base. The biosecurity response model, is also based on CIMS. Drawing on lessons from 10 years of biosecurity responses, the system also imposes a range of project management disciplines. This is consistent with the approach that agencies implement the elements of CIMS which add value, and adapt where necessary. The biosecurity response model incorporates a learning process, whereby it is continually refreshed. Staff conversant in these regularly improving systems were available and supported the WPC response.

8.3.8 The Trade Response Guide was reviewed in October 2012, taking into account the findings following a foot and mouth simulation (Exercise "Taurus").

Were the systems and processes effective in this case?

8.3.9 Please see paragraphs 10 – 27 of MPI's submission dated 3 June 2014.

8.3.10 To ensure its effectiveness, the MPI scaleable response model is customised to each response depending on the scale and complexity of the incident. At its first meeting on Friday 2 August 2013, the RSL identified response objectives. On the same day the RMT identified key immediate tasks and the teams that would be required, and the core roles of those teams.

8.3.11 The following issues relating to structure, roles and responsibilities were discussed amongst the RMT:

8.3.11.1 Technical: This workstream role included a number of key streams – diagnostics, product safety evaluations, and medical interface. This team needed to be resourced appropriately. The team was jointly managed by Debbie Morris and Veronica Herrera to bring the necessary technical experience onboard to ensure appropriate coverage of the workstream output.

8.3.11.2 Operations: MPI's Verification Services and AsureQuality staff needed to be put into field roles within Operations. This

required the establishment of clear reporting lines back to the Pastoral House WPC Response Ops team to ensure rigorous management of incoming data in order to achieve a clear picture of the state of traceability, and to answer questions from the Trade and Market Access workstream regarding product in particular markets.

8.3.11.3 Trade and Market Access: We identified the need for a seamless interface with MFAT, and created a jointly resourced team co-located at Pastoral House. The team quickly established two shifts, in order to ensure that messages and requests for information from NZ Offshore Posts received out of normal office hours were addressed.

8.3.11.4 Liaison: It was crucial to ensure we were working effectively with key agencies and stakeholders involved in the incident. MPI invited Fonterra and Danone to be co-located with the WPC Response Team at Pastoral House from early on in the response. Routine contact was maintained with NZ dairy processors, manufacturers, retailers, exporters and associated entities. Liaison with regulatory authorities occurred under the Operations workstream.

8.4 What technical and scientific advice did the regulator obtain following notification of the incident, and when?

8.4.1 MPI already had extensive internal food science capability. These in-house technical experts formed an integral part of the response structure, especially in the Technical workstream.

8.4.2 On Friday 2 August 2013, the RMT asked the Technical Team (which included representatives from the Ministry of Health) to provide a plain English description of botulism, which was circulated on the first day to the response team and was used in MPI's risk communications.

8.4.3 On Saturday 3 August 2013, MPI needed to consider the scope of products to be included in the Director-General Statement regarding Danone products. The Acting Director-General and the Response Manager contacted the Ministry of Health's expert in the field of paediatric nutrition, to seek advice regarding balancing the uncertain, but apparently very low risk of exposure in the population, against the risks associated with leaving parents and caregivers very few options to feed their children and the associated anxiety that would cause. This provides an example of the MPI's efforts to ensure decisions were informed by expert advice and a balanced consideration of risks.

8.4.4 MPI also needed further information concerning the test results supplied by Fonterra. To this end, at a teleconference on Saturday 3 August 2013 MPI scientists asked a series of questions of Fonterra's scientists. MPI still required further information, which led MPI to request via email at 10.52am on Sunday 4 August 2013 that that Fonterra release AgResearch scientists from obligations of confidence. Having not received confirmation that the obligations of confidence had been waived, MPI sent a reminder email to Fonterra at 4.31pm on Sunday 4 August 2013. A response from Fonterra at 7.56pm indicates that the company had confirmed by or about then that MPI could speak directly to AgResearch staff. Once Fonterra released

AgResearch scientists from obligations of confidence, a series of detailed technical discussions between scientists at AgResearch, Fonterra and MPI commenced on Monday 5 August 2013.

8.4.5 The RMT discussed and agreed that establishing a TAG to provide expert independent advice would be highly beneficial in validating the scientific advice generated by MPI technical experts and their informal collaboration with external experts both in New Zealand and overseas.

8.4.6 Early activity in respect of the TAG was directed towards identifying and contacting a list of potential experts. This list and a draft Terms of Reference based on pre-existing templates had been prepared by the evening of Sunday 4 August 2013. As further potential experts were identified over the next few days, the RMT decided that an internal MPI chairperson would be desirable to assist with co-ordinating the group's meetings and report writing.

8.4.7 During this period there were iterative discussions amongst RMT and MPI's food safety experts regarding the questions that should be addressed by the TAG. By Wednesday 7 August 2013 MPI had started the formal process of establishing the first of a possible series of TAG meetings and this was completed by Monday 12 August 2013. This process involved many communications with potential members to present draft terms of reference, work through confidentiality agreements (and obtain signatures), as well as agree a time when most potential members could participate.

8.4.8 The questions that the RMT and the Technical Team had determined would be put to the TAG were finalised on Friday 9 August 2013. The TAG was provided with an agenda, the questions to be answered and supporting technical and background information.

8.4.9 The TAG met once, on Monday 12 August 2013. The TAG produced a summary report the next day, which provided a high level of confidence to the RSL group and the RMT that the expert advice already generated by MPI's scientists had been validated and was a sound evidence base for the risk management decisions that MPI as the regulator was taking. The TAG chairperson finalised the group's findings in a report dated 29 August 2013.

8.5 What were the regulator's decision-making processes in response to this incident? Were these processes appropriate?

8.5.1 Please see paragraph 11 of MPI's submission dated 3 June 2014.

8.6 Were the regulator's substantive decisions and responses to the incident appropriate?

8.6.1 Please see paragraphs 3, 12 and 13 of MPI's submission dated 3 June 2014.

Response to Danone's submission

8.6.2 While acknowledging that "MPI had this crisis sprung on it", Danone has described MPI's response as "reactive". Danone makes the following points, to which MPI replies in turn below:

8.6.2.1 MPI imposed unrealistic timelines;

8.6.2.2 decision making appeared reactive;

8.6.2.3 MPI lacked of access to subject matter experts; and

8.6.2.4 MPI failed to co-ordinate on PR messaging.

'MPI imposed unrealistic timelines'

8.6.3 Product recalls and other regulatory measures are intended to safeguard consumers, and are not designed for the convenience of manufacturers. Where there are reasonable doubts about the safety of a product, it is incumbent on the manufacturer or manufacturers to establish rapidly the safety and/or location of the product. If they are unable to do so, it is the responsibility of the regulator to ensure that precautionary action is taken. In light of the purpose of product recalls, MPI did not impose unrealistic deadlines.

8.6.4 Further, MPI notes the comment by Danone on page 18 of its submission that 'best practice standards around the world specify that full product traceability should be managed within two - four hours.' Danone concedes, however, that it could not meet a two to four hour tracing timeframe during the WPC contamination incident because of the uncertainties involved and the frequent changes in product tracing information provided by Fonterra. As Danone states at pages 14 and 15 of its submission, the company could not initiate a recall until it clarified that it 'had in fact received affected product from Fonterra' and 'had an opportunity to trace that product for itself within its own supply chain.'

8.6.5 In light of the ongoing difficulty reconciling information received from Fonterra and Danone, MPI had to draw a line.

'Decision making appeared reactive'

8.6.6 Danone appears to be concerned not about a decision made by MPI, but about MPI's initial request that Danone recall all batches of stage 1 (yellow) and stage 2 (gold) formula. MPI's request was made on a precautionary basis and was prompted by uncertainty about the uses to which the affected product had been put.

8.6.7 Given the uncertainties involved and the information that it had been provided, MPI was justified in making a request that Danone make a precautionary recall of all batches of stage 1 (yellow) and stage 2 (gold) formula. We note the statement on page 18 of Danone's submission that 'No food product should ever enter the supply chain unless it had been affirmatively concluded that such product is both safe and suitable for human consumption. Any doubt requires traceback and quarantine, until all doubts are removed.'

8.6.8 MPI worked closely with Danone to establish enough certainty to limit the recall to particular batches. However, further disclosures by Fonterra resulted in the broadening of the recall as had been initially requested by MPI.

Lack of access to subject matter experts within MPI.

8.6.9 Danone makes several points about MPI's communications based on a mistaken assumption that MPI was not working closely with the Ministry of Health or making use of available expertise in human nutrition.

8.6.10 Danone's assumptions are mistaken. As is clear at paragraph 11 of MPI's submission dated 3 June 2014, the Ministry of Health was included in the incident response structure from the first day of the response. Ministry of Health representatives, including Dr Pat Tuohy, the Ministry's Chief Advisor – Child and Youth Health, worked closely with MPI, and participated in MPI's response structure. The Ministry of Health also has regulatory responsibilities in matters of public health.

8.6.11 The close co-operation between MPI and the Ministry of Health was evident publicly during the response, for example through:

8.6.11.1 the joint press conference by the Acting Director-General of MPI and the Director-General of Health at 3.30pm on Wednesday 7 August 2013; and

8.6.11.2 the online advertisements campaign about infant formula product recall run between Tuesday 6 August 2013 and Tuesday 13 August 2013; and

8.6.11.3 the joint print advertisements about infant formula product recall run between Thursday 8 and Sunday 11 August 2013.

8.6.12 The point that 'Nutricia personnel themselves had to speak to the Ministry of Health's Chief Advisor [Dr Tuohy] to explain the situation,' should be understood as an example of the close involvement of the Ministry of Health in the response. The Ministry of Health sought clarification from Nutricia in order to ensure that it had precise and accurate information in its communications with DHBs, and MPI was aware that the Ministry of Health was in contact with Danone.

Lack of coordination on PR messaging.

8.6.13 Danone expresses a concern that 'MPI seemed to consider that it was obliged to respond and react to Fonterra's messaging' and did not coordinate with Danone's messaging sufficiently. There is no basis for this concern. MPI's primary regulatory responsibility was to protect the public and, as Fonterra was the source of the concern about food safety, MPI needed to respond to the concerns raised by Fonterra. As stated at paragraph 12 of MPI's submission dated 3 June 2014, MPI needed to take a precautionary approach to protect consumer health in light of Fonterra's clear notification of *C. botulinum* contamination.

8.6.14 Further, MPI notes that co-ordinating public messages with Danone proved difficult at times. During the response, the company did not have a sizeable or dedicated communications team in New Zealand. Further, Danone did not advertise its product recall on the days or in the manner

that it indicated to MPI that it would, which required MPI to shoulder a greater proportion of the advertising obligation than originally intended. For completeness, MPI spent approximately $180,000 advertising the Danone product recall both online and in print between 6 August 2013 and 13 August 2013.

Lack of access to primary data.

8.6.15 Danone is erroneous in its assumption that the recall process was based on an AgResearch report that MPI possessed. MPI did not begin engaging directly with AgResearch scientists until Monday 5 August 2013. AgResearch's testing report was not finalised until Friday 30 August 2014. MPI's regulatory response was based on information it received from Fonterra on Friday 2 August 2013 stating that AgResearch testing had confirmed that WPC had been contaminated with *C. botulinum*.

8.7 How well was the regulatory response coordinated among relevant agencies?

8.7.1 Please see paragraphs 14 and 22 of MPI's submission dated 3 June 2014.

8.8 How did regulators in other jurisdictions respond to this incident?

8.8.1 Please see paragraph 3 of MPI's submission dated 3 June 2014 for an example of comments by one overseas regulator.

8.8.2 In the vast majority of cases regulators in other jurisdictions responded as they would be expected to. As was the case in New Zealand the safety of their consumers was their number one priority. Those jurisdictions which were identified as receiving potentially affected product were notified as soon as it was possible to do so, and relevant shipment details and batch numbers provided to the counterpart authorities in their countries. In the main, the New Zealand Embassies provided the means of contacting the relevant officials although there was also direct regulator-to-regulator communication.

8.8.3 On receipt of the information, the relevant agencies in market instituted recalls, testing regimes or held the stock prior to its distribution according to domestic protocols and the circumstances. There was some frustration expressed by counterpart agencies in terms of the accuracy of some information they received early in the incident, and perceived delays providing the full information. These frustrations paralleled those in New Zealand that MPI had in terms of product identification and the accuracy of the information the Ministry was receiving from Fonterra and others.

8.8.4 In addition to providing information to those countries which were known to have received potentially affected product, MPI directly contacted (normally though embassies) a number of other governments to alert them of the situation, while making it clear that there was no evidence that potentially affected product had entered their markets. There were also general advisories through the INFOSAN network. The responses of jurisdictions in this category were more mixed. Some took measures that appeared to be out of proportion with the incident, that is, in the circumstance that no product was identified as entering their territories. Others reacted more along the lines expected, that is, waiting for further information before taking any action.

8.8.5 The frustration of some counterpart regulators was evident. The frequent changes in tracing information provided by Fonterra meant that MPI was not in a position to categorically state that there was no possibility of any trade in the potentially affect product for some time because the product tracing work continued in New Zealand.

8.9 Are there any international best practices for regulators relevant to the response to this incident? How well were they implemented in this incident?

8.9.1 Please see paragraph 26 of MPI's submission dated 3 June 2014.

8.9.2 MPI notes the submission of FSANZ and, in particular, references to the National Food Incident Response Protocol. This protocol formalises relationships between Australian food regulators for responding to food incidents, but it does not override or substitute for the existing response protocols of individual agencies and jurisdictions. It is important in each of those jurisdictions that responsible agencies have the ability to coordinate with other agencies in terms of the institutional and government structures that exist in those jurisdictions. The same applies in New Zealand: while the Protocol is of assistance in liaising with Australian jurisdictions, the CIMS protocol provides an essential basis for coordinating with other New Zealand Government agencies that are likely to be involved in a response in New Zealand.

8.10 Did the regulator communicate effectively and appropriately with stakeholders including affected companies, consumers, public, media, and foreign markets?

8.10.1 Please see paragraphs 19 – 22 of MPI's submission dated 3 June 2014, including the Director-General's Statements and press statements included with the submission.

8.10.2 In an environment in which information was constantly changing, MPI successfully communicated the risks to consumers as we understood them at the time. We gave clear precautionary advice to drive consumer decisions, based on the most up-to-date information we had at any time. We used a wide range of channels to achieve this, and updated as new information came to hand. We worked closely with other agencies, such as the Ministry of Health, to reach key at risk groups, such as young mothers through Healthline and Plunketline, and other channels. We also developed entirely new innovations, such as using NZTE's international network of communications advisers to provide communications cover for international media calling from across multiple time zones. Once in place, this allowed MPI to run a 24-hour media operation.

8.10.3 MPI also conveyed messages about consumer health in conjunction with the Ministry of Health to ensure that the public heard from Government with one voice. The Ministries did so especially in the first week of the response when concerns about infant formula were arguably greatest. Examples of joint communications efforts by MPI and the Ministry Health are:

8.10.3.1 the joint press conference by the Acting Director-General of MPI and the Director-General of Health at 3.30pm on Wednesday 7 August 2013;

8.10.3.2 the online advertisements campaign about infant formula product recall run between Tuesday 6 August 2013 and Tuesday 13 August 2013; and

8.10.3.3 the joint print advertisements about infant formula product recall run between Thursday 8 and Sunday 11 August 2013.

8.10.4 We stayed in close contact throughout the response with communications teams at the Ministry of Foreign Affairs and Trade, the Ministry of Health, New Zealand Trade and Enterprise, Danone and Fonterra, and sought to align messages and information where appropriate given MPI's regulatory role.

8.10.5 With respect to foreign markets MPI's communication was effective and appropriate. MPI was transparent in all its communications and provided available information as soon as it was possible to do so. There were frustrations about the quantity and clarity of information at some points in the response, but this was a manifestation of the situation as opposed to a communication issue with foreign markets.

8.11 How effective were the regulator's risk communication processes?

8.11.1 Please see paragraphs 3 and 19 of MPI's submission dated 3 June 2014.

8.11.2 When MPI was formed a variety of emergency communications management manuals and approaches were bought together, which primarily focussed on how to organise for a communications response. The essential components of those were tested and applied initially in Exercise "Taurus", subsequently in several biosecurity events, and also in the WPC response. In many respects, the structural approach to organising for a communications response was best and fully articulated in the Emergency Management Communications Manual developed across the former MAF, NZSA and Biosecurity New Zealand. However, this manual is designed for a very large scale response, and the communications team has developed ways of scaling it to the matter at hand. There are also a variety of other policies that guide business as usual activities that are also relevant in an event, such as MPI's media and social media policies.

8.11.3 The Emergency Management Communications Manual formed the basis of how MPI organised itself for the WPC response. MPI's use of press conferences and communications channels, such as Healthline, Plunketline, websites, advertising and social media, was based on practises developed in other responses, and learnings from other major whole of government events over the past few years. Each communications issue is different, and the mix of channels is determined by the audience you are trying to reach. Depending on the timeframe being worked to, these are documented in either a formal or informal communications and/or marketing plan.

8.12 Has the regulator conducted a review of its response to the incident? What were the results of that review?

8.12.1 MPI's RMT undertook a de-brief session immediately after standing down the major operational workstreams on Monday 26 August 2013.

8.12.2 FSANZ convened a debrief of the Bi-National Food Incident Response Network on 19 May 2014 in Melbourne. The network includes MPI together with Australian food regulatory agencies at the Commonwealth and state levels. MPI input deliberately avoided going into matters subject to the Inquiry. An overview was presented on general lessons learned from the range of food responses in the previous 18 months. Key outcomes of the debrief were:

8.12.2.1 given the complexity of the issue, the overall incident response was well coordinated under the NFIRP;

8.12.2.2 jurisdictions collaborated well and New Zealand colleagues benefited from a well-established Australian network and an existing process for liaison;

8.12.2.3 the NFIRP was an effective means of identifying the agency responsible for intercepting implicated product in transit and preventing its sale in Australia; and

8.12.2.4 situation reports were informative and timely.

8.12.3 As for communications, MPI has not specifically updated any processes or manuals in the communications team as a result of the WPC incident response. However, a piece of work is underway to develop a common framework for risk communications. As part of its broader preparedness activities, MPI has also adopted the CIMS model for all responses and is now developing a single, scalable response model. Communications is now aligning its processes with the CIMS model.

8.12.4 Further, MPI is planning a programme of external engagement to build awareness of its systems and processes. The New Zealand food system will be a key topic covered, including how it works and what it means to us here in New Zealand and internationally.

8.12.5 MPI will proactively work with media to increase their knowledge and understanding, while helping us to reach the New Zealand public at the same time.

8.13 What lessons can be learned?

8.13.1 Please see paragraphs 27 – 36 of MPI's submission dated 3 June 2014, along with the table of Lessons Learned included with the submission.

What changes have been made?

8.13.2 Please see paragraphs 37 – 50 of MPI's submission dated 3 June 2014, along with the table of Lessons Learned and the table of actions taken to implement recommendations from Parts B and C of the Inquiry included with the submission.

9. The response of the company during the post-notification phase

9.1 What was the timeline of the company's response during the post-notification phase?

9.1.1 Please see the Chronology included as part of MPI's submission dated 3 June 2014.

9.2 Did the company provide the regulator with adequate information in a timely manner during this phase?

9.2.1 Please see the Chronology included as part of MPI's submission dated 3 June 2014, and Appendix D of Danone's submission.

9.2.2 MPI particularly notes the following occasions on which Fonterra provided new, changing or contradictory information about tracing of product:

9.2.2.1 Friday 2 August 2013 – the original notification when Fonterra informed MPI about three batches of WPC produced in May 2012 at the Hautapu plant[1], specifically notifying MPI that "Hautapu WPC has been contaminated with C.B." and "1. Contamination of WPC with Sulphite Reducing Clostridia at levels ranging from 110 – 950 cfu/g, was confirmed as *Clostridium Botulinum*";[2]

9.2.2.2 Monday 5 August 2013 – Fonterra notifies MPI of an additional 17 x 25kg bags of affected WPC, produced at Fonterra Darnum and supplied to Danone;[3]

9.2.2.3 Thursday 8 August 2013 – 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 2013;[4]

9.2.2.4 Tuesday 13 August 2013 – Fonterra advised 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;[5]

9.2.2.5 Wednesday 14 August 2013 – Fonterra informs MPI 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

[redacted]

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

the pallets. Fonterra also informed MPI about customer samples of a nougat bar that were sent to the United States;[6]

9.2.2.6 Thursday 15 August 2013 – Fonterra advised MPI and Nutricia of a correction to data concerning 14 pallets of affected powder sent from Darnum to Danone. 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;[7]

9.2.2.7 Sunday 18 August 2013 – Fonterra advised MPI about pallets sent from Fonterra Australia to Danone China that may contain potentially contaminated WPC;[8] and

9.2.2.8 Thursday 27 August 2013 – Fonterra advised MPI of possibly affected product all of which was under the company's supply chain control in New Zealand, used in three product lines.[9]

Response to Fonterra's submission

9.2.3 As acknowledged in its own submission, Fonterra struggled to provide accurate and detailed information in a timely manner.

9.3 *Did the company communicate effectively and appropriately with stakeholders including affected companies, consumers, public, media, and foreign markets during this phase?*

9.3.1 The company provided at times unhelpful information which hindered MPI's work as a regulator by putting in the public domain incorrect information that both increased public anxiety and falsely reassured. The two most notable examples (which Fonterra identifies on its timeline, but does not provide any commentary) were:

9.3.1.1 Monday 5 August 2013 when a Fonterra representative stated on TV3's *Campbell Live* that all Nutricia Karicare products had been affected by the contamination incident and were thus covered by the product recall[10]; and

9.3.1.2 Thursday 8 August 2013 when Fonterra issued a press statement "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 statement continued "our 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"."[11] Fonterra issued this press statement despite having been aware since

[redacted]

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

Tuesday 6 August 2013 of further affected product about which the company had yet to notify MPI. Late in the evening on Thursday 8 August 2013 Fonterra notified MPI of the further affected product, as the company did five more times after that day.

9.3.2 With respect to foreign markets the company generally kept MPI informed of its actions. Nevertheless the main communication was regulator-to-regulator rather than via the company. The company worked closely with MPI in terms of work around the foreign markets during the incident. It was important to ensure that communications were consistent and provided the most up to date and accurate information possible.

10. Identifying and tracing the potentially affected product

10.1 What was the timeline for the company's identification and tracing of all potentially affected product from 2 August 2013?

10.1.1 Please see the Chronology included as part of MPI's submission dated 3 June 2014 for the Ministry's experience of the tracing process.

10.1.2 For its part, MPI originally aimed to produce a comprehensive tracing and verification report by Monday 12 August 2013. However, after its initial notification on Friday 2 August 2013, Fonterra on seven occasions produced new information which materially affected MPI's tracing work. The scale and challenges associated with this task were initially underestimated. The report was signed off on Friday 23 August 2013, and publicly released on Sunday 25 August 2013.

Response to Fonterra's submission

10.1.3 MPI notes that Fonterra acknowledges the problems at the company associated with product tracing in the response and the time the tracing process took.

10.2 What were the specific challenges faced in identifying and tracing all of the potentially affected product, and why did these issues arise?

Complexity of the situation

10.2.1 WPC is an ingredient that goes into multiple products made by several plants. In some cases the product is sent overseas for processing and then back before being incorporated into the final product. The rate of addition of the ingredient into different products varied, so it was extremely difficult to establish whether all product had been used up and how much product it went into. The supply chain within New Zealand was also complicated with multiple distributors and retailers involved. It was not initially clear how many processing sites were involved and which sites belonged to which companies and made which brands. This was further complicated by product being exported as well.

Ability to trace accurately

10.2.2 The information provided initially by Fonterra kept changing, for example on 5 August Fonterra advised that another 17 bags were implicated, on 9 August they advised a further bag had been found to have been sent to FRDC. MPI using AsureQuality and its own staff carried out reconciliation of the traceback and initially found issues. Examples included errors in spreadsheets, inability of industry to explain discrepancies in data, carryover of product, (for example, when blending) and that rework and loss streams did not appear to be accounted for.

10.2.3 In some instances, staff from Danone and Fonterra appeared to be under pressure which made completion of tracing difficult.

Systems

10.2.4 Different companies have different tracing systems, which complicated matters. Product was identified by a combination of cypher (manufacturing date), batch code, pallet numbers, container seal number, and/or export

certificate number. Several products may be made on any one site on any one day, so these products have the same Cypher but other details (including ingredients) could be different, so a Cypher alone was insufficient to identify and trace product before determining status. The key identifier was found to be the batch code, but this did not always relate precisely to product movement as some batches were split up for sale to different customers.

10.2.5 Different tracing systems used different units of measure, e.g. cartons, kg, bags etc which made it more difficult to trace and reconcile. In addition there were many people gathering pieces of the puzzle, and not all of them gave information in the same format so this made it difficult to pull it all together.

10.2.6 MPI was not familiar with some of the jargon the company used and the capability of the company systems.

10.2.7 Notably, Fonterra had changed its inventory system before the incident and had used dummy data to trial the new system. The dummy data was mixed up with the real data initially.

Export

10.2.8 Export of product was by a variety of methods. Some was accompanied by official assurances which made tracking easier. Some markets do not require official assurances and it was much more difficult to verify what product had been sent to these markets. Some product was bought from retailers and then exported by individuals outside of the regulatory framework. Some products were sold online.

10.2.9 In some cases requests coming from overseas related to for example to brand, whereas information we held was by processing company and batch.

10.2.10 When product is sent by plane, the pallets will not always fit in the hold so are sometimes split onto two pallets. The way this was handled varied – sometimes the original inventory details went with the product and sometimes a new pallet number was raised.

Other

10.2.11 Many companies with affected / suspect product were in a difficult situation where their brand was affected through no fault of their own. They were trying to minimise the damage as well as protect their customers/consumers.

10.2.12 Companies wanted to get the affected product off their sites ASAP but the process for return or dumping procedure was not clear. Some companies were reluctant to move any product until compensation / cost issues were sorted out. This required a lot of communication between multiple parties. There was a lack of space to collect all suspect product in one place so in some cases it was stored in multiple places.

10.2.13 Not all products that the ingredient went into would have put consumers at risk. Some products were subject to further processing such as Ultra Heat Treatment which would have mitigated the risk. Risk assessments were needed to confirm which products were of concern.

10.2.14 Because of the extended nature of the event, the people involved changed and the people coming in were not familiar with what had already been done or not done, and some required training in what to do in a response.

10.2.15 The same people collecting the information had to report on it regularly, which interrupted the flow and analysis of information. There was also pressure to confirm final amounts and numbers when information we were getting was still changing

10.2.16 Data capture was difficult. Most ended up in spreadsheets and diagrams that needed to be updated manually. In some cases the spreadsheet was updated but not the diagrams and vice versa.

10.3 What lessons can be learned?

10.3.1 These situations are very complex, and need a lot of resourcing. Obtaining the correct, verified information takes time and needs people who are sufficiently familiar with tracing systems. It can be risky to rely on the initial information that is provided.

10.3.2 Ideally, we need to have someone technical at the site that caused the problem as soon as possible in order to:

10.3.2.1 check the company's analysis of the cause and scope of the problem,

10.3.2.2 challenge any assumptions the company made during that analysis,

10.3.2.3 verify how much product was made, how much was still on site and where product was sent and what units of measure it was sent in, and

10.3.2.4 ensure they understand what they need to do to manage the situation.

10.3.3 Companies need to "test" their recall systems in practice using real examples. Companies need to consider how they will manage carry-over of contamination into other products made later on the same lines within their recall systems.

10.3.4 We need to review the requirements relating to traceability to see if the regulatory requirements are adequate. Further guidance may also be needed to encourage companies to think about better records (such as records of ingredient usage, what happens to waste streams, how different units are dealt with, how tracing isdealt with when units are broken down for transport).

10.3.5 Lots of people became involved in this incident and not all were as familiar with the processes and produces for managing responses as they could have been. This familiarisation and training needs to happen frequently and be ongoing.

Response to Fonterra's submission

10.3.6 Fonterra suggests at paragraph 12.1.22 of its submission that there should be "increased co-operation between the regulator and industry in relation to mock traceability, recall procedures, and planning for scenarios where a

regulator response is needed." MPI concurs with Fonterra's suggestion and would be glad to help organise and participate in such scenario planning.

10.4 What changes have been made?

10.4.1 MPI held a Verifiers Summit in October 2013 where traceability was discussed and MPI emphasised the need to check the importance of this.

10.4.2 In April 2014 a Notice of Direction under section 81 of the Animal Products Act was issued to verifiers of plants producing infant formula products, infant formula base powders and WPC. This notice required verifiers to ensure operators have appropriate procedures, systems and criteria in place for the recall and tracking of dairy products.

10.4.3 The Traceability Working Group has been set up to review requirements and guidance around traceability. At least two meetings of the group have been held.

10.4.4 Dairy products which are exported with an official assurance are moving to the AP E-cert system. This will provide better information for MPI if recalls involve product exported with an official assurance.

11. Overall observations

11.1 Standing back and considering the incident overall:

MPI has already provided the Inquiry with comprehensive reflections on the WPC contamination incident in its submission in respect of Parts B and C of the Inquiry's terms of reference (October 2013) and its earlier submission in respect of Part A of the Inquiry's terms of reference (June 2013). Standing back and considering the incident response overall, and considering those earlier two submissions, MPI considers that the major lessons to be learned from, and changes made as a result of, the incident response are:

11.1.1 timely notification of the potential contamination to MPI as regulator by Fonterra would have made all the difference and would have avoided much of the confusion and effort that characterised the incident response. This point is already addressed by MPI's prosecution of Fonterra Limited;

11.1.2 prompt notification of MPI by Fonterra before the company notified its customers would also have allowed more time for MPI scientists to assess the scientific testing commissioned by Fonterra;

11.1.3 timely tracing by Fonterra, and company systems capable of supporting the tracing, would have made a significant difference during the incident response. Tracing is addressed in the Inquiry's report in respect of Parts B and C of its terms of reference, in response to which MPI has formed an expert Traceability Working Group;

11.1.4 readier access to AgResearch's scientific reports commissioned by Fonterra and the AgResearch scientists who undertook the testing could have assisted MPI in the opening days of the incident response. MPI does nevertheless acknowledge Fonterra's co-operation in allowing AgResearch scientists to liaise directly with MPI;

11.1.5 a better relationship of trust between Danone and Fonterra could have assisted aspects of the response, but the relationship was understandably damaged during the response by repeated new and contradictory tracing information from Fonterra;

11.1.6 MPI's formation of a Technical Advisory Group to review scientific conclusions was important. MPI will consider whether it needs a standing external scientific panel ready to perform as members of a Technical Advisory Group for incident responses in the future; and

11.1.7 while the Inquiry will doubtlessly provide useful conclusions as to what happened in the incident, scenario planning and preparedness exercises are clearly a vital tool to address future and unexpected events. To this end, MPI will continue to participate in and organise preparedness exercises, and would welcome joint exercises with industry participants.