



# THE WPC80 INCIDENT: CAUSES AND RESPONSES

## GOVERNMENT INQUIRY INTO THE WHEY PROTEIN CONCENTRATE CONTAMINATION INCIDENT

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## Preface

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Six months have passed since the Inquiry began stage two of its examination of New Zealand's biggest food safety scare. That scare, as most people will vividly remember, was sparked by suspicion that infant formula and possibly other products, too, were infected with botulism-causing *C. botulinum*.

In this final stage, the Inquiry has looked closely at the causes of the incident, together with the responses by Fonterra and the Ministry for Primary Industries and the roles of others. The distance of time has enabled the Inquiry to take a considered view of just how it was that the extraordinary events came to pass. At all times, it has endeavoured to do so through the lens of food safety, including its examination of the state of readiness of key participants to respond to unfolding events.

The contributions of those who assisted, from providing documents, briefing papers and written submissions, to participating in long interviews, are gratefully acknowledged. All were prepared to review the events in question openly and honestly. The Inquiry is particularly appreciative of the assistance from the core participants: Fonterra, the ministry,ASUREQuality, AgResearch and Danone.

The Inquiry is indebted to Kelley Reeve, Ned Fletcher, Sally Johnston and Annette Spoerlein as the secretariat and to Simon Mount as legal advisor; also our scientific advisor, Dr Lisa Szabo, chief scientist of Australia's NSW Food Authority, and our independent peer reviewer, Professor Alan Reilly, chief executive of the Food Safety Authority of Ireland.

We cannot thank Peter Riordan enough for his enormous contribution in assisting with the writing of this report. Also, Susan Buchanan for editing and proofing; Jacqui Spragg as designer; Jill Marwood and Maria Svensen for secretarial and administration assistance; and finally staff at the Department of Internal Affairs. As with the first stage, it was a pleasure to work with them all.

It took this incident to raise awareness that food safety cannot be taken for granted. Lessons learned from the incident provide an opportunity for all participants in the dairy food safety system – and indeed wider – to step up and meet the challenges ahead. Consumers expect no less. But the Inquiry hopes that this final report can draw this particular chapter to a close, in the knowledge that all participants will continue to work together to ensure New Zealand remains a world leader in dairy food safety.



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24 November 2014

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**FOLDOUT ADDENDUM:** Events before 2 August 2013

## Overview

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The news in August 2013 of potential *Clostridium botulinum* contamination made global headlines. In New Zealand, it was received with something approaching disbelief, in part because the country prided itself on exporting food of the highest quality. The truth is, our food was, and still is, safe, wholesome and among the best in the world.

But the botulism scare, as many call the WPC80 incident, led to a review of the dairy industry's food safety framework, a matter dealt with in the Inquiry's first report. That report concluded that the regulatory framework was fundamentally sound, but recommended improvements. Underlying many of these was the idea that the dairy industry must anticipate future risks as well as counter existing known threats.

Now, in stage two, the Inquiry has turned to a detailed examination of what began with a simple breaking of a torch lens in a Waikato dairy factory and ended in the recall of millions of product items.

How did something so insignificant come to have consequences so enormous? This report answers that question. The Inquiry is tempted to describe the account as fascinating – and certainly it is likely to be so for those at arm's length from New Zealand's biggest food safety incident. However, for those involved, or who felt its serious financial repercussions, the word grim might be more apt.

Between the torch breakage on 1 February 2012 and Fonterra's notification of *C. botulinum* on 2 August 2013, numerous people made decisions that, one by one, added their small contribution to the building momentum of events. Sometimes, those events seemed to take on a life of their own, but they were entirely avoidable – if a strong food safety culture had thrived in the workplace.

Some readers will wonder why the various individuals involved did not heed the warning signs or take the precautions that were so apparent afterwards. But to yield to that temptation would be to underestimate

the complexity of the events and also to undervalue the good intentions of all those involved (many of whom, the Inquiry can vouch, worked days on end after the crisis broke, trying to regain control of the situation).

The key immediate causes are relatively easy to determine (although the findings on pages 7-8 give a comprehensive list). They are:

- The Hautapu plant's improvised reprocessing of WPC80, without a risk assessment and in breach of its risk management programme
- The Fonterra research centre's encouragement of *C. botulinum* testing without sufficiently considering its purpose, justification and potential implications
- The decision to approve "toxin testing" without appreciating that this meant authorising *C. botulinum* testing
- Fonterra's failure to advise both the Ministry for Primary Industries and its customers much sooner of a potential food safety problem.

The direct causes do not tell the whole story. Wider factors had an influence on the crisis as a whole. Identifying those enabled the Inquiry to understand more fully why the incident happened and to compile a lessons section especially for the industry (see pages 10-11).

Contributing factors included:

*Organisational pressures:* Fonterra's workplace culture exhibited an entrenched "silo" mentality that robbed the company of some of the cohesion so vital in an organisation of its size. Both internal and external pressures also contributed to missed opportunities to correct the course of events. Communication, both within and between parts of the organisation, was often unclear – symbolised most starkly by a manager's unwitting authorisation of *C. botulinum* testing. And there was also a lack of adequate escalation procedures to deal with possible food safety problems.

## OVERVIEW

*Testing:* Fonterra and AgResearch, the research institute that tested Fonterra's WPC80 samples, approached this work from different perspectives. Communication lacked the precision and formality that might have halted testing or shifted it to a diagnostic laboratory and produced a different result.

*Readiness:* The ill-prepared inevitably pay a heavy price in a crisis. Fonterra was not ready for a crisis of this magnitude. It lacked an updated, well-rehearsed crisis plan to implement, as well as a crisis management team that could spring into action. The ministry also lacked a single, coherent food incident plan to implement straight away.

*Responses:* The WPC80 incident had a long and largely unobserved prelude, followed by a short, very public conclusion. The second phase placed most of the main participants in the crisis, but particularly Fonterra, under intense pressure to act swiftly, decisively and in concert. This did not always happen. Partly, the underperformance was the result of insufficient preparedness and partly, Fonterra's tracing problems.

With a single phone call on 2 August, the ministry was confronted with a raft of public health, trade, market access, tracing, infant formula supply and media problems. Many aspects of its response deserve credit, especially its decision to put public health first and urge a recall, knowing that more definitive test results would be weeks away. Its decision-making, however, could have been more rigorous and science-based. All parties could also have co-ordinated better during the crisis.

*Tracing:* This was an undeniably complex task. The 37.8 tonnes of WPC80 manufactured in May 2012 had, by August 2013, made their way into thousands of tonnes of products in various markets. Nonetheless, Fonterra's tracing efforts were, for different reasons, seriously deficient. That, in turn, hampered both the ministry and Fonterra's customers in their tracing of the affected production. Fonterra's initial estimate was well off the mark. It would take the company a further 16 days, and numerous amendments, before it arrived at a final, conclusive figure that enabled all suspected production to be identified.

*Food safety culture:* A food safety programme and a food safety culture are entirely different. One is concerned with documentation and processes, the other with employee behaviour and a top-to-bottom commitment to putting food safety first. The Inquiry has explored this in detail, because if Fonterra had possessed a strong food safety culture, this incident would probably not have happened.

But good can come out of bad. The WPC80 incident has spurred Fonterra into a series of comprehensive changes, from boardroom to factory floor, especially aimed at strengthening food safety and quality and crisis management capability. The ministry, too, has taken matters swiftly in hand. During the past 12 months, it has created a regulation and assurance branch devoted more or less solely to food safety. No one now can be in any doubt about where responsibility for food safety sits. The ministry is also preparing a new crisis response model for implementation in 2015.

All those changes are welcome and will put the ministry and the country's biggest dairy company on a better footing in the event of another food safety incident (as well as protecting consumers and New Zealand's economy and reputation).

Other changes may follow, too. This report contains recommendations specifically for consideration by the Government and the ministry, which would, among other things, strengthen scientific expertise, auditing, crisis planning and non-routine reworking procedures. The report also draws lessons from the WPC80 incident that could be useful for the dairy industry and wider food manufacturing sector. These would strengthen the food safety cultures, manufacturing processes and crisis planning of other companies, as well as clarify laboratory testing processes.

But perhaps the most important lesson here is one of attitude. As United States food safety expert Debby Newslow puts it: "We can no longer learn from our mistakes; we cannot allow mistakes to happen. In today's world of food safety, we must be proactive and prevent mistakes from occurring."<sup>1</sup>

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<sup>1</sup> D Newslow, *Food Safety Management Programs: Applications, Best Practices, and Compliance*, CRC Press, Florida 2014 at xix.

## Findings

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The Inquiry sets out below its main findings. They must be read with care because, as summary points, they are necessarily stripped of much of the detail that gives context to the actions of particular organisations and the individuals within them. They are no substitute for reading the report itself. Only there will nuances of perception, intention and fact be found.

### Manufacturing

- Torch lens fragments entered machinery at Fonterra's Hautapu plant on 1 February 2012, and a team leader, contrary to procedure, continued production, believing the fragments were too large to pass into the WPC80 the plant was manufacturing.
- Hautapu managers later decided there was a contamination risk and reprocessed ("reworked") the WPC80 to remove the fragments – but using an improvised method that was outside the plant's risk management programme and involved no risk assessment.
- To carry out the reprocessing work, staff employed rarely used flexible hoses and a fixed pipe, cleaning them first with a caustic (rather than acid) solution, which failed to eliminate all contamination.
- The Hautapu plant failed to follow a company guideline to disperse reworked material (up to 10 per cent) among new material, which might have avoided the incident.
- Fonterra did not test the WPC80 for the type of contamination (SRC) caused by using the inadequately cleaned hoses and pipe.

### Post-manufacturing

- In March 2013, some of the WPC80 went to Fonterra's plant in Darnum, Australia, to make nutritional powder for food company Danone, which did require an SRC test.

- Tests showed very high SRC readings in the WPC80, leading to an internal Fonterra dispute that did not take into account whether a clear failure in good manufacturing practice suggested a potential food safety, rather than food spoilage, problem.
- The very fact there was disagreement about whether the production for Danone was fit for purpose was reason to alert Fonterra's corporate headquarters, if notASUREQuality, the verifier that audits Fonterra's regulatory compliance.
- Fonterra did not investigate at the time of the dispute whether it had supplied any of the reworked WPC80 used at Darnum to other customers.
- When investigation into SRC contamination levels took place at Fonterra's Waitoa plant in the Waikato, a Fonterra manager approved "toxin testing" by AgResearch (21 June) without appreciating that she had authorised *C. botulinum* testing.
- Fonterra had no formal processes for authorising non-standard tests, including for *C. botulinum*, which might have caused Fonterra to conclude that such testing was either not warranted or should be carried out in an accredited laboratory.
- Fonterra did not inform ASUREQuality or the ministry of a potential food safety problem on 21 June when it authorised *C. botulinum* testing. Nor did it advise customers to cease using the reworked WPC80 until further notice.
- Initiating *C. botulinum* testing did not prompt any investigation in June into whether the reworked WPC80 had made its way into other products.

## FINDINGS

### Testing

- AgResearch, which accepted the request by Fonterra's research centre (FRDC) to test for *C. botulinum*, was unaware of the background to the testing and believed the samples were from production withheld from sale ("product on hold"), which was not the case.
- In seeking AgResearch's help, Fonterra was aware that the research institute was not accredited to undertake *C. botulinum* testing.
- Fonterra, and particularly FRDC, did not properly consider whether the testing had a diagnostic or research purpose – an important distinction when choosing any laboratory to conduct a test.
- Fonterra and AgResearch did not agree on the specific methodology to be used in the mouse bioassay.
- Fonterra and AgResearch disagree on whether Fonterra was made aware of deviations from the methodology, including the number of mice to be used in the mouse bioassay.
- Fonterra made the decision to proceed with a mouse bioassay (26 July) without first seeking the advice of its most senior scientist or chief executive.
- Fonterra failed to make adequate preparations in anticipation of the possible test results.
- Fonterra did not informASUREQuality or the ministry of a potential food safety problem on 24 July when it formed a critical event team, a step that would likely have led to greater scrutiny of AgResearch's brief.
- Fonterra did not notify customers on 24 July that products might be contaminated so they could start tracing and recalling them.
- Fonterra was late in notifying the ministry of the problem on 2 August and did not provide the ministry with AgResearch's preliminary report stating that *C. botulinum* was "likely", not "confirmed", which, again, might have led to greater scrutiny of AgResearch's results.

- Later testing by two government laboratories in the United States concluded the samples were harmless *C. sporogenes*, not potentially fatal *C. botulinum*.

### Fonterra's response

- Having notified the ministry, Fonterra had no well-prepared (or reviewed or rehearsed) group crisis plan to implement, including crisis communications (particularly in social media).
- Fonterra took until 18 August to trace all the affected products, a seriously deficient effort.
- Fonterra did not effectively co-ordinate its actions with those of the ministry, Danone and the Government during the crisis.
- Fonterra's communications were neither well conceived nor co-ordinated and lacked a tone that encouraged consumer trust and loyalty.

### MPI's response

- The ministry had no single, coherent (or reviewed or rehearsed) crisis plan for a food incident that it could implement straight away after receiving notification of *C. botulinum*.
- The ministry's response was hampered by Fonterra's late notification overstating the certainty of *C. botulinum* and by Fonterra's drawn-out and deficient tracing.
- The ministry deserves credit for many aspects of its response, but it should have had better-documented decision-making processes, used more rigorous science-based risk assessment, and co-ordinated better with the industry to avoid unnecessary confusion among consumers and others.

## Recommendations

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### The Inquiry recommends:

- The ministry, in consultation with the dairy industry and verifiers, should:
  - Revise the rules for non-routine reworking that requires a product disposal request
  - Ensure the industry's strict compliance with reporting times for product disposal requests, critical exception reports and export non-conformances
  - Continue to strengthen its monitoring and auditing activities to ensure early detection of potential food safety problems.
- The ministry should continue its work to ensure readiness for a food safety response, including:
  - Finalising its food incident protocol (as part of its single scalable response model), ensuring it is consistent with CIMS and benchmarked against international models. A draft should be provided to the food industry and other key stakeholders for comment before final publication
  - Undertaking regular exercises/simulations of its food incident protocol ranging from smaller desktop exercises through to large-scale, multi-agency rehearsals
  - Ensuring staff are fully trained to respond to food incidents.
- In any food incident, the ministry should:
  - Start, and document, a risk assessment identifying both scientific and strategic risks as soon as practicable and update the assessment as the incident develops
  - Document the use of statutory powers, particularly Director-General statements, including written advice from officials about available options and the underlying scientific and risk assessment information on which recommendations are based
  - Co-ordinate with all relevant parties to ensure a single integrated response.
- The ministry should re-establish a group of scientific experts along the lines of the previous NZFSA Academy.
- The law should be amended to give the ministry a specific statutory power to compel disclosure of relevant information (including test results) needed to respond effectively to a food safety incident. The power should include the ability to disclose such information to any affected party.
- The ministry should receive targeted funding to ensure it:
  - Has the resources – over and above those needed for day-to-day operations – to conduct a regular programme of simulations
  - Completes the much-needed reform of dairy regulations.
- The law should be amended to make clear what tests must be conducted in accredited laboratories.
- Industry participants should be required to seek approval from the ministry when no accredited laboratory or validated method is available for diagnostic testing, or a significant variation to a validated method is unavoidable.
- The ministry, the New Zealand Food Safety Science and Research Centre (in the process of being established) and laboratories should collaborate to establish, test and maintain:
  - Mechanisms for sourcing controls (such as reference cultures and antitoxins), if required for non-standard testing in New Zealand
  - A global register of accredited laboratories and scientific experts able to undertake, or advise on, microbiological testing, especially for pathogenic and uncommon organisms
  - Arrangements (including customs and biosecurity clearances) that ensure minimal effects on cultures during transport to overseas laboratories for tests that cannot be conducted in New Zealand.

### Lessons

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The Inquiry considers the dairy industry – and wider food industry – may usefully consider the following lessons that emerged from the incident.

#### Food safety culture

- **Commitment:** Companies must develop a strong food safety culture that goes beyond simply a documented food safety programme. The best way to develop such a culture is by:
  - Senior management creating a food safety vision, setting expectations and inspiring others to follow
  - Mid-level management visibly and practically demonstrating commitment to this vision: employees must see actions not just words
  - Employees understanding what they are expected to do to uphold the company's food safety standards
  - A free flow of information that inspires employees to action
  - Measures to channel, encourage, reward and reprimand behaviour as appropriate.
- **Openness:** Companies must encourage staff at all levels to speak up about food safety concerns so they reach the ear of those who can put things right.
- **An investment:** Food safety must be seen as an investment, not as a cost – a point of particular relevance to New Zealand's international reputation for safe and wholesome food.

#### Manufacturing

- **Risk management programmes:** These must be accessible, clear and well understood by staff.
- **Priorities:** Staff on the factory floor must understand that food safety comes first.
- **Good processes:** Companies must have formal, clear processes about:
  - **Non-standard equipment:** Companies must consider the food safety risks of temporary or idle equipment: the cleaning of such equipment must follow best practice

- **Non-standard processing:** Staff must consider carefully the need for any non-standard process and the product's intended use. A hazard identification and risk analysis should be a prerequisite. Correct escalation should ensure a second layer of protection against unsound practices.
- **Non-standard testing:** Such tests demand special consideration, as well as approval by senior employees with the appropriate expertise and experience.
- **Reworking:** Policies relating to reworking must be clear. Experienced individuals should be involved when foreign matter or microbiological contamination makes reworking necessary.
- **Risk assessment:** Staff must receive adequate training in risk assessment procedures, which should be systematic, transparent and credible.
- **Workplace processes:** Companies should institute processes including, if necessary, templates (rather than emails) that are sufficiently formal to prevent staff from approving important actions without clearly understanding the nature and consequences of the request.
- **Escalation procedures:** Companies must have escalation processes in place so staff can refer food safety concerns to an appropriate level for action. More generally, speaking up should be encouraged, not discouraged.
- **Customer and consumer focus:** From the factory floor to boardroom, everyone must remember the customer and consumer when making any decision involving a food safety risk, especially if it might mean a notification to the ministry.

#### Laboratory testing

- **Clear purpose:** The client and laboratory must have a clear, common and prior understanding of whether testing is for a diagnostic or research purpose.

- *Authorisation of non-standard testing:* Any decision to carry out such testing should take into account the likelihood and consequences of a positive result, not merely the monetary value, to ensure oversight by senior management.
- *Testing plans:* Both the client and laboratory should agree on a testing plan setting out the purpose, the methods to be used, the order in which the laboratory will conduct them and the criteria determining whether each test will proceed.
- *Variations:* Both the client and laboratory should agree in advance on any variations from the proposed methodology. Contracts should list known variations and their likely influence on the interpretation of results. Contracts should also outline reporting procedures laboratories will follow if variations become necessary as testing proceeds.

### Crisis planning

- *Crisis plan:* Companies must have a best-practice crisis management plan they regularly review and rehearse.
- *Training:* Companies should provide regular training for staff involved in crisis responses.
- *Co-ordination:* All participants in a food safety crisis must co-ordinate their efforts to ensure a single integrated response.
- *Tracing:* Companies must be able to rapidly trace and recall products.
- *Communications:* All food companies must have a crisis communications plan, including a social media component.
- *Evaluation:* Crisis plans must stipulate a timely evaluation of the company's response, so the experience can help improve performance in any future incident.

## Independent Peer Reviewer's Report

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Benjamin Franklin is attributed with the quote: *"By failing to prepare, you are preparing to fail"*. Three hundred years later, his words still ring true. The essence of all good emergency planning is anticipation and preparation. The need for emergency planning by public agencies involved in food safety has been highlighted by the national and international food crises that have plagued the global agri-food sector in recent years.

Planning and preparing for the management of food safety crises are an essential function of national food control agencies, critical for protecting consumers' health and minimising reputational damage. The management of such emergencies is rarely the responsibility of a single national authority. Timely and co-ordinated collaboration among all partners, including the food sector, is required to ensure an effective response.

The Inquiry's conclusion is at one with the wisdom of Benjamin Franklin, in correctly noting that the ill-prepared inevitably pay a heavy price in a crisis. The Inquiry found that the dairy company at the epicentre of this crisis, Fonterra, was not ready for a crisis of this magnitude. It had placed the nurturing of a genuine food safety culture in the company on the back-burner and concentrated its attention on production and market share.

A sober Inquiry finding is the sad reflection that this incident with its serious consequences was entirely avoidable, had a strong food safety culture thrived in the workplace. As the Inquiry noted, by reworking, rather than downgrading, the contaminated WPC80, Fonterra recovered about \$150,000. The cost to the company and the reputational damage for New Zealand magnified this figure many times over.

The Inquiry found that the Ministry for Primary Industries also lacked a single, coherent food incident management plan that could be implemented at the push of a button. What it had in place were untested protocols for dealing with biosecurity and food incidents that had their genesis in the former government agencies that amalgamated to form MPI.

The Inquiry concluded that MPI's response was hampered by the tardiness of Fonterra in notifying the initial problem and in supplying traceability data to assist with product recall. As a result, critical MPI communications were compromised. While MPI deserves credit for many aspects of its response, the Inquiry found it should have had better-documented decision-making processes, used more rigorous science-based risk assessment and co-ordinated better with the industry to avoid unnecessary confusion.

In short, I agree with the Inquiry that MPI's planning and preparedness fell short of best practice. A single, coherent food incident management protocol should have been implemented immediately. The ministry is in the process of preparing such a protocol.

Nevertheless, the scenario presented to MPI on Friday 2 August 2013 was one that would send ripples of fear throughout most government agencies in the world with responsibilities for food control and the remit of protecting consumers' health. The information presented that day by global dairy giant, Fonterra, was that 37.8 tonnes of whey protein concentrate (WPC80) manufactured by the company had been found to be contaminated with *Clostridium botulinum* at a very high level. Furthermore, the implicated WPC80 had been used in the production of infant formula already released to the market.

MPI was informed that two major multinational infant formula manufacturers had used the implicated WPC in some of their own products, which were also in domestic and international markets. No information was supplied on the precise location of the implicated products. The Inquiry found that it took a further three weeks before full traceability data on the implicated products was made available to MPI.

While food control agencies have crisis management plans in place and staff undergo training and simulation exercises in preparation for handling food crises, little could have prepared the senior management at MPI for the stark realities of facing up to a food scare of such magnitude and the potential risks to one of the most vulnerable groups in society. Apart from the food safety implications, the question of New Zealand's reputation as a leading global supplier of dairy products, as well as the economic and political consequences, could not have been far from the minds of MPI senior management.

Decisions taken during the first 24 hours of a food crisis are critical to the outcome. MPI took the correct decisions in putting consumer interests first and foremost and adopting a precautionary approach to managing the crisis. Food control agencies seldom have all the relevant data at their disposal during the early stages of a food crisis. The information flow is usually patchy, making risk assessment and decision-making very difficult.

In successfully managing a food crisis, there is no substitute for anticipation, planning, having dedicated food safety emergency protocols in place and ensuring staff are familiar and fully trained in their use. Staff with the relevant food safety management experience are also critical for a successful outcome.

Given the patchy nature of information provided, MPI would have been justified in recalling all implicated batches of product from the market on day one. What did unfold was an abject lesson in how not to communicate in times of crisis. The Inquiry found that during the initial stages of the incident, the regulator, MPI, and the food companies put conflicting and inaccurate information in the public domain. Little or no information or guidance for consumers to protect themselves and their infants was provided.

This demonstrates the need for close collaboration between the food industry and the regulators in managing a food crisis. Co-ordination of all communications issued in times of crisis is essential for the credibility of all involved. My own experience in managing serious food safety events confirms that co-ordination does not happen by accident. Procedures for crisis communication need to be included in written protocols, as do the roles of staff who also need to understand their own specific responsibilities. Plans for using both conventional and social media channels should also be included in such protocols.

Some of the critical decisions taken around the laboratory testing of the implicated WPC80 were central to how events unfolded and were evaluated in detail by the Inquiry. There are many lessons to be learned regarding decisions to carry out non-standard testing, what to test for, what actions to take on finding a positive result, use of accredited laboratories and the communication of results. It is fair to say that everyone breathed a collective sigh of relief when confirmatory testing showed that *Clostridium botulinum* was not present in the WPC80 and that the incident had been a false alarm. Nonetheless, the Inquiry findings point to areas for improvement.

Tracking and tracing implicated food products throughout a complex food chain in times of a food crisis presents enormous difficulties, particularly when a contaminated ingredient has been widely used in the manufacture of different food products. In its meticulous scrutiny of events, the Inquiry found that the 37.8 tonnes of WPC80 manufactured in May 2012 had, by August 2013, made its way into thousands of tonnes of products of various types and into various markets. The findings point to serious deficiencies in Fonterra's traceability systems which took a confusing 16 days to arrive at figures that enabled all suspected product to be withdrawn from the market.

The Inquiry also correctly points to the delay by the company in providing critical results of laboratory analysis to MPI. Sharing such information from the outset would have allowed the regulator to make informed decisions and to conduct an independent risk assessment. Consideration should be given to putting such requirements on a statutory basis and allowing the regulator to put such information in the public domain, if deemed necessary. Having access to all relevant data and consulting the widest possible scientific opinions are key to the successful management of a food crisis.

## INDEPENDENT PEER REVIEWER'S REPORT

The Government of New Zealand is to be complimented for commissioning this Inquiry, which has been a challenging experience for the food industry and regulators alike. It has identified the stark realities of events that happen during a major food crisis. Putting all the facts and events in the public domain in an open and transparent manner is not an easy task. It demonstrates a strong consumer focus and a commitment to learning from what happened, as well as putting in place measures to ensure that any future food crisis is handled correctly. The Inquiry report will be read by food control agencies and large food companies globally and will undoubtedly assist in crisis planning and preparation.

I can confirm that the Inquiry's approach has been thorough and meticulous. It has left no stone unturned in the investigation into the causes of this incident. A wide range of stakeholders throughout the agri-food chain were interviewed to uncover what went wrong and to identify key lessons to prevent a recurrence.

An initial task was to prepare a range of in-depth questions in order to understand how events unfolded, how decisions were made and what measures were implemented. In the interests of transparency, the Inquiry made these questions public and invited comments. I had free access to all relevant papers associated with the Inquiry's deliberations. The Inquiry report is hard-hitting and pulls no punches in identifying the root causes of what went wrong and recommending actions to ensure that such an event does not happen again. But the Inquiry has also been fair, especially in focusing on the significant improvements already made.

Among the many lessons to be drawn from the incident is the need for food companies and regulators to adequately plan and test their crisis procedures. In that way, responses to a real crisis can be swift and effective, rather than tentative and ineffectual. I fully concur with the Inquiry's findings that there can be little doubt that the WPC80 incident has, at a minimum, brought home to the industry the critical importance of food safety.

A food safety culture does not happen overnight. It takes nurturing and time. What this incident has underlined is the importance of ensuring everyone in the food industry understands its importance.

I have no hesitation in agreeing with the Inquiry finding that the ill-prepared inevitably pay a heavy price in a crisis. Since a crisis seldom gives warning of its arrival, the best course of action is preparedness in all its various forms: sound communication plans, sound tracing and recall systems, regular updating of crisis management plans, regular training and evaluation. These issues are covered in the Inquiry recommendations.

I would like to thank the Inquiry team, in particular the chair, Miriam Dean QC, for their courtesy and assistance during my task as independent peer reviewer. The findings speak for themselves, with lessons for both the global food industry and food regulators worldwide on how to prepare for, and manage, a food crisis in the interests of protecting consumers' health and keeping intact the reputation of a food company or a nation.



**Professor Alan Reilly**

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## PART ONE: INQUIRY PROCESS

### 1. Introduction

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#### The incident

During the 18 months between 1 February 2012 and 2 August 2013, an extraordinary series of events unfolded that culminated in the biggest food safety scare in New Zealand's history.

The sequence began when Fonterra suspected that whey protein concentrate (WPC80) manufactured at its Hautapu site contained pieces of plastic from the lens of a torch sucked into processing equipment.

In May 2012, it reworked – or reprocessed – the affected WPC80, a procedure that involved the non-standard use of a transfer pipe and flexible hoses.

Between July 2012 and February 2013, Fonterra supplied close to 38 tonnes of the reprocessed WPC80 to customers in various countries for use as an ingredient in a range of products, including infant formula. Its own Australian processing plant at Darnum was among the recipients.

In March 2013, finished-product testing for Darnum customer Danone identified high levels of sulphite-reducing clostridia (SRC), which Fonterra traced to the reprocessed WPC80. The probable source of the contamination was the transfer pipe and/or flexible hoses used in the reworking. Fonterra initiated further testing, including testing by AgResearch, a leading New Zealand agricultural research facility.

On 2 August 2013, Fonterra advised the Ministry for Primary Industries (MPI or ministry) of the presence of “confirmed” *Clostridium botulinum* (*C. botulinum*) in the WPC80. It was not until several days later that Fonterra gave the ministry AgResearch's preliminary report (received by Fonterra on 2 August in response to an urgent request), which said that “initial investigation” of three samples of WPC80 isolates showed they were “likely to be *C. botulinum*”, but “other close relatives” could not be ruled out.<sup>2</sup>

Early next morning, the ministry publicly announced that Fonterra-produced WPC80 might be contaminated with *C. botulinum*, which can cause botulism. The ministry's acting Director-General followed that up with a series of advisory statements warning New Zealand consumers not to use certain infant formula products. Fonterra announced precautionary recalls of the WPC80 and Danone subsidiary Nutricia did the same for certain infant formula products sold in New Zealand and overseas.

No cases of illness were linked to consumption of the affected products, although the incident generated understandable concern among consumers, especially parents and caregivers worried about the health of their babies.

International reaction was swift. Some countries closed borders to certain New Zealand dairy products, others initiated specific product-testing and several announced product recalls. Exporters immediately felt the impact through rejected shipments, withheld payments and lost orders.

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<sup>2</sup> An isolate is a culture of micro-organisms isolated for study.

On 28 August 2013, MPI announced that further laboratory testing in the United States had established the contaminant as the non-pathogenic bacterium *Clostridium sporogenes* (*C. sporogenes*), which causes food spoilage only. The incident was a false alarm.

### Inquiry's purpose

The incident had serious effects on New Zealand's reputation and economy. In response, the Government established this independent inquiry (the Inquiry). The terms of reference, set out in Appendix 1, required it to report in two stages.

The first related to regulatory and best-practice requirements for dairy food safety. The Inquiry's *Report on New Zealand's Dairy Food Safety Regulatory System* (the first report) found the system to be both fundamentally sound and consistent with international risk management principles. However, as with any system, improvements were possible, and the first stage provided the Inquiry with an opportunity to suggest exactly that.

Stage two of the Inquiry requires it to:

- Report on how the potentially contaminated WPC80 entered the New Zealand and international markets and how this was dealt with
- Make any additional recommendations it considers fit.<sup>3</sup>

Even at the first stage, without a full understanding of the facts, the Inquiry identified changes, including operational practices, that demanded action. By far the majority related to the challenges that lay ahead. The Government accepted in principle all 29 recommendations.

As a result, this second report contains a limited number of recommendations, confined to actions the Government and ministry can take. The Inquiry does, however, identify lessons that both the dairy,

and wider food, industries and regulators can take away from the incident – lessons that, if fully translated into actions, will further strengthen New Zealand's food safety system.

### Inquiry's approach

As in the first stage, Inquiry members adopted an investigative approach to the task, interviewing individuals in dairy companies, regulatory bodies, laboratories and industry organisations, as well as customers. Everywhere, assistance was fully and freely given. Appendix 2 identifies categories of interviewees at both stages of the Inquiry.

Early on, the Inquiry designated Fonterra, MPI, AsureQuality, AgResearch and Danone as core participants.<sup>4</sup> These parties provided submissions, briefing papers and other documents. Submissions responded to a set of detailed questions compiled by the Inquiry.<sup>5</sup> This material – not all of which can practicably be referred to in this report – has helped the Inquiry in reporting what happened, how it happened and participants' responses.

Also helpful to the Inquiry were:

- The report into the incident commissioned by Fonterra's board of directors (the Fonterra board inquiry report)<sup>6</sup>
- The agreed summary of facts accompanying the four charges Fonterra admitted following compliance action by the ministry (the prosecution facts).<sup>7</sup>

As with any inquiry, there was no substitute for interviews, whether with directors, chief executives, managers, scientists or operations staff. These included Fonterra personnel who, for varying reasons, were not interviewed by the Fonterra board inquiry. From all of these meetings, which were confidential to ensure full and frank disclosure, Inquiry members gained insights into how and why events occurred as they did.

3 The Inquiry is also required to provide a final report on "regulatory and best-practice requirements". The Inquiry's findings, opinions and recommendations in its first report are largely unchanged.

4 Section 17 of the Inquiries Act 2013 enables participants playing a direct and significant role in relation to some or all matters to which an inquiry relates to be designated as core participants.

5 See the Inquiry's website [dia.govt.nz/Government-Inquiry-into-Whey-Protein-Concentrate-Contamination-Incident:List of Issues](http://dia.govt.nz/Government-Inquiry-into-Whey-Protein-Concentrate-Contamination-Incident:List-of-Issues)

6 *Report of WPC80 Independent Inquiry for Fonterra Board*, 23 October 2013. This followed Fonterra management's earlier *WPC Operational Review*, 30 August 2013.

7 District Court, Wellington, 4 April 2014, CRI-2014-085-002986. Fonterra pleaded guilty to four charges of breach of relevant provisions of the Animal Products Act 1999 and was fined \$300,000.

The Inquiry was assisted by expert advice from Dr Lisa Szabo, chief scientist of Australia's NSW Food Authority, on testing issues. Members acknowledge again the valuable contribution of Professor Alan Reilly, chief executive of the Food Safety Authority of Ireland, as independent peer reviewer.

The terms of reference specifically exclude inquiring into, determining or reporting on any questions of liability.<sup>8</sup> The Inquiry has been careful not to do so, particularly because of litigation between Fonterra and Danone. This has not impeded the Inquiry in understanding what happened from a food safety perspective.

### Structure of report

This report is in seven parts:

- Inquiry process
- Context
- The wider view
- The causes of the incident
- Fonterra's response
- The ministry's response
- Testing.

## 2. The issues

The Inquiry has identified and examined four broad sets of questions:

### The causes of the incident

The essential question is what happened and why between 1 February 2012 (when fragments of a torch lens were sucked into processing equipment) and 2 August 2013 (when Fonterra told MPI about the incident).<sup>9</sup> In particular:

#### Hautapu

- How is it that the Hautapu site continued to manufacture WPC80 without having recovered all the plastic fragments?
- Why was the WPC80 reworked by Hautapu in breach of its risk management programme?

- Should there be more stringent controls over reworking?

#### Prelude to a crisis

- Should the high levels of SRC discovered in nutritional powder made for Danone at Darnum have alerted Fonterra to a potential food safety problem, and if so, when?
- What led Fonterra to commission AgResearch to test for *C. botulinum*, practically unheard of in the dairy sector?
- Why was testing for *C. botulinum* not referred to senior management?

#### AgResearch conducts testing

- What was AgResearch asked to do?
- What reason was it given for the testing?
- What led to its preliminary report that the contaminant was likely to be *C. botulinum*?

#### Countdown to crisis

- Why did Fonterra senior management learn so late that *C. botulinum* testing was under way?
- Why was extensive tracing of affected production not undertaken immediately, and customers notified, when a potential risk with the WPC80 was identified?
- Why did Fonterra not notify the ministry of the incident immediately and why did it advise MPI of "confirmed" *C. botulinum*?

### Fonterra's response

Given that all dairy (and other food) companies should adequately plan, prepare and test crisis procedures, the incident prompts the following questions:

- Was Fonterra's crisis planning consistent with best practice and had regular testing been carried out?
- How adequate was Fonterra's tracing of the potentially contaminated products?

<sup>8</sup> See s 11 of the Inquiries Act 2013, which prohibits the Inquiry from determining questions of liability: it can make findings of fault.

<sup>9</sup> The terms of reference paragraphs (a)(ii) and (iii) require the Inquiry also to report on the practices used at each stage of the WPC80 entering the market and the timeline of steps taken by Fonterra and any other party with regard to testing and reporting the potential contamination. Since these matters are interrelated to the causes of the incident (paragraph (a)(i)), they are addressed in part four. Broader testing issues are covered in part seven.

## PART ONE: INQUIRY PROCESS

- Did Fonterra work in a coherent, co-operative way with MPI and its customers?
- How well did Fonterra communicate during the crisis?

### The ministry's response

Similarly, the ministry must be equipped to handle food safety incidents, whether small or serious, raising the questions:

- What systems and processes did the ministry have in place to deal with an incident of this scale: had they been tested and reviewed?
- Were the ministry's decision-making processes appropriate in the circumstances?
- How well did the ministry co-ordinate its response with other parties?
- How effectively did the ministry communicate during the crisis?

### Testing

The incident poses questions about laboratory testing, so vital to producing safe food:

- Did AgResearch have the competence and capability to undertake *C. botulinum* testing?
- What are the differences between research and diagnostic testing?
- What tests were carried out?
- What were their results and limitations?

Some of these broad issues overlap and common themes arise, in particular:

- What are the lessons to be learned?
- What improvements have since been made?



## PART TWO: CONTEXT

As detailed as the Inquiry's examination of the incident has been, a complete understanding requires some background to the events of 2012-2013. This section briefly describes how Fonterra has developed as a company; how it responded to previous food safety incidents; how it has initiated reforms in response to this incident; and how its Hautapu plant came to operate as it did in 2012. A last useful point to understand is the various types of bacteria in the *Clostridium* family.

### 3. Fonterra

The importance of the dairy sector and Fonterra's central role in it have already been emphasised in the first report.<sup>10</sup> Through an integrated "grass-to-glass" supply chain, Fonterra has grown to become the world's leading milk processor.<sup>11</sup> The company:

- Has 10,500 farmer shareholders accounting for 88 per cent of New Zealand's production
- Processes 22 billion litres of milk annually at 76 plants in New Zealand and overseas
- Produces 2.8 million tonnes of dairy products for 100 markets, valued at NZ\$22.2 billion
- Employs 18,000 staff globally, including 11,000 in New Zealand.<sup>12</sup>

Historically, Fonterra's dairy ingredients have been sold to other companies for use in their own consumer products, including milk powder, casein and whey powder. Such commodity products are sold via Fonterra's online global auction trading platform and also directly to individual customers.<sup>13</sup>

Production of milk powder for use in infant formula has skyrocketed in recent years.<sup>14</sup>

With a shift in emphasis from producing largely commodity items to consumer-branded goods, Fonterra has built up brands including Tip Top, Anchor, Anlene and Annum. As this incident has shown, the company's goal of tapping the vast expansion potential of such brands can be realised only if there is complete consumer confidence in the safety of those products. In this respect, many consumers, particularly internationally, make little distinction between Fonterra's food safety record and that of New Zealand. Protecting this country's reputation remains paramount.

#### *Structure and management*

Created in 2001 through the merger of the country's then two biggest dairy co-operatives and the New Zealand Dairy Board, Fonterra Co-operative Group Limited is owned by New Zealand dairy farmers, with subsidiary or related companies operating domestically and overseas (Fonterra Group). One of its largest subsidiaries and the Fonterra Group's main dairy ingredients trading company is Fonterra Limited (previously New Zealand Milk Products Limited). At the time of the incident, that company was part of an even larger business unit within the Fonterra Group, known as New Zealand Milk Products (NZMP) and responsible for milk production, manufacture and sales. NZMP, then and now, is also Fonterra Limited's dairy ingredients brand.

<sup>10</sup> First report at 17.

<sup>11</sup> In its 2012 report, the International Farm Comparison Network ranked Fonterra as the world's top milk processor with a 3 per cent share of the world's milk production. Second and third were Dairy Farmers of America (2.4 per cent) and Parmalat (2.1 per cent).

<sup>12</sup> In this report figures, including quantities, have generally been rounded.

<sup>13</sup> Thirty per cent of its products are sold via an online auction platform known as GlobalDairyTrade (GDT), which Fonterra established in 2008. GDT prices largely determine the price Fonterra pays its farmer shareholders.

<sup>14</sup> First report at 18.

Frequently referred to in this report is the Fonterra Research and Development Centre (FRDC) in Palmerston North, which is part of the Fonterra Group and the hub of Fonterra's NZ\$80 million annual investment in research and development.<sup>15</sup> FRDC can claim many world firsts, including spreadable butter straight from the fridge and the Anlene range of bone nutrition products.

Fonterra's structure is complex. For the Inquiry's purposes, "Fonterra" or the "company" refers to the Fonterra Group and/or Fonterra Limited, unless otherwise noted. The distinction from a food safety perspective is largely irrelevant.<sup>16</sup> NZMP is used where appropriate to identify the actions and/or decisions by staff within the NZMP business unit.

Within Fonterra's various business units and the wider group are five teams relevant for present purposes:

- *Senior management*: top managers, including the chief executive and NZMP's managing director
- *Product assurance and standards*: a team responsible for food safety, food quality and regulatory matters
- *Quality and technical*: quality managers providing food safety-related support, and technical managers providing product support (such as nutritional advice) and process support (such as manufacturing expertise) to operations staff
- *Food assurance*: managers and staff at FRDC providing expertise on the science of food safety and quality
- *Operations*: staff, including site, plant and process managers, responsible for manufacturing dairy products.

Appendix 3 contains a diagram of the Fonterra management structure in August 2013.

### *History of producing safe dairy products*

Fonterra has continued in the footsteps of its predecessor companies as a significant manufacturer

and exporter of safe dairy products, achieved, in part, by a wide range of testing and auditing procedures, as well as by regular voluntary notifications to the regulator when food safety concerns emerge.<sup>17</sup> However, as this incident has shown, continuing recognition as one of the world's leading producers of safe, high-quality dairy food requires even greater effort.

Fonterra's first brush with a significant food scare came in 2008 when Sanlu, its joint venture partner in China, discovered that suppliers had laced watered-down milk with melamine to boost apparent protein levels. The milk was subsequently used in infant formula. The practice led to the hospitalisation of many infants and, in some cases, death. Fonterra played a role in bringing the matter to Chinese regulators' attention. The subsequent investigation by Chinese authorities extended to 21 other dairy companies in that country.

Fonterra's track record was also dented not long before the WPC80 incident when residues of the agricultural chemical Dicyandiamide (DCD) were detected in some Fonterra products. Farmers applied DCD to their pastures to reduce nitrate loss and promote grass growth. An MPI working group, of which Fonterra was a member, looked into the use of DCD and confirmed it posed no food safety risk. Nonetheless, by January 2013, manufacturers had halted production and sales of DCD for use on pastures, a decision supported by Fonterra. Like many others, the company recognised, first, the potential for its continued use to tarnish the country's food safety reputation; and secondly, that consumers were increasingly unwilling to accept any traces of foreign residue in their food.

However, some damage had already been done. A *Wall Street Journal* article, published under the headline *Milk scare hits dairy power New Zealand*, alarmed global markets. Fonterra product testing with third-party laboratories increased tenfold and the company hurriedly put together plans to limit any risk to sales and reputation. Regrettably, lessons that could have been drawn from the episode – such as the need to involve senior management

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<sup>15</sup> Previously the Dairy Research Institute (part of the Department of Scientific and Industrial Research) established in 1927 and acquired by Fonterra as part of the merger with the New Zealand Dairy Board, FRDC employs more than 350 scientists and has its own state-of-the-art pilot plant for dairy production.

<sup>16</sup> It is, however, a distinction important to the Fonterra-Danone litigation and as such, another reason why it is inappropriate that the Inquiry attribute actions to one or other company.

<sup>17</sup> Terms of reference paragraph (a)(v): a matter relevant largely only as background and so addressed in this part of the report.

early on and to draw up contingency plans for crisis communications, information sharing and testing – went largely unheeded as the WPC80 incident approached.<sup>18</sup>

*A commitment to change*

The Inquiry is in no doubt about the impact of the incident on Fonterra, from boardroom to factory floor. Two reviews, operational and board, resulted in 53 short, medium and long-term initiatives, to be tracked by seven strategic road maps.

	
<b>Review road maps</b>	
<u>Objectives</u>	
<b>OUR PEOPLE</b> FOOD SAFETY	Ensure food safety and quality are hard-wired and have the appropriate profile across the whole organisation
<b>OUR PRODUCTS</b> MANUFACTURING	Ensure clear standards that are fit-for-use and aligned with global food manufacturing best-practice processes, procedures and importing requirements for manufacturing and testing
<b>OUR SYSTEMS</b> TRACEABILITY	Ensure Fonterra can deliver product traceability to the required standards of regulators, customers and consumers
<b>OUR RESPONSE</b> TRANSPARENCY	Improve transparency and speed in our handling of critical events
<b>OUR LEADERSHIP</b> WORLD LEADER IN FOOD SAFETY AND QUALITY	Establish New Zealand and Fonterra as the world leader in dairy safety research
<b>OUR STAKEHOLDERS</b> REDEFINING OUR STYLE AND ENGAGEMENT	Enhance Fonterra's communication style and approach and enhance its management of stakeholder relationships
<b>OUR GOVERNANCE</b> INCREASED FOCUS ON RISK	Endorse "one company" and the paramount importance of food safety and quality for Fonterra. Implement a Board Risk Committee to increase focus on risk management

Broadly, initiatives cover food safety and quality, risk and crisis management, stakeholder communications, governance and operational improvements. Changes range from immediate operational adjustments (such as rules governing the use of flexible hoses) through to longer-term ambitions (such as a four-year project to develop a global dairy safety and quality benchmark).

A review of Fonterra's progress in implementing the recommendations of its own board inquiry reports good results.<sup>19</sup>

Specific changes related to the road maps are noted where relevant. The Inquiry has focused on changes made, or to be made, by Fonterra for two reasons. First, such commitment to change tangibly demonstrates the lessons Fonterra has learned and lends weight to the belief that, while other food safety scares will undoubtedly occur, a crisis on this scale should not. Secondly, many of the initiatives will provide guidance to other dairy or food manufacturing companies.

**4. Hautapu**

The sequence of events that was to climax in worldwide news of a botulism scare began at Fonterra's Hautapu plant, four kilometres from the Waikato town of Cambridge. The plant, which began modestly in 1886 but today spreads across 10 hectares and employs 300 people, proved to be the source of the contaminated WPC80.

It consists of a series of partially self-contained operations manufacturing a variety of products, most notably cheeses and powder. The WPC plant was commissioned in 1988. The adjoining SCUF (scale-up facility) plant, built in 1994, was originally intended for product development opportunities and for the past two decades manufactured mainly protein hydrolysates for export.<sup>20</sup>

The two plants have separate risk management programmes, but share the same manager and are separated only by a door. Staff largely treat the two plants as one, a point directly relevant to the 2012 reworking. The SCUF plant's original developmental purpose meant that flexible hoses and other temporary, non-standard lines were, until recently, quite commonly used.

Hautapu produces 3,500 tonnes of WPC a year. The protein concentrate level varies according to intended product use. WPC80, for example, has a protein concentrate level of 80 per cent and is

<sup>18</sup> In May 2013, Fonterra completed an internal review of the DCD incident, but by August had still to act on its recommendations.

<sup>19</sup> *Independent Inquiry Welcomes Fonterra Progress*, 3 September 2014.

<sup>20</sup> Hydrolysates are used in products for sensitive populations as well as in sports drinks.

generally used to fortify nutritional powder, yoghurts, UHT beverages, sports drinks and infant formula. At the time of the incident, Hautapu's staff did not know which product type the WPC80 was destined for: a separate part of the company is responsible for sales.

WPC is made from whey, a by-product of cheese or rennet. It is a complex process. At Hautapu, whey from a milk treatment facility is transferred to three storage silos in the WPC plant. Ultra-filtration results in a product known as retentate, which is subjected to chilling, temporary storage, heating and evaporation. Next, it is fed into a drying chamber and turned into a powder before descending on to a vibrating fluid bed for more drying. Once cool, the powder is sifted through a screen that retains particles larger than three millimetres in diameter. The manufacturing process is now over. The powder is stored in bins with a capacity of 20 tonnes, enough to hold up to two and a half dryer runs. From there, it goes to a central packing area, where each 25-kilogram bag receives an identification number, or cipher, related to the day of packing.<sup>21</sup>

### The reworking process

Reworking (or rework as it is commonly called in the industry) can be necessary for several reasons and requires careful controls. Perhaps the most common reason is that a product does not meet client or industry specifications. Out-of-specification problems may arise from a lack of homogeneity (as ingredients are mixed or blended) or from contamination (physical, chemical or biological). Yet another reason is the need to rework non-homogenous material from the beginning of a production run or residual material from the end of a production run: the industry calls this starts and stops. In short, reworking is routine.

Dairy companies generally dilute up to a maximum of 10 per cent reworked material with new material

in finished products in order to limit cross-contamination risk.<sup>22</sup> If any contamination remains after the reworking process, it will be so diluted that the risk, if any, to consumers will be minimal.

## 5. Sulphite-reducing clostridia

As the first report noted, SRC are among the oldest forms of micro-organism.<sup>23</sup> As many as 200 species of *Clostridia* exist, most of them harmless to humans. They are commonly anaerobic and as such grow only in an oxygen-free environment.

The dairy industry mainly uses SRC testing as a pointer to potential spoilage or hygiene problems, particularly in infant formula and its ingredients. SRC limits for infant formula generally range from 10 to 100 colony-forming units per gram, or cfu/g.<sup>24</sup> Three forms of *Clostridia* species are relevant here.

### Clostridia species

*Clostridium sporogenes* (*C. sporogenes*) is a common, non-toxin-producing bacterium and not a cause for concern

*Clostridium perfringens* (*C. perfringens*) is a bacterium that produces a toxin when the gut breaks down spores. In the dairy industry it is largely considered a food spoilage matter only

*Clostridium botulinum* (*C. botulinum*) is a bacterium that produces a toxin causing the muscle-paralysing disease botulism. Babies under 12 months can contract the rare infant botulism from spores because of their immature intestinal tracts

As the Inquiry noted at the first stage, SRC testing is not a reliable indicator for *C. botulinum*.<sup>25</sup> Nor has any infant botulism case worldwide been linked to infant formula.<sup>26</sup>

21 For example, cipher GW02 means the product was packed on 2 February 2012: "G" indicates February; "W" indicates 2012.

22 Companies generally use up to 5 per cent without the customer's consent; 10 per cent with consent. Finished product is that which a dairy company packs into bags and so includes ingredients.

23 First report at 46.

24 cfu/g = colony-forming units per gram. See International Commission on Microbiological Specifications for Foods, *Usefulness of testing for Clostridium botulinum in powdered infant formula and dairy-based ingredients for infant formula*, 27 August 2013 at 5.

25 First report at 46.

26 In 2001, a botulism outbreak in Britain was associated with infant formula, but experts ultimately concluded it was not the source: E Johnson, W Tepp, M Bradshaw, R Gilbert, P Cook and D McIntosh, Characterization of *Clostridium botulinum* strains associated with an infant botulism case in the United Kingdom, *Journal of Clinical Microbiology*, vol 43:6, 2005 at 2602-2607.



## PART THREE: THE WIDER VIEW

### 6. Common themes

No examination of the WPC80 incident can be complete without stepping beyond the immediate causes to examine the contribution of underlying factors. Such an examination seeks answers to why, not when or how or at whose instigation, things unfolded as they did. This has led the Inquiry to look at Fonterra's organisational cohesion, its workplace culture, its food safety systems, its day-to-day commitment to food safety and its ability to identify and respond to food safety risks and incidents. And lastly, the Inquiry has looked at changes initiated in the wake of the incident.

#### A question of outlook

When companies grow as large as Fonterra, it is no easy thing to maintain a unifying sense of one team working for a common goal. During the past three years, and with the appointment of a new chief executive, Fonterra has been promoting a "one company" vision among staff, but it is clear to the Inquiry that, at the time of the incident, the concept was far from being universally embraced.

Many of those spoken to by the Inquiry referred to the persistence with which individual business units – and even the teams within those units – continued to operate as semi-autonomous operations. Many Fonterra staff, to borrow from organisational jargon, worked in silos. Information often flowed internally up within teams, but not always externally out to other teams and beyond. This was as true of outlook as of information. As one interviewee noted:

"Silos remained very real despite the 'one company' message."<sup>27</sup>

A chronology of key events illustrates this insularity – and the consequences that were to flow from it all too clearly. Decisions were taken, and actions initiated, within one business unit or team without advising members of other units or teams, for whom such knowledge would have been of profound interest.

Since the incident, Fonterra has taken steps to reinforce the "one company" ethos and eradicate the silo mentality. The NZMP business unit has been wound up and split between two divisions (Global Operations and Global Ingredients). Other steps include strengthening corporate group functions, including food safety and quality, in order to promote consistent standards throughout Fonterra. There is also stronger emphasis now on all business units complying with company standards.

#### A rapidly changing organisation

During the four to five years before the incident, Fonterra had been grappling with a succession of changes. Some emerged in response to the rapid expansion of markets and products, principally in fast-growing Asian countries, and some were the ripple effects of frequent internal restructures. The restructuring was partly the result of the company's gradual evolution from primarily a commodity producer to a more consumer-branded manufacturer. It would be no exaggeration to describe the pace of these changes, internal and external, as relentless. Indeed, some individuals interviewed by the Inquiry

27 The Fonterra board inquiry also noted two divergent outlooks: a strong sense of Fonterra as a single organisation focused on global expansion as against a decentralised business run by an arm's-length head office: at 25.

said the burden imposed by these changes was a strong contributor to the incident. To take just one example, the nutritional technical team that commissioned *C. botulinum* testing was, at that time, undergoing its second restructure within a year.

The restructuring had an unsettling effect on staff, the Inquiry was told, especially at middle-management level. One result was the lack of precision about roles, responsibilities and reporting; another was the absence of seamless, cohesive communication of information. The failure to report problems – either at all or in a sufficiently timely or effective manner – to higher levels within the company or on to regulatory bodies was evident in the WPC80 incident and, earlier, the DCD incident.<sup>28</sup>

All organisations, of course, are subject to change, along with the turbulence and uncertainty it creates. The critical factor is how they implement change. Winning the hearts and minds of staff is at least as important as redefining responsibilities and reorganising what staff do. It is also essential that customers are shielded from the disruptive consequences of change.

To be fair, the challenges of running a large, complex and far-flung organisation while simultaneously seeking to improve it and make it more responsive to market pressures are considerable. And Fonterra must meet the many challenges of its day-to-day operations and long-term transformation while competing in the world economy.

### Escalation

The failure at numerous points before 2 August 2013 to refer matters upwards, whether at all or to an appropriate management level, was one of the most perplexing elements of the Inquiry's investigation. Five points in particular stand out as offering distinct opportunities to halt or change the momentum of events. They were the failure to:

- Notify Hautapu's on-call plant manager immediately, as procedure required, after the plastic contamination

- Refer the feasibility of a novel reworking to more senior and experienced managers for a risk assessment
- Refer a Darnum complaint about a serious quality problem with the reworked WPC80 to senior management in Fonterra's product assurance and standards team in the group's corporate head office
- Notify senior management of the decision to commission *C. botulinum* testing on 21 June
- Advise the chief executive and board of the formation of a critical event team, which met on 24 July.

Better (or indeed any) communication at any one of these points might possibly have halted reworking or *C. botulinum* testing (or at least ensured it was carried out as a diagnostic test). Or, had escalation occurred earlier, steps might have been taken to prepare for a recall (or put products on hold) while awaiting test results.

Two missed opportunities stand out. The first was when Fonterra did not informASUREQuality or the ministry that it had commissioned *C. botulinum* testing on 21 June. This might have provided Fonterra with valuable guidance about whether the testing should take place, and if so by whom. The second was when Fonterra's critical event team met on 24 July, in the knowledge that early test results had not ruled out a risk of *C. botulinum* and mouse bioassay testing was about to begin.<sup>29</sup> As the first report noted, early notification of potential food safety problems to the ministry is essential.

The question remains: why, at so many points along the way to 2 August 2013, was there a failure to communicate with, or seek advice from, others, especially interested parties inside and outside the company or more senior managers? The Inquiry has thought long and hard on this point, not least because many individuals involved could not themselves provide an answer, satisfactory or otherwise. The Inquiry concluded that a range of factors combined to create the obstacles to effective communication and escalation outcomes, including the silo mentality and restructuring pressures just

<sup>28</sup> See discussion section 8.

<sup>29</sup> See discussion section 10.

mentioned, along with the absence of a food safety culture that placed emphasis on the free flow of information (a matter discussed below).

Fonterra has since made changes to promote more open dialogue, improved escalation reporting and better follow-up on food safety problems, real or potential. Revised escalation procedures, which are discussed shortly, have been making a difference, according to staff.

### Food safety: process and practice

What sort of food safety system did Fonterra have in place at the time of the incident? Was it sound and was it consistently implemented? Or did food safety, and consumer interests, take second place to production targets? The Inquiry both asked and heard these questions repeatedly.

The Inquiry is satisfied that Fonterra's food safety system was, on the whole, sound. However, the Inquiry found serious deficiencies in practice that can be put right only by cultivating a stronger food safety culture at all levels of the organisation. The best-documented processes are of little use unless put into practice.

Like all dairy processors, Fonterra had then, and now, risk management programmes, the centrepiece of the dairy regulatory system to manage hazards and risks, including those related to food safety. These are regularly audited by third-party verifiers paid by the dairy company.<sup>30</sup>

At the time of the incident, the Fonterra Quality System was the mechanism by which the company ensured that its business units, such as NZMP, produced safe, quality food.<sup>31</sup> That system continues to be the principal means of meeting quality and safety standards, albeit with subsequent modifications, as outlined below. The three-tier system comprises outcome-based standards (to which business units must demonstrate compliance), reference documents (describing how to achieve the required outcomes) and operating procedures (which business units must follow to ensure the

implementation of standards). Fonterra, particularly Hautapu staff, emphasised that food safety was encompassed within the food quality framework.

The system put responsibility for food safety and quality in the hands of each business unit. A quality co-ordinator was accountable for each site's products. At the time of the incident, the quality co-ordinator's role was advisory only. One interviewee said such staff got "little air time" with senior operational managers. Regionally located microbiologists were – and continue to be – responsible for investigating food safety and related matters, as well as carrying out any related trace-back work. Several interviewees emphasised the importance of on-site microbiologists in monitoring food safety.

The Inquiry identified the following deficiencies in relation to processes:

*Leadership:* In April 2013, Fonterra established the food safety and quality council, a subcommittee of its management team. The subcommittee's roles were: to champion food safety and bring about a culture change; to investigate and manage emerging food safety risks; and to oversee business units' compliance with their food safety and quality obligations. However, as the company acknowledges, the council had by August received limited commitment from Fonterra's senior management team and was far from implementing its objectives.

*Performance indicators:* There is no doubt that the site, plant and process managers understood the importance at all times of delivering "safe, consistent and quality products [to] customers".<sup>32</sup> However, key performance indicators at plants were framed in terms of food quality and did not specifically refer to food safety. Indicators measured "first-time gradings" (to use the industry term), that is, how often a product was manufactured first time round to customer and regulatory specifications and did not need reworking. At the time, Hautapu was achieving a 95 per cent result for first-time gradings. Indicators also measured the direct business costs of

<sup>30</sup> See discussion of risk management programmes; first report at 20 and 29-34.

<sup>31</sup> Fonterra Quality System: [fonterra.com/nz/en/sustainability/quality](http://fonterra.com/nz/en/sustainability/quality).

<sup>32</sup> Hautapu business plan for year ending July 2012.

a quality failure. Among these tangible, measurable production objectives, there was no recognition of the more intangible but important objective of ensuring food safety.<sup>33</sup>

**Self-assessments:** In March 2013, after publication of new quality standards, business units were told to carry out self-assessments to identify any gaps in compliance with those standards. Notably, NZMP had not done this by the July deadline. The self-assessments were a first step to achieving a general measure of compliance, without committing extra resources for conventional compliance audits. Yet auditing is central to a sound food safety system.

**Training:** Staff training in food safety and quality was variable. Fonterra acknowledges “some sites were better at it than others”. Nor was the training freely shared with other sites and it tended to have a strong technical, rather than a behavioural, flavour.

**Escalation:** The DCD incident highlighted the need for Fonterra to have mechanisms to notify senior managers promptly about potential food safety, quality and regulatory risks so they could evaluate and manage them. By June 2013, a group set up for this purpose had developed the relevant mechanisms, but again, putting those procedures into practice fell far short of what was needed when a real crisis emerged soon afterwards.

This last point underscores an important wider issue. It is one thing to have food safety systems and processes in place, but quite another to have a workplace culture that puts conscious emphasis on food safety, day after day, against all circumstances and pressures to do otherwise. As one staff member noted: “A food safety document is only any good if it’s followed and changes workplace behaviour.” Indeed, a culture shift, as noted by the Inquiry at the first stage, would be one of the most effective ways of preparing New Zealand’s dairy industry for future challenges.<sup>34</sup>

Some interviewed by the Inquiry expressed the view that Fonterra is tougher on its farmers than it is on itself when it comes to food safety and quality. Farmers, they said, must comply with strict quality standards or else face penalties, and Fonterra’s processing plants should be held to the same exacting standards. Whether or not that is justified, Fonterra should at least recognise that some hold this viewpoint.

Overall, it is the Inquiry’s view that, although the company is by no means alone in this, it had done little at the time of the incident beyond the formal establishment of systems and processes to foster such a food safety culture. Fonterra also acknowledges this. It recognises that its board and senior management could have done more to elevate the profile and priority of food safety. The question is whether the Inquiry can be satisfied that, as a result of the incident, Fonterra is now committed to a stronger culture of food safety and quality. From changes already under way and the determination with which Fonterra is implementing them, the answer is yes.

### Food safety culture

The concept of a food safety culture is still emerging worldwide – that much is clear to the Inquiry from its many interviews and its literature search. Many companies have come to recognise the importance of a health and safety culture, but the same cannot yet be said of food safety culture. However, producing safe food is, as noted in the first report, critical to public health and New Zealand’s economy and prosperity.

Creating a food safety culture is not a solo affair. It requires the application of best science with best management and best communication systems. The third dictates compelling, rapid, relevant, reliable and repeated food safety messages using a variety of mediums.<sup>35</sup> The authoritative text on the subject is generally regarded as *Food Safety Culture: Creating a Behavior-Based Food Safety Management System* by Frank Yiannas.<sup>36</sup>

33 Key performance indicators did not take into account whether a plant was making commodity or specialist products.

34 First report at 48-49.

35 D Powell, C Jacob, B Chapman, Enhancing food safety culture to reduce rates of foodborne illness, *Food Control*, vol 22:6, 2011 at 817-822.

36 Springer, New York 2009. Yiannas was Walt Disney World Corporation’s Director, Safety and Health, for 19 years. In 2008, he became Walmart’s Vice-President – Food Safety.

The United States expert's main point is very simple: companies must create a food safety culture, not just a food safety programme. As Yiannas says, "to improve food safety ... you must change the way people do things". Put simply, "food safety equals behavior". He spells out six core elements necessary to achieve this: see inset at 28.<sup>37</sup>

In the Netherlands, Graeme Armstrong makes a similar point. A food safety culture goes beyond the predictable building blocks (regulatory compliance, standard operating procedures, policies, training and auditing) to include communication, awareness of responsibilities, management commitment and a holistic view that everything in an organisation affects food safety.<sup>38</sup> Changing the culture, he says, will lead to changes in frontline behaviour.

Readers may also find useful Debby Newslow's recent publication, *Food Safety Management Programs: Applications, Best Practices, and Compliance*.<sup>39</sup> Her textbook examines every aspect of food safety, including existing food safety certification systems.

Like Yiannas, Newslow emphasises the need for a food safety management "system" (including culture). For her, the three essentials are internal audits, corrective and preventive actions and management review. As she says, "the road to compliance is not sugar-coated, but it is worth the effort".<sup>40</sup>

Closer to home, a group of Massey-based experts recently conducted a survey to identify the most important factor in implementing a good food safety culture. The finding (valid despite relating to the non-regulatory area) was commitment by top management. Second was employee attitude and commitment, and third was food safety knowledge.<sup>41</sup>

A food safety culture must take precedence over other competing priorities.<sup>42</sup> Cost-cutting at the expense of food safety clearly has the potential to do significant damage to a company's reputation and bottom line. As one interviewee said: "The cost of a product downgrade to eliminate risk is nothing next to the cost of a loss of reputation." The Inquiry would add, in New Zealand, the whole industry and indeed country's reputation can suffer.

Companies should not see food safety as a cost, but rather as an investment. As one commentator has observed: "Food safety can be used as a selling point. The food businesses that use the best science to promote microbiological food safety, and couple that with employee commitment, will capture the imagination of a hungry public."<sup>43</sup>

The growing consumer awareness of food safety is reflected in the popularity of books such as Eric Schlosser's *Fast Food Nation* and Michael Pollan's *The Omnivore's Dilemma*. This is borne out by a Michigan State University study that found "consumers are not only aware of food safety issues, they are actually changing their shopping habits due to food safety concerns".<sup>44</sup>

Yiannas notes, too, the growing interconnectedness of the global market. "Today, the way we get our food from farm to fork, the food system, has evolved into an increasingly complex network interdependent on many businesses, sectors and individuals ... As our global community expands, the business of moving food from the farm to the dinner table has become increasingly complex. Food is being distributed further than ever before, sometimes from one distant country to another, and foodborne disease outbreaks have the growing potential of being widespread."<sup>45</sup>

37 Ibid at 1.

38 G Armstrong, Towards integrated hygiene and food safety management systems: the Hygieneomic approach, *International Journal of Food Microbiology*, vol 50:1, 1999 at 19-24.

39 Fn 1.

40 Ibid at xxi.

41 E Chen, S Flint, P Perry, M Perry and R Lau, Implementation of Non-Regulatory Food Safety Management Schemes in New Zealand: A Survey of the Food and Beverage Industry, *Food Control*, vol 47, 2015 at 569-576. Although relating to retail food establishments, another survey reported that the most important factors for developing a food safety culture are management commitment and worker food safety behaviour: J Neal, M Binkley and D Henroid, Assessing Factors Contributing to Food Safety Culture in Retail Food Establishments, *Food Protection Trends*, vol 32:8, 2012 at 468-476.

42 C Griffith, K Livesey and D Clayton, Food Safety Culture: The Evolution of an Emerging Risk Factor, *British Food Journal*, vol 112:4, 2010 at 426-438.

43 D Powell, a professor at Kansas State University, quoted by T Lytton in *Kosher: Private Regulation in the Age of Industrial Food*, Harvard University Press, Cambridge, Massachusetts 2013 at 145.

44 DNV and Michigan State University findings on United States food safety, quoted by T Lytton, *ibid*.

45 Fn 36 at 2-3.

### How to foster a food safety culture

To set up a food safety programme in a company is one thing; to have a food safety culture in that company is quite another. What separates the two? The emphasis on employee behaviour. In the first, it is largely a by-product of the system's operation; in the second, it stands centre stage.

Food safety expert and author Frank Yiannas says the hard science of food safety (microbes, processes, contamination prevention protocols and so on) is well documented and greatly emphasised, with the result that too little is made of the effect of human behaviour and culture on food safety.

Six key features of a strong food safety culture are:

**Leadership:** A food safety culture starts at the top and flows downwards. Senior management must create the food safety vision, set expectations and inspire others to follow.

**Middle managers:** They must visibly show their support for this vision and demonstrate their commitment to food safety in practical ways.

**Employee confidence:** Staff must be certain the company values food safety. That means managers must prove it by "walking the talk". Actions, not words, count.

**Accountability:** All employees must understand what they are expected to do to uphold food safety standards – and be held accountable for their performance. Going through the motions is not enough. Employees must believe in, and be committed to, food safety.

**Communication:** There must be regular sharing of information, in a way that not only educates but persuades employees to take action. This goes beyond mere training.

**Guidance:** There must be practices in place to channel, encourage, reward and reprimand behaviour, as appropriate. All these practices, taken together, form a food safety system that focuses as much on people as processes. The best-documented food safety processes and standards in the world, unless consistently put into practice, are "useless".

The Inquiry notes that the Global Food Safety Initiative, with input from the US Food and Drug Administration (FDA), is working on an assessment tool for industry, known as a food safety assessment grid, which it aims to publish in March 2015. A key focus of this tool will be the development of a food safety culture.

In the eyes of many Inquiry interviewees, the enormous strides made in health and safety can teach everyone how to promote a strong food safety culture. It should begin at the board table and spread throughout all levels of a company. One pre-eminent health and safety expert, Professor Andrew Hopkins, can testify to the difference a corporate culture makes. He was asked to help with a United States Chemical Safety and Hazard Investigation Board inquiry into the BP refinery disaster in Texas City in 2005.

In his subsequent book *Failure to Learn: The BP Texas City Refinery Disaster*, Hopkins labels the lack of a corporate safety culture a key factor in the accident.<sup>46</sup> Other factors he singles out – some of which are relevant to the WPC80 incident – include inadequate training; poorly drafted policies and inadequate risk assessments; bonus schemes that encouraged cost-cutting ahead of safety; cost-cutting that limited the capacity to respond to lessons from earlier incidents; a decentralised structure that undermined process safety; leadership that failed to set a proper tone towards safety; and finally, inadequate regulatory oversight.

Hopkins repeats the point that operator error is better seen as a starting point for any inquiry than an explanation in its own right. Companies can be quick to blame individuals. But asking why operators made the mistakes they did brings into view a host of factors of far greater importance from a prevention perspective. What is needed are effective organisational practices to encourage the reporting of incidents and allocate resources to make safety systems work successfully.<sup>47</sup>

<sup>46</sup> CCH Australia, Sydney 2010.

<sup>47</sup> Ibid at 7.

Some simple, instructive advice can be found right at our doorstep. The Ministry of Business, Innovation and Employment's *People Come First: Building a strong health and safety culture in New Zealand mines, quarries and tunnels* offers some clear, practical guidance about how to establish and promote a safety culture. It suggests five interconnected courses of action: build trust and respect; lead by example; communicate clearly; involve everyone; and keep learning.<sup>48</sup>

It is perhaps surprising, but nonetheless pleasing, that KPMG's *Agribusiness Agenda 2014* contains food safety questions for the first time in its five-year history.<sup>49</sup> Even better, survey respondents attributed high "strategic importance" to food safety.<sup>50</sup> There can be little doubt that the WPC80 incident has, at a minimum, brought home to the industry the critical importance of food safety. As the KPMG report notes, food safety scares "are a constant and inherent risk to New Zealand's reputation" – a fact of life everyone in the primary sector needs to bear in mind at all times.<sup>51</sup>

A food safety culture won't happen overnight. It takes time and nurturing. Newslow describes it aptly as a "journey".<sup>52</sup> What this incident has underlined is the importance of ensuring everyone in the food industry understands this point. If Fonterra's food safety culture had been on a par with its health and safety culture, this incident would probably not have happened.

### Fonterra's improved food safety system

The incident was a watershed moment. Fonterra realised in a most profound way that food safety was the one thing without which it was impossible to achieve any other company priority, whether continued sales and profits, a sound reputation, strong consumer confidence or a secure future on the world stage. With that realisation came a root-and-branch reappraisal of all facets of its operations. Food safety is now assuming its rightful place in the top tier of Fonterra priorities. The company, however, still has a way to go.

Some of the changes initiated in the wake of the incident have already been described. They form part of a comprehensive programme of work under way to ensure, in the words of one Fonterra manager, that "food safety and quality are hard-wired into the start and end of everything we do". It is the start of the company's journey to establishing and maintaining a strong food safety culture.

This work extends not only from the start to the end of all manufacturing and other processes, but also from the top to the bottom of the company structure – beginning at the top. As the Inquiry noted in its first report, developing a food safety culture begins at the highest level of an organisation.<sup>53</sup>

Food safety is now, in the words of one board member, emphatically one of the "top two agenda items" as the board strives to achieve a food safety culture, not just a programme of food safety. The Fonterra board has now established a risk committee with governance oversight of risk management, including food safety and quality risk. Board charters have also been amended to reflect the paramount role of food safety and quality.

A senior position has been created to focus solely on food safety and quality policies, processes and metrics. The group director of food safety and quality reports to the chief executive and chairman of the board's new risk committee. The food safety and quality council now has more commitment from senior management, as it rightfully deserves.

The chief executive has given priority to instilling in staff the central place of food safety, with regular updates to employees about food safety-related topics: see inset at 30. The message has been getting through that Fonterra is in the business of making food and that consumer safety comes first. This might seem obvious, but to staff who work in the automated, stainless steel environment of a modern dairy plant, it is a message that can easily be forgotten.

48 September 2013. See also the Institute of Directors, *Good Governance Guideline for Managing Health and Safety Risks*, May 2013.

49 KPMG *Agribusiness Agenda 2014*.

50 Ibid at 15.

51 Ibid at 41.

52 Fn 1 at 20.

53 First report at 49.

All employment contracts for senior staff now include clauses about food safety and quality. Importantly, dairy plant managers now have three key performance indicators relating specifically to food safety. One recognises that “escalation and transparency are mandatory”, the second that “food safety compliance is not to be compromised” and the third sets food safety objectives specific to each manager and his or her plant.

Escalation procedures have been much improved. Incidents are now referred to one of three teams:

- *Business unit critical event teams*: short-term incidents are the focus for these teams, which review incidents from a site or plant and refer serious events to the incident management team.
- *Incident management team*: this team was formed to review incidents forwarded by business units and manages the appropriate response, or alternatively refers the matter back to the business unit for resolution.
- *The food and safety quality council*: this body oversees food safety and quality. A team has been set up within it to identify and assess medium and long-term risks, analyse any wider company impact and, if necessary, notify the council.

Assessment procedures (with limited exceptions) are now mandatory for conducting non-standard (or non-routine) testing. The quality and compliance manager must approve the proposal before it goes to the general manager of Fonterra’s product assurance and standards team for approval.<sup>54</sup>

The company has also set up a confidential hotline – in effect, a whistle-blower line – so staff can report any practice or problem with food safety implications.

The Inquiry has considered how these revised escalation procedures would have averted the incident, had it been replayed today. Appendix 4, which contains key moments during the incident and corresponding escalation (and other) processes

in place today, gives the Inquiry confidence in Fonterra’s assurances. The company acknowledges the need to close one gap identified by the Inquiry. At present, the conclusion of a business unit critical event does not mean the problem has been solved, but simply that it has been referred back to the business unit for resolution as part of regular operational duties. The system has no means of checking the result, but Fonterra informed the Inquiry that it is looking at ways to rectify the problem.

In 2013, Fonterra started reviewing its training programmes and assessing their effectiveness, not merely in technical terms but also in their ability to build a food safety culture. The company is conscious that training alone is not enough and that it needs to be part of broader staff education about food safety.

#### From Fonterra’s chief executive

21 March 2014: I heard another good food safety and quality story this week – this one has come from our Te Awamutu site. The pasteurisation status of a tanker was put in doubt when a contractor lifted a lid to check how things were going during loading. Rather than ignore it, the supervisor stopped the pumps, reprocessed the product, cleaned and reloaded the tanker – and still got the product to the customer on time. These actions show that we do not cut corners when it comes to food safety and quality. Well done.

Changes have so far taken place to improve food safety at Hautapu and nine other sites. Hautapu has been certified under the internationally recognised FSSC 22000 standard for the auditing and certification of food safety.<sup>55</sup> As part of certification, the company carried out a complete review of the plant’s HACCP plan.<sup>56</sup> Separately, the company has established a team on site charged solely with food safety. It has also raised the quality co-ordinator role to that of a decision-maker so that he or she has the authority to manage food safety risks, even to the extent of stopping production at the plant when needed. Also, the co-ordinator reports ultimately to the new group director of food safety and quality, not senior operational staff.<sup>57</sup>

54 The form to request approval for non-standard testing requires details of the relevant business unit, the customer affected, relevant testing, reasons for the request, outcomes, and actions and responses in the event of an unfavourable outcome.

55 It is proposed that all other New Zealand sites be certified to this standard by April 2015.

56 HACCP refers to Hazard Analysis and Critical Control Points, principles used worldwide: first report at 10 and 19.

57 This was a specific recommendation of the Fonterra board inquiry report at 88.

The Inquiry observes that, despite these changes, the quality co-ordinator still seems to have insufficient status within Fonterra – and, indeed, the same applies in other food manufacturing companies. Yet such roles are critical to ensuring best practice.

A final change, but perhaps the most ambitious, is the development of a four-year programme to elevate food safety and quality processes, and related staff behaviour, to levels equalling Fonterra's health and safety behaviour and processes. Fonterra expects its "trust in source" strategy to put the company on a path to "becoming a global food company that can be trusted to deliver safe, high-quality dairy food".<sup>58</sup> If successful, it could be a model for other food companies.

### Crisis planning and management

The WPC80 incident has brought home to New Zealand food companies the potential for things to go very wrong very quickly. Among the many lessons to be drawn from the incident is the need for companies and regulators to adequately plan and test their crisis procedures. In that way, their responses to a real crisis can be swift and effective, rather than tentative and ineffectual.

How Fonterra and MPI responded to the crisis is examined in parts five and six. The Fonterra board inquiry has already closely studied, and made recommendations on, the company's crisis planning, management and performance. This report focuses primarily on the ministry's response.<sup>59</sup>

In the Inquiry's view, both could have done better, particularly Fonterra. But their shortcomings provide an opportunity for the food industry and the ministry to learn and lift their performance. The WPC80 incident highlights the necessity of acting on the following aspects of crisis planning and performance for all New Zealand food businesses:

*Preparedness:* Things happen fast: there is seldom time to plan a response, just time to implement it, making preparation the key.

*Protocols:* Everyone must know instinctively the procedures to follow in a crisis, which comes only from training.

*Risk assessment:* Sound decisions depend on getting and assessing the best available information and following risk management principles.

*Decisions:* Everyone must know who will make the key decisions. Otherwise, there is the risk of incoherent decision-making and general confusion.

*Co-ordination:* A food safety crisis invariably involves many organisations. Without effective co-ordination (especially over the release of information to the public and media), there is a risk of undermining a single, integrated response.

*Tracing:* Companies must have information at their fingertips to enable the rapid tracing and recall of products: tracing systems must be more sophisticated than in the past.

*Communications:* Good crisis communications are essential. Mainstream media outlets will always have a powerful role to play in disseminating information, but too often organisations overlook the usefulness of social media channels.

*Evaluation:* Every crisis must conclude with an examination of what worked and what did not. Otherwise, there is no way to learn and improve next time.

As the *KPMG Agribusiness Agenda 2014* report emphasised: "Whichever company is unlucky enough to be at the eye of the storm [next time] will need to get their crisis management right or the whole industry will feel the consequences."<sup>60</sup> The Inquiry wholeheartedly agrees.

<sup>58</sup> The full title is "Trust in source: looking after what matters most to our customers and our consumers".

<sup>59</sup> Fonterra board inquiry report at 8-11 and 30-34. Appendix H of the Fonterra board inquiry report is a paper commissioned from Professor Hallman and colleagues at Rutgers University, New Jersey, outlining best practices in food crisis communications.

<sup>60</sup> Fn 49 at 40.

### Collaboration and capability

The dairy sector must increase its capability and expand its collaboration if it is to protect its world standing, lift its food safety performance and provide a sounder springboard for growth.<sup>61</sup> This point was emphasised in the Inquiry's first report. It deserves further mention in this second stage, especially the need to boost the number of people who understand how dairy processing works.

Many interviewees again expressed concern about the continuing lack of dairy industry knowledge and expertise within the ministry's ranks, especially at the operational level. A high proportion stressed that experience in the meat sector is no substitute for experience in the dairy sector. The same was said of biosecurity and food safety experience. Recruiting staff with dairy expertise is not easy, but, as the first report observed, the Government's goal of doubling primary sector exports by 2025 will not be easily achieved unless the ministry can lift dairy capability.<sup>62</sup>

The ministry has convened a working group, as recommended by the Inquiry, to develop a strategic plan to increase dairy capability industry-wide, including within MPI's own ranks. This plan will include short and long-term measures. In the interim, the ministry has extended one official's secondment with a dairy processor. However, the Inquiry senses from the industry that the ministry needs to make increased dairy capability a higher priority.

As to collaboration, the Inquiry continues to believe that dairy companies, the ministry and verifiers need to act in a more co-operative manner if the sector is to have a greater chance of achieving its goals.<sup>63</sup> One interviewee said a yearly round-table meeting of government and industry representatives to discuss trends and challenges to food safety would be of real benefit. The new Food Safety and Assurance Advisory Council could consider leading a summit once a year for this purpose.

An example of the very sort of collaboration the food sector needs is the New Zealand Food Safety Science and Research Centre, currently in the process of being established. The Government has committed \$2.5 million a year towards set-up and research costs, with an immediate \$500,000 to cover initial costs. The food industry, however, has yet to commit its half share towards the \$5 million annual cost for the next five years, with support varying across sectors. Those already committed include Fonterra.

The Inquiry understands the financial pressures on the food industry, but \$2.5 million represents a fraction of the economic loss and damage to reputation that a food safety incident can cause – and that the centre will help to prevent. Such a centre is long overdue, especially considering food exports account for half (\$25 billion) of New Zealand's annual exports and that similar centres have existed for many years in other countries. It will also create a real opportunity for collaboration with food safety research institutes in countries such as China that are important markets for food exporters.

Some interviewees suggested that, in the longer term, the centre's scope could be widened to that of an umbrella organisation for all food safety research – including, for example, that funded by the Primary Growth Partnership fund and the Ministry of Business, Innovation and Employment. There may well be eventual merit in such an expansion of the centre's scope, but in the meantime, the priority should be to get the centre up and running. As one interviewee put it, the first step is to "get some runs on the board".

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<sup>61</sup> First report at 23.

<sup>62</sup> Ibid at 24.

<sup>63</sup> Ibid at 27.



## PART FOUR: THE CAUSES OF THE INCIDENT

The chain of events that prompted Fonterra to notify *C. botulinum* on 2 August 2013 is on one level complex. But with the benefit of hindsight, and after speaking to the key individuals who have reflected on events, the Inquiry is satisfied that the main causes of the incident can be readily identified and understood. The lessons inherent in this part of the report should be of interest to many. Specific suggestions for the industry, ministry and auditors also follow. For those wanting an overview of key events, a chronology is provided as an addendum.

### 7. Hautapu

#### A torch breaks

During the manufacture of WPC80 on 1 February 2012, an abnormal pressure reading on a dryer led the operator to suspect a blockage. Taking a torch, he shone it down an air intake pipe to check for obstructions. The strength of the suction inside the pipe pulled the operator's hand towards the pipe's opening and the torch hit the side of the pipe, breaking the plastic lens.

The operator recovered the lens pieces he could find and notified the shift team leader. Instead of following procedure and informing the on-call plant manager, the team leader continued production, believing that any missing lens pieces would be too large to pass into the WPC80 through the fan, radiator and static fluid bed.<sup>64</sup>

Plant staff reviewed the incident on 2 February. They reassembled the broken lens and established that two pieces were missing. Production stopped while they conducted a full inspection of plant machinery. Fragments equivalent to one of the two missing pieces were found on the radiator. Plant staff determined that the final missing piece was wedge-shaped and 15 x 25 millimetres in size. Production resumed for a short period.<sup>65</sup>

The plant manager and quality co-ordinator decided there was a risk, albeit low, that the missing piece could have finished up in the powder.<sup>66</sup> They followed procedure and filled out a critical exception report, which classified the incident as a "category B" event (foreign matter contamination of more than two millimetres in any dimension). As a category B event, it had to be referred to AsureQuality as the company's verifier.<sup>67</sup> Hautapu was several days late in reporting the incident to AsureQuality on 8 February.<sup>68</sup>

The potentially contaminated powder was packed and put to one side, labelled as ciphers GW02 and GW03, pending a product disposal request to AsureQuality for approval of Fonterra's proposed action to rectify the problem. A total of 42.05 tonnes was affected: 18.2 tonnes manufactured during three drying, or production, runs on 1-2 February and 23.85 tonnes manufactured earlier and stored in bins into which the later production was mixed. If production had ceased when the torch broke (and a thorough clean of the equipment carried out), only 16.4 tonnes would have been

<sup>64</sup> The spacing between the radiator fins is less than 3mm and the diameter of the airflow perforations on the floor of the static fluid bed is 0.75mm.

<sup>65</sup> After the torch was broken and before the inspection on 2 February, 12.1 tonnes were produced. A further 2.7 tonnes were produced after the inspection and before the dryer and fluid bed received a full clean (their first since before the torch was broken).

<sup>66</sup> The quality co-ordinator was called the product safety co-ordinator at the time.

<sup>67</sup> If Fonterra had determined that no fragment could be more than 2mm, it could have classified the incident as a "category A" event and dealt with it internally.

<sup>68</sup> Relevant reporting rules require notification of critical exception reports within 24 hours.

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affected, or 3.4 tonnes if staff had placed the contaminated powder to one side.<sup>69</sup>

In establishing the precise quantities of potentially contaminated powder, the Inquiry differs in three respects from findings in the Fonterra board inquiry report and the prosecution facts. First, the torch was broken on 1 February, not 2 February. Secondly, the plant produced 3.4 tonnes (not one tonne) before the torch was broken. And thirdly, the plant produced 14.8 tonnes, not 41.05, between the torch breakage and production ceasing.<sup>70</sup> On further examination, Fonterra agrees with these points.

Not long afterwards, Fonterra installed a grate on the end of the fan in the air intake pipe to prevent objects from falling through.<sup>71</sup> The team leader received product safety coaching, and the lessons from the events of 1-2 February were relayed to other shifts at Hautapu.

### Reworking the contaminated powder

#### *First request*

On 20 February, Fonterra submitted a product disposal request form to AsureQuality. This form can seek approval for a variety of actions, ranging from reclassifying the intended use of a product, to restricting the markets in which it is sold, reworking the product, disposing of it as stockfeed or destroying it. In this instance, Fonterra sought approval to supply the 42.05 tonnes of powder to restricted markets.

In response to a request from an AsureQuality auditor to clarify its intentions, Fonterra explained that it wanted to prevent any sale of the powder to the Japanese market. One segment of that market had specific medical needs. Reclassifying the powder to lower “general market” specifications would have the effect of excluding it from sale to Japan.<sup>72</sup>

The auditor, after visiting Hautapu in early March, indicated that he would approve the request because the powder was unlikely to be contaminated with plastic – or at least with plastic fragments more than two millimetres in size. His recommendation, however, was subject to peer review and two senior auditors rejected it. First, a request to supply to “restricted markets” was beyond AsureQuality’s scope to approve, since only the Ministry of Agriculture and Forestry (MAF)<sup>73</sup> could grant such approval.<sup>74</sup> Secondly, the peer reviewers could not see how simply preventing the sale in a particular market would deal with the risk of contamination, which, if permitted, would merely – and inappropriately – shift any risk to other markets. The Inquiry agrees.

On 12 March, AsureQuality suggested Fonterra provide further details in support of an application for unrestricted use – grounds on which it could grant approval without MAF’s involvement. However, Fonterra did not want to apply for unrestricted use and asked AsureQuality to refer the request to MAF without amendment. AsureQuality did so, but withheld its support, expressing concern “that the company [was] not confident that there [was] no foreign matter in the product and therefore [we do] not support this option and think ... further processing with filtration may be more appropriate”.

On 16 March, MAF declined the disposal request. AsureQuality notified Fonterra and suggested it “reconsider other product disposal options, for example, further processing”.

#### *Second request*

On 30 March, Fonterra submitted a revised request to AsureQuality seeking approval to rework the WPC80; alternatively to use it for stockfeed or to destroy it. Fonterra’s intention was to remove a suspected foreign matter contamination and release

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69 The 3.4 tonnes could have been set aside in one empty storage bin, but in line with normal practice it was placed in a bin containing 13 tonnes of powder of the same specification and so 16.4 tonnes were contaminated.

70 The Fonterra board inquiry was unaware that the 14.8 tonnes, along with the extra 2.4 tonnes it had not accounted for before the torch broke, had been combined with the 23.85 tonnes produced earlier and stored at the plant.

71 Fonterra has grates at some sites, but not others. For those sites where it is impractical to install grates, it has since reinforced the need for all staff to notify the plant manager immediately any food safety issue arises in production.

72 One use of WPC80 for Japanese customers required application via feeding tubes that could be blocked by particles more than 2mm. Fonterra conservatively decided not to supply the Japanese market, despite believing no particle would exceed 0.75mm.

73 Now incorporated within MPI.

74 Animal Products (Disposal of Non-conforming Dairy Material or Dairy Product) Notice 2010 No 2.

the WPC80 for “unrestricted use”, that is, without constraints on markets into which it could be sold.<sup>75</sup>

The preferred first option sought approval “to wet rework this product at Hautapu factory 1239 [the WPC plant]. Product to be filtered through a 300mm [sic – 300µm/micron] filter then evaporated and dried”. No more detail was supplied, but the Inquiry established that such brevity, when making rework requests, appears to be standard practice in the industry. Sometimes, the company might discuss a rework plan with an auditor, but not on this particular occasion.

### Key events

1 February 2012	Torch breaks; production continues; 42.05 tonnes of WPC80 affected
16 March 2012	MAF rejects first product disposal request, to supply WPC80 to “restricted markets”
11 April 2012	AsureQuality approves second request to “wet rework” WPC80
2 May 2012	Hautapu prepares rework plan, but does not follow risk management programme
15-18 May 2012	Reworking takes place; two hoses and a pipe inadequately cleaned and SRC contamination occurs
17-22 May 2012	Hautapu packages 37.8 tonnes of contaminated WPC80 and gives it cipher numbers JW17, JW18 and JW22

At the time, staff at Hautapu had not prepared a detailed rework plan. The proposal for a “wet rework” (turning the powder back into slurry before beginning the filtering processes) meant that the company would have to use the SCUF plant because the WPC plant could not reconstitute the powder in this way. The request contained no mention of this fact. It referred only to the WPC plant. Such use of the two plants was novel and outside Hautapu’s risk management programme. AsureQuality approved the request without further question. Hautapu’s verifier was unaware of the departures from the risk management programme.

### The reworking

Staff scheduled the novel reworking for mid-May. The process manager and quality co-ordinator were both on leave. Therefore the manager of the WPC and SCUF plants, who had been only recently appointed to the role, asked the WPC production supervisor to prepare a detailed reprocessing plan using experienced staff from both plants.

The rework plan was an adaptation of a process used to rework hydrolysates in the SCUF plant. Reworking hydrolysates was relatively common at the time; reworking WPC80 was not. After the WPC80 powder had been turned into slurry at the SCUF plant, the slurry would be sent to the WPC plant for filtration, evaporation and drying.<sup>76</sup> Transfer from one plant to the other involved use of two flexible hoses and a fixed 25-metre section of a stainless steel pipe to bypass two unnecessary stages of standard WPC manufacturing processes.<sup>77</sup> The plan also proposed using a third flexible hose to bypass an unnecessary stage of the hydrolysate rework process.

The plan outlined no procedures for cleaning the flexible hoses or the fixed pipe.<sup>78</sup> Yet the fixed pipe had not been used in two years, a fact neither noted in the plan nor discussed among the staff preparing the plan. The flexible hoses had been used only intermittently over the same period. Only standard clean-in-place (CIP) processes were contemplated.<sup>79</sup>

The WPC production supervisor did not need approval to proceed with the plan. Nonetheless, he sought comment from a quality co-ordinator from another plant, who was standing in for the co-ordinator on leave, asking: “Is this info here going to fly for a plan to do rework[?] [!]t is not a common thing.” Her response was merely to direct the production supervisor to “have a look” at the rework section of the company’s operating manual, the *Fonterra Standard of Excellence on Good Manufacturing Practice*, and to keep good

<sup>75</sup> Ibid.

<sup>76</sup> Under the plan, a 250 micron filter was to be used, rather than the 300 micron filter referred to in the product disposal request.

<sup>77</sup> The full length of the pipe was 120 metres, of which 25 metres formed a section connecting the SCUF and WPC plants. This is why the Fonterra board inquiry report and the prosecution facts referred to a 25-metre pipe.

<sup>78</sup> The pipe remained in place to be used periodically. After the incident, Fonterra decommissioned it.

<sup>79</sup> This is an industry term for the automated, day-to-day cleaning processes: “clean in place” or CIP.

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records. Section 3.5 of the manual states that any reworking should take account of a range of factors, including “limitations on [the] amount of rework to be used”, “reprocessing steps” and “special handling requirements”.

Neither the plant staff who prepared the plan nor the quality co-ordinator who reviewed it noticed that the reworking would fall outside Hautapu’s risk management programme and staff would need to follow Fonterra’s change control procedure.

In July 2011, Fonterra formally adopted a new procedure to deal with any changes with “the potential to introduce a new, or increase an existing, health and safety hazard or [that] could affect product quality”.<sup>80</sup> When triggered, the procedure required staff to complete a formal change request (specifying what modifications would occur) and to perform a risk assessment, assisted by relevant experts. As at July 2012, Fonterra had not included reference to this new procedure in section 3.5 of the operating manual.

It is clear to the Inquiry from many interviews that this new procedure was little known within Fonterra in 2012. No one at Hautapu had received training in it. To the extent that staff were aware of it, some regarded it as best practice – as discretionary, not mandatory – and others as applying to significant modifications to plant, a category that did not, in their view, extend to use of flexible hoses. As a result, there was no change request: the new procedure was not followed.

The Inquiry was informed it is usual for auditors to ask about any changes to the risk management programme at quarterly audits. But AsureQuality was not told about the new change control procedure. There is scope for verifiers such as AsureQuality to consider ways to ensure operators bring any new procedures to their attention.

The reworking took place between 15 and 18 May. Beforehand, all plant equipment to be used in the reworking, including the flexible hoses and the fixed pipe, received two automated washes with a caustic solution. There was also a wash between each run and at the end. Fonterra told the Inquiry it was a mistake not to have washed the flexible hoses and pipe with an acid, rather than a caustic, solution. It said the length of time since the pipe and hoses had last been used, together with the risk that product residues were present in them, gave rise to the possibility of contamination. A more aggressive acid wash would have removed the microfilm that had built up in the pipe and hoses.

If staff at Hautapu had followed the company’s change control procedure and carried out a risk assessment, they might have identified a potential microbiological risk and either taken steps to mitigate it or decided against reworking the WPC80 at all.

The WPC80 was packed on 17, 18 and 22 May and coded with the ciphers JW17, JW18 and JW22. Samples were tested – although not for SRC – and the reworked powder was deemed to have met all regulatory requirements as well as customer specifications. The company did not follow best practice, as embodied in the rework “limitations” of section 3.5 of its operating manual, that reworked material should not exceed 10 per cent of any new product batch.<sup>81</sup>

Reworked production is generally blended into new material that is within specification. Fonterra acknowledges that, strictly speaking, it should have followed the 10 per cent guideline. There were two reasons why it did not. First, the guideline was not part of a mandatory written procedure at the time (a gap since closed). Secondly, the reprocessing occurred at the end of a season when there was no finished production with which to blend the reworked WPC80. Had Fonterra followed its own guideline, the incident might not have arisen.<sup>82</sup>

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80 The process applies irrespective of whether changes relate to equipment, buildings, raw materials, processing, packaging or systems and is set out in Fonterra’s *SYSM19, FTO Change Control, version 4*, 22 July 2011.

81 See discussion at 22.

82 If new material had been available, the SRC levels would have been diluted to approximately 10 per cent of the levels encountered, which would have reduced the maximum final SRC level in the Darnum nutritional powder to less than 50cfu/g: see discussion at 40. But, if recall procedures had been triggered nonetheless, the quantity to be traced would have been at least 10 times greater.

Between July 2012 and February 2013, Fonterra sent 37.8 tonnes of the Hautapu WPC80 to customers, including 13.5 tonnes to the company's Darnum plant and 3.6 tonnes to its Waitoa plant. The original 42.05 tonnes of WPC80 became 37.8 tonnes as a result of first, the reworking process itself, and secondly, the consignment of 1.985 tonnes to stockfeed (as part of the normal manufacturing process).<sup>83</sup> The value of the reworked WPC80 was about \$150,000.

In October 2012, in accordance with usual practice, Fonterra advised AsureQuality of the "closure", or completion, of its product disposal request. The document identified the dates of the reworking but contained no other new information. AsureQuality did not check with Hautapu about how it had carried out the reworking.

The Inquiry was told "closures" are simply a routine acknowledgement that a disposal, in whatever form it might be, has gone ahead. But this suggests a need for follow-up checks, especially if the disposal involves a non-standard reworking – something AsureQuality agrees would be useful. Several interviewees pointed out that such a check would probably have exposed the fact Hautapu had carried out the reworking in breach of its risk management programme. This was a missed opportunity to avert the incident.

### Lessons

The events at Hautapu are a cautionary tale for all New Zealand food manufacturers. For it is possible they, too, may one day face choices like those confronting Hautapu in February to May 2012: whether to continue on, assuming it unlikely some fragment or other contaminant will find its way into production, or take no chances and halt processing. Or, to consider whether to do reworking, and if so, how.

Every manufacturing plant is naturally focused on achieving maximum production. It is the way of the commercial world. But what took place at Hautapu

shows there are limits. Production cannot be at the expense of food safety. "Business as usual", as one interviewee described it, cannot be "shifting and processing milk" alone. In fact, nothing can be allowed to compromise food safety. It must be at the forefront of everyone's minds. It must, as the Inquiry has already noted, prevail over all other considerations.

The Inquiry suggests the following lessons can be drawn from events:

*Non-standard equipment:* This is an obvious source of risk and requires extra precautions, especially when equipment (here the fixed pipe and flexible hoses) have not been used for long periods. Food manufacturers should think seriously about the food safety risks associated with using temporary or idle equipment. Fonterra has since removed redundant equipment at Hautapu, while flexible hoses are no longer used in manufacturing.

*Non-standard processing:* This needs great care – but also referral to the right level of management for approval first. Correct escalation ensures a second layer of protection against unsound practices. Fonterra's new policy requires the approval of the plant's quality co-ordinator before any non-standard processing can begin. Requests must specify why the process is considered necessary and the product's intended use and customer. A food safety risk assessment must be carried out. In some cases this may lead to escalation to a critical event team. Other food manufacturers may wish to consider these procedures.

*Risk assessment:* Identifying and systematically managing potential food safety risks are prudent and worthwhile measures. Comprehensive risk assessment is also critical to New Zealand's outcome-based legislation. To be effective, such assessments must be done by capable people – a point Hopkins stresses: risk assessments, albeit for health and safety hazards, "can go totally awry when they are made at the local level, under the

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<sup>83</sup> First bags of WPC off the packer line are routinely bagged as stockfeed due to lack of homogeneity.

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influence of local pressures, and without scrutiny by more competent people”.<sup>84</sup>

For its part, Fonterra has begun a review of every operational process at every plant it owns, whether in New Zealand or overseas, to identify any food safety risks: part of a “back-to-basics programme”. All plants must identify non-standard equipment and update their HACCP plans accordingly. They must also ensure they have reviewed and approved non-standard processes. And they must generally develop a food safety risk “heat map” to demonstrate how they will deal with any food safety risks.

From interviews with many Fonterra staff, it is clear that they want training in good risk assessment processes and the Inquiry encourages Fonterra to provide this. More broadly, it is clear to the Inquiry that Fonterra’s overall approach to risk management suffered from, as one interviewee said, “a lack of resources and commitment” to ensure a “one company approach to risk assessment”. Fonterra’s risk management was described as “fragmented on sites between operational, quality and regulatory assurance teams”.

*Cleaning processes:* Cleaning procedures deserve greater thought and vigilance. Fonterra now subjects equipment left idle for more than 24 hours to various sanitising processes; if left idle for more than 48 hours, the equipment is subject to a full CIP procedure (including an acid wash). Deviations are recorded. Auditing – whether internal or external – of CIP processes must also occur, although the Inquiry detected some uncertainty from Fonterra personnel about whether this auditing is being done. If not, the company should follow this up. More widely, MPI has carried out a review of CIP processes and examined failures in order to determine causes, analyse trends and provide guidance to the industry.<sup>85</sup> A review of dairy regulations under way will consider MPI’s recommendations.

*Specifications:* Best practice demands that all manufacturers ensure their product specifications are consistent with customers’ most rigorous requirements.<sup>86</sup> Fonterra’s ingredient specifications for SRC limits differed from one major customer’s end-product specifications: indeed, no SRC specification for WPC80 applied at that time. Fonterra has now introduced WPC80 specifications that meet end-customer requirements (particularly for infant formula) by including SRC testing. MPI is also reviewing specifications for infant formula and this sensibly extends to the ingredients used in production of infant formula.

Understandably, manufacturing plants will not always know the end use of their products at the time of manufacture, particularly ingredients that are used in many different products. However, despite this, Fonterra is emphasising to staff the need to think constantly of the consumer throughout the manufacturing process.

*Reworking:* Only experienced staff should make decisions about whether to reprocess contaminated material. It needs wise heads, particularly if companies are to avoid the sort of risky improvised reworking that occurred at Hautapu. To add an extra measure of security, the Inquiry considers it would be worthwhile to require a manufacturer to certify in any non-routine rework application (made in a product disposal request) that it will do the reprocessing in accordance with its risk management programme. Although this would simply make explicit what is implicit, it might nevertheless serve as a useful reminder that reworking must comply with regulatory requirements.

It is arguable whether such reworking needs more regulatory controls. Done in accordance with risk management programmes, particularly HACCP plans, reworking should mitigate any risks. These include the risk that diluting such material with new material may complicate any future tracing by greatly expanding the amount of affected product.

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<sup>84</sup> Fn 46 at 50.

<sup>85</sup> MPI, *Review of CIP provisions for dairy processors*, 10 December 2013.

<sup>86</sup> A conclusion also of the Fonterra board inquiry report at 22.

This is a good reason to pause before proceeding with any reworking for microbiological or physical contamination.

As to what are best-practice requirements, that, in the Inquiry's view, is for the dairy industry, the ministry and verifiers to agree. MPI is drafting new notices under the Animal Products Act 1999 specifically for infant formula, and the general feeling of interviewees was that there should be limited reworking of material intended for susceptible population groups such as infants and the elderly.<sup>87</sup>

The Inquiry has previously recommended that verifiers should be more involved in any novel or improvised reworking that requires regulatory approval. Other suggestions are that for non-routine reworking for food safety reasons:

- Product disposal requests should describe reworking processes in greater detail than current practice. This should include a detailed plan, and certification that it complies with the relevant risk management programme.
- If directed by the ministry, a verifier should be on site to supervise any novel reworking.
- Following reworking, the verifier should confirm that the company followed processes properly at the next performance-based audit.

To be clear, any such additional requirements would apply only to rework applications in a product disposal request. The ministry has told the Inquiry it is prepared to review the relevant notice, although it believes the notice is sufficiently flexible to cover the above suggestions.

*Workplace attitude:* Insufficient focus on food safety goes hand in hand with an over-emphasis on the Kiwi can-do attitude, which in this case led to improvisation – a slippery slope, indeed, in food production. As one Hautapu staff member recalled: “The mindset was to make the rework happen.” In place of this get-the-job-done attitude, Hautapu has now adopted a “stop-and-think-first” approach,

as staff described it to the Inquiry. It is an infinitely preferable outlook.

As Hopkins emphasises in *Failure to Learn – The BP Texas City Refinery Disaster*, casual compliance with policies, as occurred here, is a palpable symptom of the absence of an appropriate culture.<sup>88</sup> The Inquiry also notes that a subsequent ministry investigation uncovered a significant number of breaches by Fonterra of the requirement to submit product disposal requests (also critical exception reports and export non-conformances) within the required 24 hours; and indeed the ministry failed to monitor Fonterra or hold it to task for these breaches. The industry needs to comply strictly with reporting times and the regulator needs to enforce this.

*Verification:* More needs to be done to invigorate verification (also known as auditing), which is critical to a well-functioning food safety system. Conducted methodically and with prompt follow-up of results, audits can reveal strengths and weaknesses in a food safety system. The Inquiry has previously reported that independent auditing of the dairy industry, while sound, could be strengthened. Encouragingly, some measures have since been taken.<sup>89</sup>

Auditors stand at the heart of any verification system, including New Zealand's. Put simply, audits must go beyond being the mere ticking of boxes. This second stage has reinforced the Inquiry's view that a greater evaluation component, without compromising independence and impartiality, would be worthwhile to help ensure that auditors are a company's “ears and eyes” in risk detection.<sup>90</sup> Checklists against which audits are currently undertaken can also helpfully be reviewed by the ministry, verifiers and the industry at this time.

Supporting that view is a recent article, *Audits and inspections are never enough: A critique to enhance food safety*.<sup>91</sup> It notes: “Effective audits require more than just a checklist. They require paying attention and thinking. The individual ability of an auditor has

<sup>87</sup> These notices will be issued by the end of 2014. One proposal is that non-routine reworking of ingredients for use in infant formula products will not be permitted without explicit ministry approval.

<sup>88</sup> Fn 46 at 10-12 and 37.

<sup>89</sup> These include notices of direction to verifiers to audit traceability and recall processes; a review of lessons drawn from the incident by verifiers, including CIP processes, sampling, testing and traceability (verifier summits, October 2013 and February 2014); and legislation and policy reviews, including a periodic re-evaluation of risk management programmes: first report at 33.

<sup>90</sup> First report at 41-42.

<sup>91</sup> D Powell, S Erdozain, C Dodd, R Coster, K Morley and B Chapman, *Food Control*, vol 30:2, 2013 at 686-691.

a significant impact on the outcome of the audit. ... Effective auditors must be able to assess risk, particularly in unique situations, and synthesise the information provided to determine effectiveness of the food safety management system.”

The Inquiry’s view is that auditors – both regulatory and third party – also have a role to play in developing a food safety culture. Indeed, the authors of the above article consider that the use of audits to help create and improve a food safety culture holds the most promise in preventing foodborne illness and safeguarding public health.<sup>92</sup> The Inquiry has already recommended in its first report that the ministry and recognised agencies should work together with the industry to identify mechanisms to achieve the desired outcome.<sup>93</sup> The Inquiry notes with interest that the FDA is considering how its auditors can assess food safety culture as part of its new Food Safety Modernization Act programme, and the ministry, auditors and the industry may wish to monitor developments.

*Risk management programmes:* As the Inquiry noted in its first report, the complexity of companies’ risk management programmes (which can run into thousands of pages) remains a concern.<sup>94</sup> Their simplification needs to follow the simplification of regulations (see part six). The latter is still some way off, so companies should not be deterred in the meantime from reviewing their programmes to ensure staff understand them.

Plainly, this was not the case here, with staff failing to follow the change control procedure set out in the risk management programme, a breach for which Fonterra was convicted and fined. Moreover, it is essential that all companies provide their staff with comprehensive training in risk management programmes, without waiting for these to be revised. Time and time again, the Inquiry heard from interviewees that “a document does not make a process”. The Inquiry is pleased to note Fonterra has already started to review, revise and simplify its own risk management programmes rather than wait

for the ministry’s simplification of the tertiary layer of regulation.

## 8. Prelude to a crisis

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### Phase one: Darnum

Fonterra’s Darnum plant is in the small Victorian town of the same name, 110 kilometres east of Melbourne. At the time of the incident, more than 90 per cent of its production was nutritional milk powder.<sup>95</sup> Virtually all its production went to the French multinational Danone to make various infant formula products.

During March 2013, Darnum manufactured 1,688 tonnes of nutritional powder for Danone. This was packed into 17 ciphers (or 17 days’ production). About 75 per cent of the nutritional powder, or 1,266 tonnes, was made using reworked WPC80 from the ciphers JW17 and JW18, at concentrations of between one and three per cent.<sup>96</sup> The amount of reworked powder used was 13.4 tonnes.<sup>97</sup>

Danone’s specifications for nutritional powder included a requirement to test the finished product for sulphite-reducing clostridia (SRC), raised levels of which can point to potential spoilage or hygiene problems.<sup>98</sup> Danone’s specifications permitted a maximum SRC level of 50cfu/g. By late March, testing revealed that 12 batches (from six of the 17 ciphers) exceeded this limit, with one as high as 360cfu/g.

Darnum began an investigation to establish whether raw milk or another ingredient was the likely cause, consulting, among others, FRDC’s food assurance team. Both Darnum and FRDC quickly concluded that an ingredient was the more likely source. Darnum sent samples of the nutritional powder to FRDC for testing and also asked NZMP’s technical account management team responsible for Danone to arrange for testing of JW17 and JW18 samples retained when Hautapu packaged the WPC80.

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92 Ibid at 690.

93 First report at 49.

94 Ibid at 33.

95 Owned by Fonterra Australia, Darnum employs 160 staff and can produce up to 300 tonnes of milk powder a day.

96 Darnum’s 13.4 tonnes of reworked WPC80 consisted of 4.75 tonnes of JW17 and 8.725 tonnes of JW18.

97 Hautapu shipped 13.5 tonnes of WPC80 to Darnum, but 100 kilograms were damaged during shipment and downgraded.

98 See earlier discussion in part two, section 5.

The results Darnum received on 3 April showed SRC levels of between 6,700cfu/g and 8,200cfu/g for JW17 samples, and between 400cfu/g and 800cfu/g for JW18 samples.

Darnum went back to FRDC to request that the centre use a mass spectrometry technique known as MALDI-ToF to establish whether the high SRC levels in the nutritional powder samples indicated the presence of *C. perfringens*.<sup>99</sup> Darnum made the request because Danone's specifications for nutritional powder included the requirement that SRC levels above 25cfu/g trigger testing for *C. perfringens*. And Darnum, facing the prospect of having to write off some of its production, was keen to convince Danone to accept the powder, despite the high SRC levels. Establishing that levels for *C. perfringens* (generally a food spoilage indicator) were low would help its case.

On 15 April, FRDC replied to Darnum that its MALDI-ToF testing indicated the nutritional powder samples "clearly ... contained *C. sporogenes*", a common and naturally occurring bacterium, incapable of producing a toxin. Darnum asked FRDC nonetheless to undertake a round of testing on the JW17 and JW18 samples to confirm that:

- There was no appreciable presence of *C. perfringens* in the Hautapu WPC80
- The high SRC levels were predominantly *C. sporogenes*, the same as that in the Darnum nutritional powder<sup>100</sup>
- The Hautapu WPC80 contained organisms with a profile consistent with the *C. sporogenes* identified in the Darnum powder, establishing conclusively that this ingredient was the source of the problem.

### Conference call

On 23 April, representatives from Fonterra and Danone had a conference call to discuss the out-of-specification production. Before the call, Fonterra gave Danone a report (dated 22 April 2013) identifying the 12 batches from the six ciphers that

exceeded Danone's 50cfu/g limit. Fonterra advised Danone that it had done a "comprehensive trace back exercise" and had identified a "clear and compelling correlation" between the high SRCs and the JW17 and JW18 ciphers. The report identified the other batches in the six ciphers that were under 50cfu/g. With a single exception, none had used JW17 or JW18.<sup>101</sup> It also noted that Fonterra had "cleared sublots compliant with Danone specification criteria". The report did not mention the 854 tonnes of nutritional powder in the 11 other ciphers manufactured in March that had used JW17 and JW18 WPC80 but had given readings under 50cfu/g.

During the conference call, Fonterra recommended that Danone accept all 12 batches, despite their excessive SRC levels, on the basis that it had not detected any *C. perfringens* in them and therefore no food safety risk existed. Discussions and correspondence ensued. Danone refused to accept the batches exceeding 50cfu/g, based on the advice of its microbiologist in Germany, who emphasised the importance of the SRC specification in guarding against infant botulism. Danone shared these comments with Fonterra by email on 25 April. The two parties discussed reworking options. Ultimately, Danone agreed to accept the batches, provided Darnum reworked them and subjected them to intensive testing. In the event, Darnum decided on 7 May to downgrade all 12 batches over 50cfu/g, or about 430 tonnes, to stockfeed.

Fonterra and Danone disagree about the interpretation of the 22 April report. Fonterra maintains that the report – and its request that Danone accept nutritional powder made from JW17 and JW18 powder – related to out-of-specification batches only. Danone says it understood both the report and request to relate to all batches containing JW17 and JW18. It says it did not appreciate at the time that it was receiving any nutritional powder from Darnum containing any of the reworked WPC80.

It is not necessary for the Inquiry to resolve this disagreement for the purposes of this report. What is not disputed, however, is that Danone subsequently received 1,759 tonnes of nutritional

99 The technique produces a protein profile for each organism that is compared against a database containing profiles of known organisms: see part seven.

100 The qualification "predominantly" was used because FRDC had identified other organisms able to grow anaerobically in the samples tested.

101 The one batch that had used JW17 and JW18 tested at 30cfu/g. In the event, it was not supplied to Danone.

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powder from Darnum. This powder was made up of batches that used JW17 and JW18 but tested under 50cfu/g, as well as ciphers that might have contained traces of contaminated WPC80 as a result of normal carry-over or wet-blending manufacturing processes and were also under 50cfu/g.

### Further testing

On 8 May, FRDC, which, in the meantime, had received Danone's microbiologist's advice, gave Darnum the preliminary results of the further testing of the Hautapu WPC80 samples. Its MALDI-ToF test had identified the organism as predominantly *C. sporogenes*, but FRDC said "they 'cluster' close to *C. perfringens*". FRDC also raised the possibility that the organism could be *C. botulinum*, noting that "nothing in microbiology is simple. So, you should also know that a *C. botulinum* is simply a *C. sporogenes* without [sic - with] the toxin gene".

FRDC went on to add that it was "EXTREMELY UNLIKELY that these organisms ... are carriers of the toxin gene" but "we would be derelict in our duty if we did not consider the possibility". FRDC told the Inquiry it reached this view partly because of the concern of Danone's microbiologist, but chiefly because the MALDI-ToF analysis identified the close relationship between *C. sporogenes* and *C. botulinum*. FRDC had initiated inquiries the previous day with AgResearch's Hopkirk research institute in Palmerston North about how to distinguish the harmless *C. sporogenes* from the toxic *C. botulinum*. AgResearch proposed three methods, including a mouse bioassay.

At this time, no one within Fonterra considered whether the JW17 and JW18 powder might have been used in other finished products, or whether any product tracing was needed. Nor did anyone think it necessary to notifyASUREQuality or the ministry that testing for *C. botulinum* might be justified. Fonterra stressed to the Inquiry that its staff considered the *C. botulinum* risk to be remote, and that they simply intended any testing to confirm *C. sporogenes*, given that *C. botulinum* was almost unheard of in dairy products.

### Manufacturing complaint

On 9 May, Darnum advised Hautapu directly of the difficulties its WPC80 had caused and subsequently sent a formal complaint, to the effect that the "excessively high" SRC levels "demonstrate[d] a significant GMP [good manufacturing practice] failure and render[ed] the product unfit for the purpose for which it was supplied". The estimated cost to Darnum was A\$1.1 million.

For its part, Hautapu took the view that it had manufactured the WPC80 to specifications and that Darnum was trying to shift the blame elsewhere for its own mistake, namely, either the failure to have an SRC specification for WPC80 or the failure to have tested the WPC80 itself before use. Hautapu did not regard the complaint as raising food safety questions, although it did recognise the need to investigate what had caused the high SRC readings in the JW17 and JW18 ciphers. It soon traced the problem to the reworking in May 2012, concluding it was in all likelihood due to the use of the fixed pipe and flexible hoses.

### Key events

March 2013	Darnum uses JW17 and JW18 to make nutritional powder for Danone; tests show high SRC levels
April 2013	FRDC testing shows <i>C. sporogenes</i> (not <i>C. perfringens</i> ); Danone rejects powder over 50cfu/g; Darnum downgrades it to stockfeed
May 2013	Darnum complains about NZMP's WPC80 as "unfit for purpose"; FRDC recommends Darnum get AgResearch to <i>C. botulinum</i> test; Darnum tells FRDC no need for testing

On 20 May, the Darnum complaint was logged into Fonterra's complaints system. But the cost of the claim was understated, with the result that the manufacturing failure did not activate the usual escalation processes and senior management remained unaware of it.<sup>102</sup> In late May, during a regular audit at Hautapu, an ASUREQuality auditor noted a complaint in Fonterra's system about high

<sup>102</sup> A narrow view of what was affected meant the complaint was logged as a loss of A\$62,000 rather than A\$1.1 million.

SRC levels in WPC80 powder manufactured there. She told the Inquiry that no details were provided, which was unusual, but did not investigate further because she considered high SRC levels to be a question of food spoilage, not food safety. In the absence of anything more on record, she left, oblivious to how high the SRC levels had been. She was also oblivious to the fact the cause was the reworking, or that Darnum considered there had been a significant hygiene failure with the WPC80, or that Fonterra had breached its risk management programme.

On 20 May, FRDC sent Darnum its full test report. The report said that both the Hautapu WPC80 and Darnum nutritional powder samples contained *C. sporogenes*, but the fact that *C. sporogenes* was *C. botulinum* without the toxin-producing gene raised the question about whether the organism had the potential to be pathogenic. Consistent with its earlier advice, but still reiterating that the risk of *C. botulinum* “appear[ed] to be low”, FRDC recommended screening isolates of *C. sporogenes* taken from the Darnum nutritional powder for any ability to produce the *C. botulinum* toxin. FRDC recommended that AgResearch be contracted to carry out a mouse bioassay of three isolates at a cost of \$2,000 a sample. The alternative, it said, was to “withdraw the product in question from the infant food chain”.

However, on 25 May, Darnum told FRDC that “all product affected by this incident has been rejected by Danone and has been withdrawn for sale as either stockfood or edible disposal for general population. That is, all product has been withdrawn from the infant food chain”. There was therefore no justification for the *C. botulinum* testing. The email’s author told the Inquiry that by “all product affected” he meant all nutritional powder that was outside specification and had been rejected by Danone (that is, not powder that had tested under 50cfu/g or that might have been affected by carry-over or wet blending).

As will become apparent, however, it was this advice that led both FRDC and NZMP in June to

believe, when Waitoa products were later tested for *C. botulinum*, that there was no cause for concern about Darnum nutritional powder because Darnum had said (or so both FRDC and NZMP understood) that it had downgraded all potentially affected material to stockfeed. They did not appreciate that Darnum had supplied nutritional powder that used JW17 and JW18 powder as an ingredient and that had tested under 50cfu/g. Nor, as at 25 May, did anyone at FRDC or NZMP (including Hautapu) think about whether any JW17 and JW18 powder had been supplied to other customers, or what had become of JW22 powder (the third cipher of reworked WPC80).

On 27 May, FRDC advised AgResearch that it would not be going ahead with *C. botulinum* testing, adding that “our Australian business ... got such a big scare that they downgraded the product for destruction. So, they assumed [the] worst case and did what was right”.

Two days later, Fonterra Australia made a formal compensation claim to NZMP, which set off much discussion. The Inquiry was told that internal complaints between plants were often the most difficult to resolve – hardly consistent with the “one company” ethos. NZMP considered it had no liability because the product was made to specification. Darnum considered it was wrong for NZMP to “hide behind the ‘not [sic] in-spec’ excuse” when such a “significant deviation from normal hygiene conditions or process” had occurred. On 7 June, however, the managing director of NZMP (who by now had become aware of the dispute but not the full extent of the SRC problem) agreed to split 50/50 the claimed amount with Fonterra Australia.<sup>103</sup>

Nonetheless, the complaint raised questions for investigation. NZMP formed a “serious event team” (as Fonterra called it) to examine, among other things, the reworking process and why there had not been a proper triggering of the company’s complaint processes. About the first, it said questions requiring answers included “who authorised 100 per cent rework”; whether Hautapu had “follow[ed] change control [procedure]”; and whether an “adequate risk assessment” had been done.

<sup>103</sup> Fonterra’s chief executive, having spent time at Fonterra Australia in May, knew of a dispute between Darnum and Hautapu, and that Darnum was looking to write off at least A\$500,000. But he was told nothing about the dispute itself.

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The team looked into all these matters and agreed to changes in procedures. Oblivious to FRDC's *C. botulinum* concerns, the team did not consider where, apart from Darnum, the JW17, JW18 and JW22 powder had been sent. As will shortly be explained, just as the serious event team was being wound up in late June, NZMP's nutritional team gave the go-ahead for FRDC and AgResearch to conduct *C. botulinum* testing on output from Fonterra's Waitoa plant that contained Hautapu-sourced WPC80.

A final point: Darnum argued in its compensation claim that the Hautapu WPC80 was "unfit for purpose". Even FRDC raised the question whether "despite SRCs not being in the specification, [it was] reasonable to state that product was unfit for purpose".

Despite this being a commercial dispute over liability, the mere fact that there was disagreement about fitness for purpose was reason to alert Fonterra's product assurance and standards team, if notASUREQuality.<sup>104</sup> Either step would have led to further scrutiny of whether this was a food quality or potential food safety question. The Inquiry notes that under Fonterra's revised procedures, any significant food safety risk – including high SRC levels – will trigger critical event processes using an escalation template (see Appendix 4).

### Phase two: A review of WPC80 specifications

While NZMP and Fonterra Australia were still arguing about the Darnum liability, Fonterra Australia drew NZMP's attention on 6 June to the fact Waitoa did not have an SRC test as part of its WPC80 specifications. (About 40 kilometres from Hamilton, the Waitoa plant is one of Fonterra's biggest, employing 500 staff and producing 65,000 tonnes of nutritional powder, whole milk, cheese and complex lipid powder a year, much of it for export.) Quite correctly, NZMP instructed its quality and technical team to review Waitoa's ingredient specifications (including for WPC80) before the start of the new season in August.

On 10 June, the quality and technical team, in turn, delegated the task to the nutritional technical team. The former's general manager instructed the latter to look at two options: that plants test SRC levels in WPC80 before adding it to finished products; or alternatively, that Fonterra prepare and introduce an infant formula WPC80 specification that included SRC testing. The nutritional technical team manager assigned the review to two Waitoa-based team members responsible for nutritional product design, but retained oversight.

What the nutritional technical team did not know was that, as far back as 10 April, Darnum had asked NZMP's product technical team to amend the specifications of the WPC80 it made for use in nutritional products. That team had investigated various options in April and May.

On 15 May, it recommended adding an SRC test (with a limit of 100cfu/g) to the specifications of general market WPC80 (which Darnum and Waitoa both used).<sup>105</sup> Here was a clear example of one part of NZMP working in ignorance of what another was doing. On discovering this, on 12 June, NZMP's product range and alignment manager approved the May recommendation, but as an interim measure only while the nutritional technical team carried out its fuller review.

At this time, the review was confined solely to deciding on final, future specifications. The team eventually recommended an infant specification for WPC80, with an SRC limit of 100cfu/g, to take effect from August 2013.

### Phase three: The decision to commission *C. botulinum* testing

How did a review of specifications for infant formula ingredients lead to a decision scarcely two weeks later, on 21 June, to commission *C. botulinum* testing without the knowledge of senior managers? The decision originated at a meeting on 13 June attended by the nutritional technical team manager and the two Waitoa-based team members instructed to carry out the review.

<sup>104</sup> Clause 13(3)(a), Animal Products (Risk Management Programme Specifications) Notice 2008: risk management programmes must contain a procedure to report any "significant concern about the fitness for intended purpose of animal material".

<sup>105</sup> The 100cfu/g limit would not have put the nutritional powder Darnum made for Danone over Danone's 50cfu/g limit because it was adding WPC80 at a rate of 1 to 3 per cent during the manufacturing process, in effect diluting the SRC.

The three agreed on the scope of the review, for which the manager set a two-week deadline. They also decided more information was required on the risks the Darnum episode had exposed, in order to work out what changes, if any, they needed to make to infant formula specifications. To that end, they decided to find out more about the contamination of Hautapu's WPC80; the use of WPC80 in New Zealand-made nutritional products and other ingredients potentially at risk of SRC contamination; and the work that had been done for the interim WPC80 specification change.

Their combined knowledge at this point was very limited. They scarcely knew more than that Darnum had experienced a problem with high SRC caused by Hautapu-sourced WPC80. They did not know what ciphers were involved, what the SRC levels were, or that FRDC had recommended *C. botulinum* testing of Darnum powder. But they did appreciate that Hautapu and Darnum would be the right places to go for assistance. They also decided to approach FRDC, not because they knew of its involvement over the Darnum episode, but because the research centre was recognised for its microbiological expertise on SRC.

They also decided to find out whether the Hautapu WPC80 had been used in any nutritional products in New Zealand. This was not something they had been asked to investigate and was arguably not connected to the review. Nevertheless, the Inquiry regards it as an entirely reasonable question to have asked given Darnum's downgrading decision (and indeed it is perhaps surprising that Hautapu, NZMP senior managers or the serious event team did not consider this aspect much earlier).

### Investigation begins

The first week of investigation – which included getting information from Hautapu, Darnum and FRDC – was unremarkable for the two team members undertaking the review. The turning point came on 20 June when three developments converged.

First, the pair learned that Waitoa's nutritional products plant had used JW17 powder from Hautapu in three orders totalling 258 tonnes, two for a customer in January 2013 and a third for a customer in March 2013.<sup>106</sup>

Secondly, they received Darnum's background paper to its complaint about Hautapu WPC80, dated 10 May, as well as FRDC's test report on the Darnum nutritional powder and the Hautapu WPC80, dated 20 May. From these documents, the pair became aware for the first time that SRC testing of the WPC80 had revealed levels of up to 8,200cfu/g, and also that FRDC had raised the possibility of *C. botulinum* and had recommended contracting AgResearch to test the Darnum powder.

Thirdly, the first two developments came up at a pre-arranged meeting between the pair and an FRDC representative. At this meeting, FRDC was confronted with the realisation that the Hautapu WPC80 had been used elsewhere besides in the downgraded Darnum output; and the review team was confronted with the news that FRDC's *C. botulinum* concerns, formerly confined to Darnum and put to rest, were now revived and directed towards Waitoa.

FRDC believed there was a risk, admittedly low, that Waitoa output containing Hautapu WPC80 might be able to produce the *C. botulinum* toxin and testing was warranted. The alternative was to withdraw suspected production from sale. FRDC pointed out that the only reason *C. botulinum* testing of Darnum powder had not gone ahead was that Darnum had downgraded all production containing Hautapu WPC80 to stockfeed (or so FRDC believed).

The review team deferred to FRDC's advice. The pair agreed to put an urgent recommendation to their manager that Fonterra's Te Rapa laboratory test the three Waitoa orders containing JW17 for SRC and *C. perfringens*.<sup>107</sup> If testing detected high SRC levels, they would seek a decision on whether to isolate the clostridia and carry out toxin testing.

<sup>106</sup> The review team obtained this information from Waitoa after learning from Hautapu of the existence of the three ciphers.

<sup>107</sup> This laboratory, as the microbiological test site for Waitoa nutritional products, had responsibility for such testing.

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### *Botulinum testing unwittingly approved*

The pair put the recommendation for testing to the manager the same day (20 June). An email, with an attached summary paper, advised: "Please note that we have found today that this same affected WPC80 has been used in [Waitoa nutritionals plant] production (3 different products). We need to send off retention samples tomorrow to test for SRC and *Clostridium perfringens*. If levels are high we need to decide if we take further action to determine a food safety risk (isolate the *clostridia* and determine if it is toxin producing or not)."

The recommendation in the paper itself used more or less the same wording, noting the need for SRC and *C. perfringens* testing, and also for "analysis for toxin risk" if levels were high. The paper said a minimum of three samples would be necessary. A "contract lab" would then "perform the confirmatory testing". This would "rule out a food safety issue relating to *C. botulinum*, leaving only the process hygiene/product quality issue". Attached to the paper were the Darnum and FRDC reports of 10 and 20 May respectively.

Their manager's reply, on 21 June, approved the recommendation, but with an amendment to the sequence of testing, from a single-track to a twin-track approach: "I would like to take a very rapid and cautious approach to this," she said, "so I suggest, to ensure we quickly gain background on any potential risk, we initiate the toxin testing at the same time."

This was a critical moment in the evolution of the incident. As remarkable as it might seem, the manager did not appreciate that in approving "toxin testing", she had authorised *C. botulinum* testing.

Because of the heavy volume of emails she received, the manager did not always read every attachment to every message in her inbox. The Inquiry is satisfied that this was the case with the two attached May reports. It seems likely she read the 20 June summary paper her team wrote, but the Inquiry accepts her explanation that she missed the sole reference to *C. botulinum* at the very end of the three-page paper (and quoted three

paragraphs above). The paper's recommendations section and the covering email both laid emphasis on SRC and *C. perfringens* testing, with possible further testing for "toxin risk" to follow.

The Inquiry is satisfied the manager believed her authorisation gave approval for nothing more than testing for toxin production, as she understood it in relation to *C. perfringens*. Further, it is satisfied that in spite of discussions with, and written updates from, her team, the manager did not appreciate until almost a month later, on 20 July, that *C. botulinum* testing was under way. When she did, she referred the matter the same day to her manager, the head of the quality and technical team.

#### Key events

6 June 2013	NZMP learns Waitoa plant has no SRC test as part of WPC80 specification
10 June 2013	Nutritional technical team told to review Waitoa ingredient specifications
13 June 2013	Waitoa review team decides to find out if Hautapu WPC80 was used at other plants
20 June 2013	Review team learns Waitoa used JW17 in three orders; on FRDC advice, it recommends to manager that samples be tested, including possible "analysis for toxin risk" to rule out <i>C. botulinum</i>
21 June 2013	Manager says to start "toxin testing" immediately, unaware she is approving <i>C. botulinum</i> testing

For their part, the two Waitoa team members not only considered that their manager had authorised *C. botulinum* testing, but also assumed she had notified more senior managers. They based this assumption on her remark in a later email that she had "covered [the matter] off at a high level" with the general manager of the quality and technical team. In fact, she had merely given him a brief update on the review's progress – an update that might have included mention of the fairly routine testing she believed the team was initiating. She did not mention *C. botulinum* testing because she was unaware of it.

The emailed request and reply constituted the extent of any decision-making process. There was no careful or structured consideration of how testing would be done, what the possible outcomes might be, or what steps might need to be taken if the results were positive for *C. botulinum* or another toxin. No one gave any thought to informing AsureQuality or the ministry. Nor did anyone consider whether to trace and put on hold, pending test results, the three Waitoa orders containing JW17 powder. Nor did anyone consider where the rest of JW17, along with JW18 and JW22, had gone.

Four days later, on 25 June, in another exchange of emails, the review team told FRDC it had “initiated testing of the NZ manufactured product to confirm the presence of any SRCs/*C. perfringens*”. This was a purely advisory gesture: the team had set in motion testing by the Te Rapa laboratory on 21 June. The team then requested that FRDC “initiate the toxin testing in parallel to this”. Such a step would require FRDC to isolate clostridia organisms to pass to AgResearch to carry out actual toxin testing.

FRDC replied seeking clarification about what the team wanted it to test: the WPC80 itself or the products in which it had been used. FRDC also sought confirmation that its task was to establish whether there was a possible link between *C. sporogenes* and *C. botulinum*. The fact FRDC needed clarification further supports the conclusion that the nutritional team manager did not know she had authorised *C. botulinum* testing. It is unclear how the review team responded to that query. But the following day, on 26 June, FRDC advised AgResearch that it had received approval for “*sporogenes/bot* confirmation”.

The emails confirm the Inquiry’s view that the decision to test for *C. botulinum* would not have happened without FRDC’s encouragement.

## Lessons

The factors at play here could be said to be specific to Fonterra – the silo mentality (exemplified by the Darnum-NZMP dispute), the organisational pressure (especially on the nutritional technical team) and

the inadequate escalation procedures (resulting in testing that, properly understood, would have been of interest to no less than the chief executive, but was, in fact, not known even to the manager of the person who unwittingly authorised it). Nonetheless, the lessons here will have some application to all in the dairy industry, if not the wider food manufacturing sector.

**Workplace processes:** Formal processes, including the use of templates, should take the place of email exchanges when staff make key decisions – especially when those staff work long hours and must respond to hundreds of emails in the course of a day. This step distinguishes such decisions from the welter of everyday correspondence. Another recommended process change, especially pertinent to large and complex companies, is to ensure that a designated individual or body keeps a strategic eye on a matter under investigation by several teams. The risk is that individual teams, assigned to only one aspect of the question, are not well placed to see the broader objective.<sup>108</sup> In the same vein, companies need some definite oversight mechanism to guard against duplication or, worse still, a failure to appraise information for its relevance to every part of the organisation.

**Communication:** The earlier the better, especially when it involves both the ministry and auditors, which have the experience and expertise to help when required. The ministry encourages early, informal notification of food safety problems (real and potential), and on many occasions before August 2013, Fonterra had done just that. The opportunity existed to inform the ministry or AsureQuality, if only informally, of a potential food safety problem on 21 June, when testing for *C. botulinum* was authorised.

The Inquiry recommended in its first report that the industry, the ministry, auditors and laboratories agree to defined escalation paths that could sit alongside legally required reporting criteria. The industry needs to know it can contact the ministry without potentially invoking a disproportionate response, even enforcement action. Having spoken

<sup>108</sup> This was regarded as a contributing factor in Canada’s listeriosis outbreak in 2008: Government of Canada, *Report of the Independent Investigator into the 2008 Listeriosis Outbreak*, July 2009 at 30.

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to the ministry and industry representatives, the Inquiry understands there has been good progress in developing such escalation paths, which are vital to encouraging the earliest possible contact with the ministry when any potential food safety question arises.

There is a recent example of the process working well. In April 2014, Fonterra contacted the ministry about a potential contamination in a dairy product, and while awaiting the results of further testing, the two organisations examined possible public health risks and aligned potential communication strategies. As it happened, the tests were negative.

*Customer and consumer focus:* Companies overlook customers and consumers at their peril. Every decision, one way or another, has an impact on both, and in food manufacturing, the first question should always be: will this decision expose consumers to potential risk? Had NZMP on 21 June investigated the location of the WPC80 and alerted customers to put it on hold, the scope of the eventual recall would have been significantly narrower.<sup>109</sup>

Indeed, if NZMP had even earlier (late May) considered the implications for its customers of extremely high SRC levels raising at least questions about fitness for purpose, it is unlikely any consumer-level recall would have been necessary. In practical terms, Fonterra could have advised customers not to use the affected WPC80 until further notice. At that time, Nutricia's Auckland plant had only just started making infant formula using the affected WPC80 and would have been able to set that product aside.

*Non-standard testing:* Any company commissioning a test – particularly non-standard – must ask itself why it wants the test; it must ask the laboratory how it will conduct the test; and it must prepare itself for one of three inevitable outcomes: positive, negative or inconclusive. Non-standard testing in particular demands special consideration: see part

three on Fonterra's new processes for such testing – a good model for other companies to consider. Other lessons in relation to such testing, indeed all testing, are discussed in part seven.

### 9. AgResearch conducts testing

On 26 June, an FRDC microbiologist (not the same microbiologist who was responsible for liaising with NZMP) told AgResearch that FRDC "finally [had] approval to continue with the *sporogenes/bot* confirmation of the 3 strains we [identified] as *sporogenes*".<sup>110</sup> In the same email, he advised AgResearch that Fonterra had "product on hold, pending [the] outcome of your work".<sup>111</sup> He also said FRDC required "a letter stating that these organisms are either *Clostridium sporogenes* or *C. botulinum* and does/not have the ability to produce BoNT [the *C. botulinum* toxin]".

He told the Inquiry he asked for the results by letter because Fonterra was seeking a prompt, albeit definitive, answer. And preparation of the usual scientific report, which AgResearch ultimately supplied as later agreed, would have caused unnecessary delay. A letter, he added, offered some formality – certainly much more than an email or phone call – but could still be drafted quickly.

#### Key events

26 June 2013	FRDC tells AgResearch it has approval to test "product on hold"
18 July 2013	AgResearch tells FRDC samples "look different to <i>sporogenes</i> "
19 July 2013	Fonterra and AgResearch sign contract
29-30 July 2013	First mouse bioassay; first mouse dies
31 July 2013	Second mouse bioassay; three mice show symptoms and one later dies
2 August 2013	AgResearch gives FRDC preliminary report: "Likely ... <i>C. botulinum</i> ... although we cannot rule out other close relatives"

<sup>109</sup> Nutricia infant formula was made at its Auckland plant between 21 May and 30 June 2013, as well as on its behalf at the Hamilton plants of Dairy Blenders Limited (19 June to 30 July) and Dairy Goat Co-operative (NZ) Ltd (2 July to 2 August). Most of the Hamilton production could have been halted, plus a month's Auckland production. Also, while some of this output had already entered overseas supply chains, some did not arrive until late June and July 2013 at destinations such as Saudi Arabia and Vietnam.

<sup>110</sup> The reference to three strains relates to tests FRDC conducted on the Darnum nutritional powder and the Hautapu WPC80 in April and May 2013 that showed the *C. sporogenes* strains appeared to fall into three principal clusters of *sporogenes*.

<sup>111</sup> The email referred to "two sets of product". However, the following day the review team advised FRDC it wanted three products tested that had been made at Waitoa using JW17.

The email was the first time AgResearch had heard from FRDC since the research centre advised it a month earlier that Fonterra was not proceeding with *C. botulinum* testing because its Australian business had downgraded affected production for destruction. The effect of FRDC saying it had approval to “continue with the *sporogenes/bot* confirmation of the 3 strains we [identified] as *sporogenes*” was that AgResearch believed that Fonterra was commissioning it to test samples from Australian product after all.<sup>112</sup>

In light of the month-long gap, it is understandable that AgResearch did not appreciate any potential inconsistency between “downgraded for destruction” and the latest email’s mention of “product on hold”.<sup>113</sup> Here was one more example of individuals and organisations speaking at cross-purposes for want of more precise communication.

AgResearch read “product on hold” and took FRDC at its word. But this belief was, of course, wrong: the samples were from three orders that had left Waitoa after manufacturing in January and March. The review team liaising with FRDC had never advised such a thing.

When questioned by the Inquiry, the two FRDC microbiologists could not explain the assumption that the samples came from production that had been placed on hold. As to why one of them spoke of continuing, rather than initiating, testing, he explained he thought that the three clusters of *C. sporogenes* were probably common to Waitoa, Darnum and Hautapu samples, and in that sense testing was carrying on.

AgResearch replied the same day to FRDC’s email of 26 June. Having been commissioned, in effect, to conduct *C. botulinum* testing, AgResearch said it would need to conduct genotypic (DNA) analysis as a prelude to the mouse bioassay.<sup>114</sup> Testing was to begin some time around 8 July: see part seven for a full description of the testing process.

The following day, FRDC told AgResearch they had a month between them “to come up with an answer” once samples arrived. Preparing the isolates, it reminded AgResearch, would take a week. Could it provide preliminary results from the mouse bioassay within a week? AgResearch replied that it could obtain initial DNA results “fairly quickly”, but did not give a timeframe for the mouse bioassay.

AgResearch added that there was a complication. It was reluctant for biosecurity reasons to send the organisms by courier to its Ruakura research centre, near Hamilton, if genotypic analysis suggested they were closer to *C. botulinum* than to *C. sporogenes*. An AgResearch microbiologist could fly to Hamilton with the samples on 30 July, or earlier if Fonterra met the cost. The two parties deferred a decision, partly because genotypic analysis might produce a presumptive negative for *C. botulinum*, making the mouse bioassay unnecessary.<sup>115</sup> FRDC said it expected testing to confirm that the organisms were *C. sporogenes*. Detection of *C. botulinum* was not expected by anyone.

AgResearch did not regard FRDC’s request for a quick response as out of the ordinary. As AgResearch staff told the Inquiry, urgent testing requests were far from uncommon. In this case, they attributed the urgency to the storage costs Fonterra was incurring while affected production awaited clearance (a view reinforced by a later email).

### *Contract negotiations*

AgResearch sent a further email to FRDC on 27 June, with a draft contract attached. The work was to be undertaken between 8 July and 9 August for a fee of \$7,500 plus GST. Fonterra, however, wanted the contract to be on its template and in-house lawyers became involved. Despite the apparent urgency, a contract was not signed until 19 July. The price remained the same, but the start and finish dates became 16 July and 29 August. AgResearch was to supply a report “in scientific format” on the finish date.

112 The AgResearch microbiologist to whom FRDC’s 26 June email was addressed sent an email the same day to the AgResearch toxicologist saying that Fonterra “has some product on hold in Australia that needs confirmation that a contaminating spore forming bacteria related to *C. sporogenes* (by Maldi tof) is not toxigenic *botulinum*”.

113 This was the 27 May email discussed at 43.

114 Genotypic analysis is essentially DNA fingerprinting. A mouse bioassay is a series of tests on sets of mice to confirm the presence of a toxin: see part seven.

115 A presumptive test provides less certainty than a conclusive or confirmed test.

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Under the contract AgResearch became a consultant. Its task was to “use DNA fingerprinting, PCR and Mouse Bioassay to determine the relatedness of three bacterial isolates (identified by Fonterra by MALDI-TOF Biotyping, and provided by Fonterra to the Consultant for testing) to *C. sporogenes*”. There was no explicit mention of *C. botulinum*.

The reference to “testing” for *C. sporogenes* was an amendment insisted on by AgResearch lawyers. Previously, the contract had described AgResearch’s role as “confirming” *C. sporogenes*. AgResearch told FRDC the change related to legal liability questions. It explained that further to the Inquiry, saying the amendment was intended to remove any suggestion that it was performing confirmatory, or diagnostic, testing – it undertook research testing only. Diagnostic testing is generally understood by the industry to be routine product testing for regulatory or food safety purposes.

Despite the alteration, other parts of the contract – and correspondence at the time – continued to refer to “confirming” *C. sporogenes*. AgResearch explained that “confirming” in this context meant validating the results, rather than carrying out diagnostic testing. Fonterra agreed to the contract changes. A series of internal Fonterra emails recorded that, with the change in dates, “product will stay on hold for another week incurring significant cost to Fonterra”. An FRDC microbiologist forwarded this email chain to AgResearch.

### Genotypic testing

The legal delay had no impact on the work of FRDC’s scientists. They took delivery of Waitoa samples on 2 July, purified them and selected three isolates, which they sent to AgResearch on 8 July, as originally envisaged. At that point, the FRDC microbiologist updated the Waitoa review team, noting that the isolates were being taken to AgResearch for testing for toxin genes. The email was blunt: “If these [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.”

On 17 July, FRDC inquired whether AgResearch had received any results from genotypic testing. AgResearch explained that it was having difficulty processing the isolates for DNA extraction, but added that the form and structure of the organisms “look[ed] different to *sporogenes*”. FRDC says this was reiterated in a meeting the next day when, as recorded in an internal Fonterra email, AgResearch’s microbiologist told the FRDC microbiologist the isolates were more comparable with *C. botulinum* than *C. sporogenes*. The email recorded that “AgResearch’s recommendation [was] not to read too much” into this. The AgResearch microbiologist does not recall this meeting.

As will become apparent, the news somewhat dented FRDC’s confidence that testing would show the organism to be *C. sporogenes*, not *C. botulinum*, and caused it to ask NZMP’s review team whether all the WPC80 had been traced. The effect of that inquiry was to bring the reality of *C. botulinum* testing and the possibility of a positive result to the attention of NZMP’s more senior managers for the first time.

Over the next few days, AgResearch proceeded to conduct genotypic testing. In essence, the results were inconclusive. Attention shifted to the mouse bioassay as the definitive test.

On 19 July, AgResearch told FRDC that the mouse bioassay could not begin before 29 July because the mice had only just been weaned and needed 10 days to grow sufficiently. On 22 July, AgResearch prepared the samples for the mouse bioassay and asked FRDC whether Fonterra wanted to fly them to AgResearch’s Ruakura laboratories that week, rather than wait for an AgResearch microbiologist to deliver them on 30 July. After some delay within Fonterra deciding who would pay for this, Fonterra replied that it would meet the cost and also arrange for an FRDC microbiologist to transport the samples.

On 23 July, an FRDC microbiologist collected the samples and the next day he delivered them to AgResearch's leading toxicologist at Ruakura. They talked for a short while in a corridor. The two men gave the Inquiry different accounts of their discussion. They agreed that they discussed whether the samples were from production that had been destroyed or was on hold. They agreed that the FRDC microbiologist said Fonterra wanted the results as soon as possible.

The key difference was that the toxicologist maintained he told the microbiologist he was short on mice (without saying how many he had) due to a breeding failure. He further maintained he said it would take four to six weeks to breed more mice, but he would do what he could with the mice he had available.

For his part, the microbiologist said the toxicologist never mentioned any shortage of mice. From his knowledge of the trial AgResearch had conducted for Fonterra into *C. botulinum* in cheeses in 2011-2013, he knew that the accepted FDA method for mouse bioassays demanded a large number of mice.<sup>116</sup> Had the toxicologist given any indication AgResearch lacked sufficient mice to follow the protocol, it would have set off alarm bells and he would not have agreed to proceed. The Inquiry's terms of reference are such that it does not need to decide between these accounts.

### Mouse bioassays

On 29 July, the AgResearch toxicologist performed the first mouse bioassay with eight mice. FRDC emailed AgResearch that morning, and again in the afternoon, seeking an update. AgResearch told FRDC the following day that the result was positive, but further testing was necessary. A single mouse had shown symptoms characteristic of botulinum toxin. The mouse was euthanised on the morning of 30 July.

In a reply that afternoon, FRDC said the news had led to "internal discussions and a plethora of questions regarding the next steps", including whether the strain of *C. botulinum* was toxic to animals but

not to humans, how to test for this and how long it would take. FRDC asked AgResearch's microbiologist to come to FRDC the following afternoon to discuss the matter. She agreed.

On the morning of 31 July, the AgResearch toxicologist performed the second mouse bioassay with six mice. FRDC received the early results at midday. Three mice showed either "positive" or "strongly positive" results. Later, after the email was sent, and four hours after dosing, one of the mice died.

### Aftermath of testing

The AgResearch microbiologist and FRDC personnel met in the afternoon. FRDC staff were in a state of disbelief at the toxicology results and wanted to know whether they could be false positives. FRDC says the AgResearch microbiologist told them the results were positive for *C. botulinum*. The AgResearch microbiologist does not agree she gave such a definitive view.

Much of the meeting focused on how to determine whether the *C. botulinum* was toxic to humans or animals. FRDC personnel also discussed widening testing to output from other Fonterra plants, given, as will soon be explained, that NZMP senior management had by this time become aware of the *C. botulinum* testing. Both NZMP and FRDC now knew it was wrong to believe that all affected production had either been downgraded or placed on hold. However, none of this was made clear to the AgResearch microbiologist, who left the meeting knowing only that FRDC wanted to extend the scope of testing and that this would require more work by AgResearch.

Accounts of the meeting differed in one important respect – whether the AgResearch microbiologist explained to FRDC personnel that the results were presumptive only because AgResearch (as a research laboratory not accredited for *C. botulinum* testing) could not confirm *C. botulinum*. The microbiologist

116 See part seven for further discussion of the FDA protocol and the 2011-2013 cheese trial.

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said she made clear the distinction between research and diagnostic testing. FRDC personnel denied this happened. One of those at the meeting said such a distinction would have flown in the face of what he considered was AgResearch's contracted task, which was not to do "fundamental research", but to "clear product". FRDC staff told the Inquiry they took away the clear message that the results could be relied upon, that is, AgResearch had confirmed *C. botulinum*.

The different views about the 31 July meeting mirror differences between AgResearch and Fonterra about the nature and purpose of the work AgResearch undertook. The Inquiry was interested to test this with the FRDC and AgResearch scientists. What it found was that the difference between them was not as great as first seemed.

FRDC staff acknowledged that what they wanted was a definitive result so Fonterra could decide what to do with production on hold, but they did not consider this to be diagnostic testing. In their eyes, diagnostic testing was "routine product testing". They were fully aware that AgResearch was not accredited to test for *C. botulinum*. They described the work as "investigative".

For their part, AgResearch staff acknowledged the testing was not pure research like the 2011-2013 cheese trial. They described it as "retrospective quality assurance research" to enable Fonterra to decide whether to sell or destroy production it was holding. It was not diagnostic testing. AgResearch had no idea its work would be used to determine whether infant formula products already on supermarket shelves were safe to consume.

In the Inquiry's view, both appeared at the time to regard the tests as falling somewhere between research and diagnosis, although AgResearch put the tests closer to the research end of the spectrum, and FRDC to the diagnostic end. What they were both clear on, in hindsight, was that there was an absence of clear purpose and informed communication between them, the implications of which are discussed in part seven.

The next day, on 1 August, FRDC asked AgResearch for a preliminary report. AgResearch regarded this as an unusual request, but agreed and emailed a preliminary version to FRDC on 2 August (watermarked "draft"). AgResearch's microbiologist told the Inquiry she believed that the preliminary report's purpose was to enable Fonterra to prepare the way for further testing as discussed at the 31 July meeting.

The preliminary report described itself as an outline of "results of initial investigation". It declared that AgResearch "is not a registered diagnostic facility and the results described in this study are for research purposes only". It concluded:

- "All Fonterra samples were shown to be toxigenic in the [mouse bioassay] and dosed mice exhibited classic symptoms to *botulinum* toxin."
- "Fonterra isolates are likely to be *C. botulinum* ... although we cannot rule out other close relatives."
- "At this stage we are unable to [determine] the toxin type."

It was not until 3 August that AgResearch scientists were astonished to learn through the media that Fonterra had advised MPI of confirmed *C. botulinum* in products on sale in New Zealand.

### Lessons

Clear communication once again emerges as the indispensable, yet underrated, feature of effective organisations and sound food safety systems. The following lessons transcend this incident.

*Clear purpose (client):* The company commissioning testing must be in no doubt about the function of the testing: is it for diagnostic or research purposes? Understanding the distinction cannot be overstated. The Inquiry also recommends procedures for non-standard testing, something Fonterra has already taken steps to establish and implement.

*Clear purpose (research laboratory):* In turn, research laboratories accepting testing for food products,

including (and perhaps especially) for products on hold, must understand the purpose of testing because this will influence testing attributes. Contracts need to include a clear statement about whether results will be suitable for diagnostic or research purposes. Laboratories may even wish to require the company commissioning the testing to guarantee the accuracy of information it provides.

**Risk assessment:** Tests, as the WPC80 incident so amply demonstrates, need to be seen in their wider context and not solely through a narrow scientific lens or from a purely commercial perspective. Any decision to carry out non-standard testing should take into account the likelihood and consequences of a positive result – not merely the monetary value (here \$7,500) – to ensure oversight by the most senior managers.

## 10. Countdown to crisis

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Returning to developments within Fonterra, on 19 July (10 days before the first mouse bioassay) things changed. For the first time, the manager of the Waitoa review team learned about the *C. botulinum* testing.

She might have learned a week earlier, but for the deletion of several key words from correspondence from one of the review team. He had updated her on 12 July with an emailed recommendation to “complete clostridium toxin investigation to determine food safety risk on 3 affected batches of Nutritional products made in Waitoa”. He also attached a revised version of the 20 June summary paper – but minus any mention of *C. botulinum*. As a result, she told her superior, the general manager of the quality and technical team, who had been copied in on the email, that the investigation involved “no serious risk [and was] purely precautionary”.

The Inquiry is fully satisfied that the general manager of the quality and technical team did not receive any information that might have alerted him to the fact *C. botulinum* testing was under way.

On 19 July, FRDC emailed to advise the review team member that, in AgResearch’s view, the isolates were behaving more like *C. botulinum* than *C. sporogenes*. FRDC noted that AgResearch had said not to read too much into this for the time being. It explained that the next step was a mouse bioassay, which “according to FDA ... is required to confirm absence/presence of *C. botulinum*” and this would start “towards the end of next week”. FRDC ended its email with “one important question we have”. Had Fonterra tracked “all the whey powder”, irrespective of whether it was still in the form of WPC80 or had been used as an ingredient in nutritional products? The question was typed in bold.

The FRDC microbiologist who sent the email told the Inquiry FRDC continued to believe the samples were from production Fonterra had yet to release into the market. But he asked the question nonetheless because the matter deserved the greatest caution in light of AgResearch’s observation that the organisms were behaving more like *C. botulinum* than *C. sporogenes*. The review team member replied that he would follow up on this question. He forwarded the email to his manager, drawing her attention to this and asking whether anyone in the quality and technical team had begun any tracking.

The manager read the email the next day, a Saturday, and learned for the first time of the *C. botulinum* testing. She told the Inquiry she felt sick on reading it.

The manager immediately emailed the quality and technical team general manager about the “suspicious preliminary results for clostridial toxin testing” and the planned mouse bioassay. She explained that her team member did not “understand the potential severity” of a positive result and therefore had not mentioned it to her the previous day. Although AgResearch had said not to read too much into the results at this point, she added that the potential impact on the company was “fundamental and critical if [the] results are pathogenic”.

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She rightly pointed out that NZMP would need to track all Hautapu WPC80 and that her manager would need to make a decision about whether to notify more senior managers or wait for further information.

The review team had identified three Waitoa orders that used Hautapu WPC80. But it had not initiated any tracing of these orders, which it knew were not on hold. Nor had it taken steps to identify any other products that might have contained Hautapu WPC80 and their location.

One team member told the Inquiry that during June and July, he thought the WPC80 had been used only at Darnum (believing that all contaminated production had been downgraded) and Waitoa (the three orders undergoing testing).<sup>117</sup> Until FRDC asked its tracing question on 19 July, the thought had not occurred to him. He assumed that the quality and technical team had traced the orders as part of a wider NZMP project. In hindsight, he agreed it was “glaringly obvious” that product tracing should have started earlier. The other review team member made a similar point. She told the Inquiry the pair were working on their “little Waitoa piece” and believed others higher up in NZMP had more information.

Senior Fonterra managers interviewed by the Inquiry said affected production should have been put on hold or silently recalled as soon as the decision was made to test for *C. botulinum* on 21 June.<sup>118</sup> The Inquiry agrees.

### NZMP responds

On Monday morning, 22 July, many NZMP staff became involved and began to try to absorb and understand the news. As a result, FRDC’s phones rang off the hook. There was general surprise that one part of the business had commissioned *C. botulinum* testing, that FRDC was involved and that AgResearch was about to do a mouse bioassay. A tentative start was made on tracing the contaminated Hautapu WPC80 and products made from it.

No one gave much thought to reviewing the decision to test or to seeking scientific advice from outside FRDC’s food assurance team. At this point, NZMP considered that having pursued testing to the point of a definitive test (the mouse bioassay), it seemed only right to see it to its final conclusion. It fully expected mouse bioassay testing to confirm *C. sporogenes* because *C. botulinum* was virtually unheard of in dairy powder.

On 23 July, NZMP’s director of operations was told the news and a critical event team was formed. That afternoon, the team agreed that Fonterra should put all affected production within its control on hold, but should defer a decision about contacting customers.

On Wednesday 24 July, the team held a conference call to allocate work among its members. NZMP had barely increased its knowledge of the size of the problem since the weekend. It still did not know, for example, whether the three Waitoa orders were the only products that contained Hautapu WPC80. It was moving without great haste, in part it seems because it did not expect the mouse bioassay results until 5 August. Priority tasks arising from the meeting were to:

- Investigate how SRC contamination in Hautapu’s WPC80 happened and make recommendations to prevent a recurrence
- Trace Hautapu WPC80 and Waitoa nutritional products in anticipation of a product test or recall
- Review testing to date to determine if it was appropriate and if more testing was necessary.

Fonterra gave no thought to advising AsureQuality or the ministry at this time that its Hautapu WPC80 had not been manufactured in accordance with its risk management programme. Although it was yet to do further work (as noted above), it now knew, as a result of “suspicious preliminary test results”, that the reworked WPC80 was the source of a potential food safety problem. In the Inquiry’s view, Fonterra should have notified AsureQuality or the ministry on 24 July that it had significant

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<sup>117</sup> This perception is reflected in the review team’s 12 July summary paper, which gave the impression that the Waitoa orders were the only affected production: “Australian downgrade product, has initiated an investigation ... 3 cyphers of NZ made product have also been affected but not downgraded.”

<sup>118</sup> A silent recall is typically a precautionary withdrawal of products before any public notification of a confirmed food safety issue.

concerns about the fitness for purpose of the WPC80 (if not earlier on 21 June when *C. botulinum* testing was initiated).<sup>119</sup>

### Conference call

On 26 July, there was a conference call involving NZMP's most senior executives to discuss the decision to test. This included NZMP's managing director, who had learned of the issue some time between 24 and 26 July (the precise date is not clear), the director of operations and the head of Fonterra's risk management group. A briefing paper explained that *C. botulinum* was very uncommon in New Zealand and almost unheard of in dairy powder.

That information, together with inconclusive genotypic results and the fact contaminated products had probably been on sale for months without reports of health problems, led one of those present to argue that a mouse bioassay was unnecessary. However, the prevailing view was that, having been alerted to a possible food safety risk, however remote, Fonterra had no option but to rule it out. One executive described the company's predicament to the Inquiry as like being "in the chute" – it couldn't back out.

The two apparent choices were to proceed with a test that would almost certainly come back negative for *C. botulinum*, or to run the extremely small risk – but one that in the words of an executive could "kill the company" if it turned out badly – that no baby fell ill. The executives decided they had no choice but to continue with testing. The head of the risk management group was asked for his opinion as the company's "conscience" and he agreed with the decision.

The Inquiry does not criticise this decision – except to say that Fonterra should by this time have sought advice from outside FRDC's food assurance team on the risk of *C. botulinum* and the arguments for and against a mouse bioassay. Surprisingly, in the Inquiry's view, Fonterra did not call in its own senior scientist nor consult an external expert on *C. botulinum* until after the 2 August notification.

Instead, the conference call bypassed discussion of AgResearch's testing methods, having been reassured that FRDC was entirely satisfied with AgResearch's expertise. The executives' view was that it was hardly their place to overrule or second-guess FRDC's microbiologists on scientific questions.

That same day, they also confirmed the decision to place on hold all suspected production within Fonterra's control, but to continue to delay contacting customers until they had received test results (still anticipated on 5 August). They agreed to review this on 31 July.

On 29 July, AgResearch began the first mouse bioassay as described in section 9. On 30 July, one mouse was euthanised. On 31 July, AgResearch advised FRDC that another mouse had died in the second bioassay. However, by some twist of communication, NZMP executives were told "three out of three" mice had died – news that triggered the formation of a crisis management team. More accurately, six mice had been tested in the second bioassay, and one had died (although three samples were controls: see part seven).

Had the executives received the correct information – that four mice had shown positive symptoms across both bioassays but only two had died (one by euthanasia) – would anything have changed? The answer is probably not. The miscommunication did not alter Fonterra's view of AgResearch's findings. But only two deaths might have cast the seeds of doubt, prompting the executives to ask whether this was enough to validate *C. botulinum*. However, the manifestly incorrect advice that every mouse injected in the second mouse bioassay had died left no possible room for doubt, closing the door firmly on further discussion.

It is worth noting how differently things might have been if further scientific advice had been sought. But there was not even direct communication between NZMP and AgResearch. A simple phone call to AgResearch might have detected the error over the three mice (a mistake never satisfactorily explained to the Inquiry and one that stunned a

<sup>119</sup> Fonterra admitted in the prosecution facts that on 24 July it held significant concerns that the reworking was outside its risk management programme.

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senior executive on learning of it from the Inquiry). That aside, the involvement of another scientist could have led to a view that two, even three, deaths were not necessarily significant for a mouse bioassay, a questioning of the reliability of the results or greater scrutiny of AgResearch's methodology.

An American professor of bacteriology, whom Fonterra later brought to New Zealand, raised immediate concerns, especially about the limited number of mice tested and deaths.

### *Crisis management team*

The crisis management team held its first conference call that evening. Many present told the Inquiry the call was unsatisfactory because there was little solid information on which to base discussion. The team decided to resume next day, once more detailed information was available.

A PowerPoint presentation put together overnight advised:

- The mouse bioassay – the “definitive test” – had “confirmed pathogenic *Clostridium botulinum* toxin” in WPC80
- “Initial mouse bioassay 1/3 mice dead”; “confirmation test ... 3/3 mice dead”
- The WPC80 had been used as an ingredient in infant formula and this product was in the market [details were provided]
- The number of spores required to cause infant botulism still had to be confirmed but was “possibly 10-100”; also “low SRC results = lower risk”
- Fonterra was “legally obliged to notify MPI”.

At the rescheduled meeting on 1 August, the starting point for discussion was that *C. botulinum* was confirmed. Discussion moved to the question of carry-over. Participants came to appreciate that Darnum, while making nutritional powder for Danone, had transferred SRC contamination during manufacturing, from runs using JW17 and JW18 powder to subsequent runs not using it. (NZMP still had no idea that Darnum had supplied Danone with

11 ciphers of nutritional powder that tested under 50cfu/g.) Discussion also covered the level of SRC below which products were deemed to be safe to consume. At that time, FRDC's advice was 20cfu/g.

The meeting never doubted that Fonterra would have to report to the ministry.<sup>120</sup> Rather, discussion centred on when the 24-hour notification period was deemed to have started and also what Fonterra would tell the ministry. The meeting felt keenly that the clock was ticking.

### Key events

19 July 2013	FRDC asks review team if Fonterra has “tracked all the whey powder?”
20 July 2013	Review team manager learns of <i>C. botulinum</i> testing and alerts her manager
23 July 2013	NZMP sets up “critical event” team
26 July 2013	Senior executives decide to proceed with mouse bioassay
29-30 July 2013	First mouse bioassay; first mouse dies (euthanised)
31 July 2013	Second mouse bioassay, three mice show symptoms and one later dies; NZMP executives told “three out of three” mice died; crisis management team forms
1 August 2013	Crisis management team decides to notify MPI; NZMP tells Darnum to start tracing; Fonterra chief executive briefed
2 August 2013	Fonterra notifies MPI of “confirmed” <i>C. botulinum</i>

Executives at the meeting told the Inquiry they felt “under pressure” and “constrained” by the 24-hour deadline. They still had no idea which products were affected. They also decided they had to speak to their customers first. They had three reasons: it was a matter of courtesy and good customer relations; they did not want any ministry action to catch their customers by surprise; and their customers knew something Fonterra didn't – the location of their products. Until this point, the very decision not to contact customers had acted as a real barrier to tracing efforts.

120 Section 51(c), Animal Products Act 1999.

The meeting decided the company had to be more prepared before notifying MPI, even if that meant missing the notification deadline.

Fonterra's wariness about approaching the ministry without the full facts – or at least a more complete set of facts – at its fingertips is, at one level, completely understandable: no company would wish to look ill-prepared or not in control of events. But what this brought to the surface was Fonterra's lack of trust in the ministry to respond in a predictable, proportionate way to the news of *C. botulinum*. This puzzled the Inquiry, in light of the fact it was also told that Fonterra had frequently approached MPI about food safety problems and received help to resolve them before they grew. The industry's perceived view of a mishandled response by the ministry over the DCD incident may be part of the explanation.

On 1 and 2 August, Fonterra personnel scrambled to call customers and gather information to trace products. New information radically compounded the difficulty of the task. FRDC advised that any product containing Hautapu WPC80 would be safe to consume only if the SRC level was 0cfu/g – not 20cfu/g as previously advised. Fonterra was left playing catch-up as the scale of the product recall rapidly ballooned.

On 1 August, and without revealing the precise nature or the seriousness of the matter, Fonterra tried to arrange a conference call with the ministry, but the relevant staff member was unavailable. It was rescheduled for 11am on 2 August.

On the evening of 1 August, the managing director of NZMP briefed Fonterra's chief executive (in Europe for a family funeral). The chief executive directed him to advise Fonterra's board before notifying the ministry. The managing director briefed the board's chairman next morning, the timing of which forced Fonterra to delay the 11am call to the ministry until midday.

The conference call itself was short. As soon as Fonterra disclosed a confirmed case of *C. botulinum*, officials said the ministry would invoke its own

response processes and get back to the company. At 12.35pm, Fonterra emailed through a slightly expanded version of the PowerPoint presentation shown to its executives the previous day, identifying the WPC80 as SRC-contaminated Hautapu WPC80 and reiterating that it had been "confirmed as *Clostridium Botulinum*".

FRDC had by now received AgResearch's preliminary report, but it did not reach NZMP executives until after Fonterra had notified the ministry – too late for officials to read its more guarded statement that "initial investigation" showed "Fonterra isolates are likely to be *C. botulinum* ... although we cannot rule out other close relatives".

### Lessons

The factors at play during the initial unfolding of the crisis persisted into the final stages: the silo mentality, failure to escalate and lack of sufficient focus on customers and consumers. Elements of the lessons are relevant to Fonterra alone, but the wider food sector may benefit from them.

*Escalation:* Senior managers should encourage staff, from frontline operators upwards, to speak up about food safety concerns (or any other concerns, for that matter). Two obvious opportunities were missed to turn the tide of events during this period.

The first was the failure on 24 July to seek the professional view of Fonterra's most senior scientist during the decision on whether to proceed with a mouse bioassay. The second was the failure to notify the chief executive the same day, irrespective of the strong expectation of a *C. sporogenes* result.

As a general point, unconnected to this incident, chief executives everywhere should examine their companies' escalation procedures to ensure nothing impedes information from reaching the most senior levels. They should also take active steps to ensure a culture of encouraging staff to report, rather than suppress, so-called bad news.<sup>121</sup> Chief executives, no matter how busy, must also ensure their door is always open for those reporting such concerns. That much is necessary if a strong food safety culture is to flourish.

<sup>121</sup> As Hopkins noted, the prevailing belief within BP was that only good news flowed upwards to the chief executive. He quotes the view of one observer that "no one dared say the wrong things or challenge the boss". Fn 46 at 108.

## PART FOUR: THE CAUSES OF THE INCIDENT

*Preparation for tracing and product recall:* When in doubt, recall. Not only is it the prudent course of action, it also contains an implicit message for customers and consumers that their interests and welfare are the company's highest concern. The Inquiry has already noted that the scope of the recall might have been significantly narrower if NZMP had begun tracing work and contacted customers when concerns first arose in late May, or on 21 June when *C. botulinum* testing was approved. The delay was inexcusable by 26 July, when Fonterra approved the first mouse bioassay and decided to put all production within its own control on hold.

*Communication:* There is no substitute for clear and concise information if companies are to operate as a single, coherent whole. Internally, and particularly during a critical event, the more direct the interaction is, the better. Despite the involvement of NZMP's most senior executives, communication between AgResearch and Fonterra was limited to each organisation's microbiologists. With the best will in the world, mix-ups happen, especially in big companies with complicated reporting lines. Sometimes there can be no better course of action than to pick up the phone and speak directly to the person in the know.

Externally, Fonterra should have informedASUREQuality or the ministry before 2 August and sought guidance on whether to continue with a mouse bioassay.<sup>122</sup> Such a referral would probably have led to greater scrutiny of AgResearch's brief. While the Inquiry understands the wariness some NZMP executives felt about approaching the ministry, food safety concerns should have trumped every other consideration.

*Notification to regulator:* The 24-hour notification requirement exists for a very good reason: invariably, time is of the essence. That is why companies must notify MPI's Director-General as soon as possible, or, at the latest, within 24 hours of learning that dairy product is unfit for purpose. By 31 July, with a positive toxin result, Fonterra knew it had a food safety crisis on its hands and should not have

deferred notification until one day after the deadline: another breach for which Fonterra was convicted and fined.<sup>123</sup> Forewarning the ministry even 24 hours earlier on 1 August – and critically, before alerting customers – would have given all concerned another valuable 24 hours to prepare. Some interviewees felt companies should have more than 24 hours to compile the necessary information for the ministry. However, many overseas regulations are even tighter, requiring immediate notification, and the Inquiry does not consider the 24-hour notification period should be extended.

### Recommendations

The Inquiry recommends:

- The ministry, in consultation with the dairy industry and verifiers, should revise the rules for non-routine reworking that requires a product disposal request.
- The ministry, together with verifiers, should ensure the industry's strict compliance with reporting times for product disposal requests, critical exception reports and export non-conformances.

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<sup>122</sup> The Inquiry disagrees in this respect with the Fonterra board inquiry, which said it was "not satisfied that such a course was either feasible or appropriate" at that time: at 65.

<sup>123</sup> Sections 134(1)(d) and 51(c), Animal Products Act 1999.



## PART FIVE: FONTERRA'S RESPONSE

Fonterra's actions after news of suspected infant botulism broke on the world stage, like its actions beforehand, have come under intense scrutiny, first by the media and then by the company itself. This took the form of two inquiries, one by management and another at the instigation of its board.

The board inquiry devoted considerable effort to the way in which Fonterra dealt with the unfolding crisis, noting that it was not sufficiently clear about the precautionary nature of the recall, nor apologetic for the inconvenience and disruption, nor consistent in its tone, which was "sometimes quite alarming, at other times seeking to minimise".<sup>124</sup>

The Fonterra board inquiry report went on to say: "The persistent adjustments to the estimates of affected product were corrosive of Fonterra's credibility with Ministers and officials. There is a significant body of research and 'best practice' knowledge on how to promote strong relationships and communicate during usual times, and in times of risk and crisis, so as to maximise trust and credibility. Fonterra's communication style and substance did not consistently demonstrate the characteristics of that knowledge."<sup>125</sup>

The Inquiry agrees. Given the Fonterra board inquiry report's detailed examination of the topic, this Inquiry focuses on three pivotal aspects of the company's response: planning and readiness; traceability; and lastly, co-ordination and crisis communications.

### 11. Planning and readiness

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Fonterra was ill-prepared. About this there can be little dispute. Its crisis management plan had undergone intermittent revisions and rehearsals since it was produced eight years earlier, but no serious testing or review had taken place.<sup>126</sup> Fonterra acknowledges that such testing as occurred was far from adequate.

The plan was the responsibility of Fonterra's group risk management team, which had organised a short, high-level desktop biosecurity exercise involving the whole group in December 2007. NZMP had also participated in several joint exercises with the ministry (into which, notably, the Fonterra team had no organisational input), and it took part in the national biosecurity Exercise Taurus led by the former MAF in March 2012.

Overall, the plan had never been rigorously or regularly practised for likely risks, including a global product recall. Even the important lessons to emerge from the DCD incident had not, as already noted, been acted on by 2 August. Furthermore, no crisis management team existed at the time. The absence of such a team, so essential in any crisis, may well have contributed to the unease of so many Fonterra staff interviewed by the Inquiry over deficiencies in the response.

Yet again, as one Fonterra senior executive put it, "the silo mentality got in the way of a unified response". Another interviewee described activity behind the scenes as "controlled chaos"; still another

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<sup>124</sup> Fonterra board inquiry report at 8.

<sup>125</sup> Ibid.

<sup>126</sup> Ibid at 90-91.

said "Fonterra was caught on the back foot and found it incredibly hard to get back on the front again". Whether real or perceived, such reactions to a company's crisis planning and management are undesirable for any organisation.

Granted, the company's performance improved after four or five days, but the first 72 hours were critical in establishing credibility and gaining the trust of all involved, including, most importantly, consumers.<sup>127</sup> Fonterra's own later interviews with government, media, industry and farming figures confirmed that it largely lost the battle in the first 24 to 72 hours (the so-called "golden hours" in crisis management). "Most [interviewees] conceded things improved after the first few days," noted the report, "but that before that happened the damage had been done."<sup>128</sup>

## 12. Tracing

It is hard to appreciate the complexity of the task confronting Fonterra on 2 August when it began searching in earnest for the 37.8 tonnes of WPC80 manufactured at Hautapu in May 2012. In the intervening 14 months, the concentrate had been added to thousands of tonnes of products – not only infant nutritional powder, but also yoghurt, beverages and sports drinks – and these products had now made their way on to shelves in New Zealand, Australia, China, Saudi Arabia, the Philippines, Vietnam, Thailand and Malaysia.

To exacerbate matters, the company also faced the complication of carry-over, a normal feature of food manufacturing, in which products using JW17, JW18 and JW22 as an ingredient had overlapped with other products during the manufacturing process. Fonterra had to identify and trace these products, too.

Repeatedly, information provided to customers turned out to be inaccurate. This in turn caused turmoil for tracing of their own products. The ensuing delays and uncertainties meant the ministry provided advice to the public based on incomplete and ever-changing information.

A question commonly put to the Inquiry was why Fonterra could not trace products rapidly and accurately based on the "one up, one down" principle, that is, identifying where the ingredients it received came from (one up) and where the resulting products went (one down). The answer lies in the failings in Fonterra's product tracing system – especially technical problems – discussed below.

Fonterra's failure to trace contaminated products quickly and accurately seriously compromised its ability – and that of Danone and MPI – to respond to the crisis decisively, especially in the vital early days. Indeed, nothing could have hamstrung that ability more thoroughly than this deficiency – underscoring, in the Inquiry's view, the absolute importance of sound tracing and recall systems, a subject of the Inquiry's first report.<sup>129</sup> For reasons that will be explained, the company struggled mightily but often vainly with what was, as one interviewee described it, "one of the most complex challenges a company has to deal with".

### *Reliability of information*

As noted earlier, Fonterra began to grasp the scale of the problem only shortly before it notified the ministry – when its scope expanded again with a change of scientific advice that lowered the "safe" SRC limit for any suspected products from 20cfu/g to 0cfu/g.<sup>130</sup> Not surprisingly, initial information to the ministry proved inaccurate. The PowerPoint presentation emailed to the ministry after notification identified 871.1 tonnes of production as "in market product impacted". Of this, 850.5 tonnes was "high risk" infant formula, made up of 590.5 tonnes for Danone (but subject to confirmation) and 260 tonnes for another customer, a United States-based healthcare products company. The remaining 20.6 tonnes were "low risk" yoghurt, yoghurt beverages and protein drinks.

In fact, very little of the 871.1 tonnes was finished product ready for sale. Rather, it was predominantly nutritional powder containing JW17, JW18 and JW22 powder that had been shipped to customers for final manufacturing into infant formula. A small

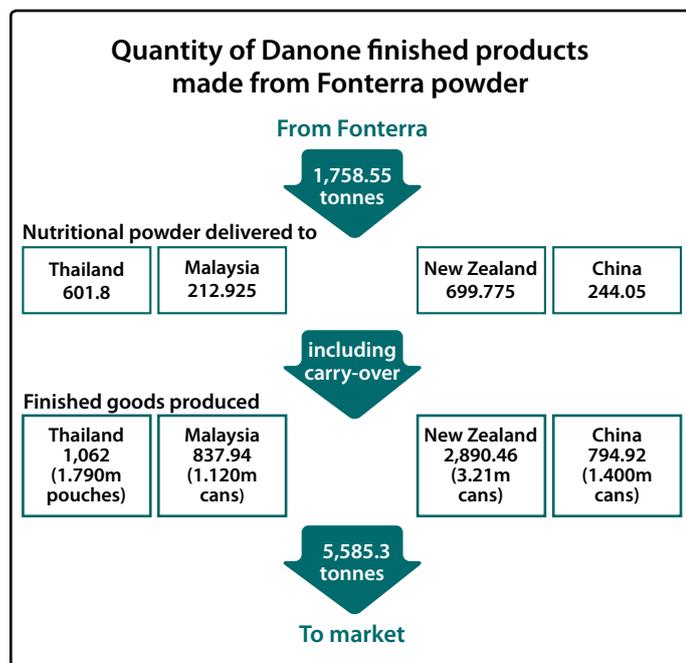
127 Ibid at 35.

128 Ibid at 147.

129 First report at 53-58.

130 See earlier discussion in part four, section 10.

amount was straight JW17, JW18 and JW22 powder. Had the 871.1 tonnes been finished products, the tracing task would have been far less complex.



By 2 August, those 871.1 tonnes had been dispersed as an ingredient among many thousands of tonnes of products. And those products were either en route to stores in New Zealand and seven other countries, already on retail shelves, or already purchased (and possibly consumed). Among the yet-to-be-quantified thousands of tonnes of products were as many as 6,000 tonnes of infant formula.

Another point: at the time of notification, NZMP understood that the only contaminated nutritional powder from Darnum was carry-over production. This was based on the PowerPoint presentation to NZMP executives the previous day that said the Danone production had been downgraded to stockfeed except for 229 tonnes affected by carry-over. By 2 August, that 229 tonnes had risen to 590 tonnes, when Fonterra realised that WPC80 had also found its way into “stops and starts” production.<sup>131</sup>

It would not be until late on 2 August that NZMP realised that Darnum had supplied Danone with 11 ciphers of nutritional powder containing WPC80 from Hautapu, which had given readings under 50cfu/g. Remarkably, Darnum had not been notified of the unfolding crisis until the previous day (1 August) and had only then begun identifying and tracing affected production. It would take another 24 hours to identify that the problem was not limited to carry-over.

It later emerged that Darnum supplied Danone with almost 1,759 tonnes of potentially contaminated nutritional powder. Including carry-over, this was used in 5,585 tonnes of infant formula, or up to 7.5 million cans and pouches, at plants in New Zealand, China, Thailand and Malaysia: see inset.<sup>132</sup>

On 2 August, Fonterra had not much more than a broad outline of the problem confronting it. Yet with assistance from customers and the ministry, it began to make progress. Early on, MPI assisted by ruling out any risk of botulism in yoghurt, yoghurt beverages and protein drinks – products identified in Fonterra’s PowerPoint presentation as “low risk”. By 4 August, an assessment by the ministry’s technical and scientific staff concluded that these products had been heat-treated in such a way as to all but rule out any risk of botulism. Another early success was the tracing of 435 tonnes of infant formula destined for the US-based healthcare company (not the 260 tonnes in the PowerPoint presentation). Its tracing system, which included putting batch codes on the company’s cans, ensured it could trace these products with relative ease.<sup>133</sup>

With one or two exceptions, Fonterra’s tracing difficulties centred on the 1,759 tonnes of nutritional powder Darnum supplied to Danone. The problem was Fonterra Australia’s inability to verify the quantity of affected production, its whereabouts or the relevant tracing information (such as ciphers, batch codes, pallet numbers and export certificate numbers). In those circumstances it is hardly surprising Fonterra’s numbers moved about wildly in the following days and weeks.

<sup>131</sup> See earlier discussion at 22.

<sup>132</sup> The 5,585.3 tonnes of finished goods included products affected by carry-over.

<sup>133</sup> The company then dealt with overseas regulators to take appropriate actions based on the ministry’s provision of all related export certificates.

## PART FIVE: FONTERRA'S RESPONSE

For example, Fonterra advised Danone and the ministry on 2 August that it had supplied Danone with 590.5 tonnes of contaminated production. Three days later, that figure had jumped to 1,631.1 tonnes, an increase of 176 per cent. By 18 August, contaminated production had climbed to its final peak of 1,759 tonnes. But even those numbers fail to give a true sense of the fluidity of the situation. Altogether, Danone received 17 variations to product totals during the 16-day period. Information given to MPI changed eight times between 2 and 27 August.

Many amendments, no doubt frustrating for the recipients, were delivered with assured finality, only to be contradicted shortly afterwards. At 7.43pm on 3 August, for example, Fonterra told Danone the latest information it had supplied was the "final product listing", or "final data" set, of all shipments and products at risk. And at 3.24am on 5 August, after three changes of information in between, Danone received what was said to be a "final reconciliation", or "final confirmation", of all products at risk. But of course there were still many changes to come. Fonterra's performance was, to borrow its own words, "slow and poor".

### *Product tracing systems*

Fonterra Australia's troubles stemmed from failings connected with its database management system – or more correctly systems – because at the time of the incident it was in the process of switching from a set-up requiring some manual input to a fully computerised SAP replacement. Fonterra Australia decided to replace its previous system in 2010, but a long period of planning, followed by three months' training in early 2013, pushed back the switchover date to 1 April 2013 – at the exact time Darnum was dispatching its nutritional powder containing Hautapu WPC80 to Danone.

The changeover meant tracking anything containing the WPC80 was particularly challenging. Problems included the following:<sup>134</sup>

- Staff transcribed pallet numbers and volume amounts incorrectly into the existing system.
- No one noticed that some pallets had been split for airfreight purposes and given new pallet numbers when put into the SAP system.
- The contents of some pallets were ignored because the pallets were assumed to be "dummies" as part of the system changeover.
- Staff assumed that pallets contained 56 bags (when often there were only 55), skewing overall tonnage calculations.

However, the lack of any tracing procedures or experience in tracing exercises by those involved is the greater concern to the Inquiry (as it was to the Fonterra board inquiry). Australian personnel had not undertaken any tracing before, had no detailed procedure to guide them and had inadequate knowledge of both systems – including the links between them. The help that did eventually arrive came far too slowly. Such problems, on their own, might not have been so bad, except that Fonterra's tracing inadequacies:

- Stymied Danone's ability to trace its products in New Zealand and overseas because of its heavy dependence on Fonterra to trace the contaminated WPC80 first
- Hindered the ministry's ability to provide detailed, solid information and advice to customers and others about the location of affected products and required extra work to verify the inaccurate tracing information.

Danone's hands were, if not tied, at least lightly bound as it attempted to undertake its own tracing work in global markets. The New Zealand market demonstrated its difficulties. Its subsidiary Nutricia received about 700 tonnes of Darnum nutritional powder in New Zealand. By 2 August, and allowing for possible carry-over contamination, Nutricia had used it to manufacture 2,890 tonnes of infant formula at two plants in Hamilton and one in Auckland. This infant formula was either on sale locally (where some had already been purchased and consumed) or had been exported.

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<sup>134</sup> See also Fonterra board inquiry report at 84-85.

In the face of Fonterra's constantly shifting data, Nutricia struggled to trace the incoming Darnum nutritional powder and where it had fanned out into its own plants and products. It was helped in this work by the ministry andASUREQuality. Nutricia's own stock management and tracing system contributed to some of the difficulties: it was not fully electronic. The ultimate source of its difficulties, however, was Fonterra's constant amending of information.

Anyone not yet convinced of the complexity of the tracing work the incident entailed should read the ministry's *Whey Protein Concentrate Incident Tracing and Verification Report*, 25 August 2013. For the sake of consumers, the industry and the country's reputation, it must be everyone's hope that there is no repetition of the experience. Changes are under way to strengthen tracing: see the discussion below.

### 13. Co-ordination and crisis communications

Fonterra's overall lack of readiness made it unlikely the company would perform well in the crucial elements of a crisis response: co-ordination with other key participants and clear, accurate and decisive communication. Many lessons were learned the hard way.

A first step is for key participants to ensure in advance that their crisis plans dovetail as much as possible. The more that plans use similar principles, protocols and language, the lower the chances of confusion or of acting at cross-purposes. Individuals work separately but towards a common goal: a speedy resolution of the crisis in all its aspects. Naturally, this should extend to how each participant communicates with its various audiences during a crisis, a question dealt with below.

The Inquiry highlights some examples. Fonterra did not co-ordinate with the ministry to ensure a documented risk assessment took place, based on best available scientific data. The Inquiry has already noted that Fonterra did not give the AgResearch preliminary report to the ministry until two days into the response.

Nor was its co-ordination with customers adequate enough to allow them to carry out reliable risk assessments of their own. In particular, Fonterra provided information slowly and without the level of detail required to enable Nutricia to make informed recall decisions.

Another telling example concerns a Palmerston North school. On 9 August, Fonterra announced that it had given part of a 25kg bag of potentially contaminated WPC80 to the school for a science project. Fonterra had received this information on 6 August, but told the ministry only on 8 August. Furthermore, Fonterra representatives visited the school without first informing the ministry. The late notification undermined a timely co-ordinated response, something that was essential when the news inevitably grabbed media attention.

The Inquiry notes that Fonterra's board inquiry reported a perception that Fonterra focused on its own immediate interests and was insufficiently concerned with the interests of others.<sup>135</sup> At the time of a food crisis, it must be clear to all concerned that consumers' interests come first.

Fonterra's board inquiry concluded that key stakeholders, including government agencies and its main customers around the world, should regularly participate in joint simulation exercises to improve co-ordination.<sup>136</sup> The Inquiry agrees. There is no better way to achieve this than through simulation exercises, large and small.

#### Crisis communications

The company's crisis communications preparedness was seriously deficient. The Fonterra board inquiry noted that even the efforts of many committed staff working tirelessly to take control of the fast-moving crisis could not undo this fact. A ghost website, ready to be populated with the company's key messages and crisis-specific information, did not exist. Fonterra's translations for critical markets, such as China, were also 24 hours behind the news cycle. More generally, a view was expressed that the Fonterra Group's communications team was under-

<sup>135</sup> Ibid at 8.

<sup>136</sup> Ibid at 95.

resourced. It was only the day before the crisis broke on 2 August that the group director, communications (a new role) took up his appointment.

Despite its size and its international reach, the company lacked a sophisticated social media presence. As this incident illustrated, the absence of a social media strategy can be costly to reputation and bottom line.<sup>137</sup> The Fonterra board inquiry report quotes Steven Fink: "If your company finds itself in a crisis, and you have not prepared your social media network well in advance ... this could be your death knell."<sup>138</sup> Fonterra had neither a social media crisis communications plan nor a social media manager to monitor and respond to daily digital comment. And it was not until a week into the crisis that the company had a website dedicated to the incident.

The damage that can result from a failure to prepare was driven home in the *KPMG Agribusiness Agenda 2014*. The consensus of 157 industry leaders was that Fonterra's woes could be attributed to the "uncoordinated response to the recall, and the resulting communication uncertainty with fact and speculation becoming blurred". Nor did it help, they said, that media coverage "did little to put the recall into context, given the tiny fraction of New Zealand dairy product [affected]".<sup>139</sup>

The lack of preparedness made itself apparent early on in the crisis. During a live current affairs show on 5 August, the NZMP managing director (who, in fairness, had not been fully briefed) wrongly told viewers that "all" Nutricia Karicare products were potentially contaminated. In fact, only two products were suspect. Having failed to confirm the position with Nutricia in advance, Fonterra walked into a public relations disaster of its own making.

Then on 8 August, Fonterra issued a media release containing assurances that were not accurate. It said that "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". This was far from reality.

It is said that good crisis communication involves communicating with compassion, concern and empathy.<sup>140</sup> This is considered to be a key element in maintaining consumer trust and loyalty during a crisis. Such concern was absent from early media releases. Indeed, it was not until 7 August that Fonterra's chief executive apologised for the anxiety caused by the incident, and not until 8 August that the board did so.

Several interviewees emphasised that Fonterra's lack of co-ordination with the ministry over public statements damaged New Zealand's reputation. One put it well when she said: "The ambiguity in timing between the ministry and Fonterra did not give a good impression – it was not just the company's reputation on the line, but the whole country's." The Inquiry agrees.

As but one last example, on 28 August, Fonterra publicly pressed the ministry to release the results of mouse bioassay testing by United States laboratories. Fonterra was understandably impatient for the outcome of the further testing to be made public at the first opportunity. It was particularly frustrated that it heard about the test results from others before any notification from the ministry. Critics said Fonterra had taken a narrow view of its interests by publicly demanding immediate release of the test results, rather than working co-operatively with the ministry to achieve this. Whether or not the criticism was justified, closer co-ordination would have been preferable for all concerned.

A final point, and a good one, was made by a senior food-industry executive about any potential food safety scare:

"A company that is more focused on its own commercial reputation in a crisis does so at its peril. Companies should think about consumer safety first and reputation second. If consumers lose trust in a company, that will be its undoing."

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137 Appendix G of the Fonterra board inquiry report at 97 discusses Fonterra's social media response, particularly in China, and, more importantly, recommendations of value to all companies.

138 *Crisis Communications: The Definitive Guide to Managing the Message*, McGraw Hill, New York 2013; Fonterra board inquiry report at 98.

139 Fn 49 at 44. See also Appendix I of the Fonterra board inquiry report, which gives stakeholders' ratings of Fonterra's crisis performance. Half gave Fonterra's handling of the incident 1 or 2 out of 5.

140 Fonterra board inquiry report at 124.

## 14. Fonterra's improvements

The ill-prepared inevitably pay a heavy price in a crisis. Since a crisis seldom gives warning of its arrival, the best course of action is preparedness in all its various forms: sound communication plans, sound tracing and recall systems, regular updating of crisis management plans, regular training and evaluation. Fonterra has since made strides in all these areas. The improvements listed below will provide useful guidance for any company looking to benefit from the lessons Fonterra learned at considerable expense.

*Planning and simulation:* Responding to the board inquiry, Fonterra is comprehensively overhauling its incident management processes. These now require two simulations a year, one of which will be a response to a food safety incident that may require a recall involving customers. These exercises will include simulated media involvement.

In May 2014, Fonterra conducted an eight-hour, group-wide crisis exercise. The scenario presented to staff grew steadily more severe and complicated, requiring first, formation of an incident management team and then of a group crisis management team. External observers, including two from the ministry, provided feedback.

At the Inquiry's request, Fonterra provided a copy of the debriefing. Many aspects worked well, but others less so, including the absence of a clear chain of command; the delay in involving the group crisis management team after the initial incident management team assessment; and confusion over who would initiate tracing to name but some. But what emerged clearly from the Inquiry's review of the debriefing was a strong desire to identify weaknesses and suggest corrective actions, as well as a general awareness of the need for everyone to lift their performance.

Sound crisis planning and rehearsals should not be limited to Fonterra. All participants in the dairy, and wider food, industries need to demonstrate a commitment to crisis management readiness

through regular simulation exercises. This imperative applies equally to private-sector companies and public-sector agencies.

*Tracing:* Recognising the inadequacy of its tracing capability, Fonterra has embarked on a programme, scheduled for completion in 2017, that will aim to give consumers instant online access to a product's history stretching back as far as the dairy farming region where Fonterra sourced the ingredients.

Fonterra has short, medium and long-term goals to achieve this. It is undertaking a series of systems upgrades so it can trace a significant proportion of what it produces anywhere in the world in less than 48 hours. It aims to meet that target by the end of 2014. Through further improvements, it aims to cut that time to 24 hours by the end of 2015; and by still more improvements to reduce it to three hours by the end of 2016.

Much of the enhanced performance will come through improved systems, including updated product identification, labelling and coding standards, and making some of its systems compatible with MPI's animal product E-cert system (see later discussion). The company is also writing traceability and recall protocols (including cautionary holds) into customer contracts.

Fonterra's efforts need to be seen in the context of a worldwide push for improved tracing. In a recent report comparing the traceability requirements of 21 OECD countries, New Zealand (along with Australia, Canada, Japan, Brazil and the United States) received an overall ranking of "average". European Union nations scored highest. The *Comparison of Global Food Traceability Regulations and Requirements* report did note, however, that some countries, including New Zealand, were developing traceability regulations, or preparing to do so.<sup>141</sup>

Indeed, in 2014, as recommended by the first report, the Government established a dairy traceability working group to consider the most appropriate regulatory provisions for the traceability of dairy products. The working group's second task, to

141 S Charlebois, B Sterling, S Haratifar, S Kwaw Naing, *Comprehensive Reviews in Food Science and Food Safety*, vol 13:5, 2014 at 1104-1123.

develop a code of practice to guide industry participants in implementing those requirements, is already under way.

The Inquiry interviewed the working group's independent chair, Dr John Larkindale, and was pleased to learn that its members have made good progress. The group's proposals, to be submitted to MPI's Director-General by the end of 2014, will take a very meaningful step towards strengthening New Zealand's dairy food safety systems.

In the meantime, tracing should be simplified as the dairy industry moves to the ministry's animal product E-cert (APE-cert) system, designed to provide MPI with up-to-the-minute information about the movement of all products around the country before export. APE-cert should significantly improve the ministry's ability to trace dairy products, both backwards and forwards through the supply chain. Transitional arrangements begun in September 2014 will go through until 1 May 2015. From that date, dairy operators must enter into the system details about the movement of goods intended for certain markets.

*Communications:* Fonterra's communications team is developing what it calls a master communications crisis management plan. This will align with the incident management team's plan and be tested twice a year. The team is also preparing template documents that, like the master plan, will cover foreseeable scenarios, but will be sufficiently flexible so that overseas offices can adapt them to local market conditions and stakeholder needs.

*Co-ordination:* Fonterra recognises the importance of keeping all those involved in a crisis response effort abreast of its intentions, and that co-ordination is impossible without such transparent communication. To that end, Fonterra has begun a programme to improve stakeholder engagement, both at times of crisis and more generally, with ministers, regulators, overseas diplomats and customers. One measure, engagement with key customers to understand their expectations during a crisis, has resulted in a customer engagement and transparency protocol, to

be followed at the time of any incident. Fonterra is also discussing a similar engagement protocol with the ministry. And Fonterra's government and trade team is developing a response plan that will actively involve government agencies and industry bodies in a co-ordinated way during a crisis.

*Training:* Fonterra has committed itself to quarterly training for all key staff designated to join in any crisis response. Individual business units will also hold their own training exercises as part of regular duties. New staff joining incident management processes will receive training and support so they can participate effectively in any response.

*Science:* Acknowledging the need for a pool of scientific experts who can help immediately as part of a crisis response, Fonterra has built relationships with, and secured commitments from, a range of such experts. Each is matched to a specific risk in the company's risk register, to be called upon in times of crisis. Fonterra is committed to supporting the new Food Safety Science Centre, set up as a result of the Inquiry's first report.

*Logistics:* Fonterra will incorporate a crisis command centre in its new Auckland headquarters, scheduled for completion in mid-2016. The centre will meet the need for a dedicated space large enough to ensure a successfully co-ordinated crisis response.



## PART SIX: THE MINISTRY'S RESPONSE

Fonterra's phone call on Friday 2 August came as a huge shock to the ministry. The news of "confirmed *C. botulinum*" arrived without warning and posed obvious and enormous implications for consumer health, the dairy industry and New Zealand's trade and reputation. The news also presented huge challenges for the ministry. It had plans in place to deal with just such an eventuality, but was it sufficiently prepared and practised? And how did it perform when a real-life crisis arose? These are important questions because the ministry, in addition to its critical food safety role, acts as protector of the country's primary industries, the backbone of New Zealand's economy.

As to the first of these questions, the Inquiry's view is that the ministry needs to improve its state of readiness for food incidents. As to the second, the ministry deserves credit for many aspects of the response and it quite rightly took a precautionary approach in urging product recalls without waiting for conclusive test results. But it should have had better-documented decision-making processes; used more rigorous science-based risk assessment; and co-ordinated more effectively with others, especially with Nutricia over recall decisions. The ministry acknowledges it can make improvements in these areas and has a comprehensive programme under way to do so.

### 15. Protocols and readiness

At the time of the incident, the ministry had two protocols relevant to food safety incidents: its food incident response protocol (food protocol) and its

trade response guide (trade protocol).<sup>142</sup> Both are current, but will be replaced by MPI's new single scalable response model, due for implementation in 2015 (discussed in section 16).

The food protocol was drafted by MAF (the former Ministry of Agriculture and Forestry) in June 2010.<sup>143</sup> This 42-page document, based on a previous version used by the New Zealand Food Safety Authority (NZFSA), describes how to respond to an incident, including structures, roles and responsibilities, and procedures to follow. It remains in draft form, having never received formal approval by MAF or MPI, as required.

The food protocol states that it is to be reviewed annually. No review had taken place by June 2011, June 2012 or June 2013, meaning a re-evaluation was more than two years overdue when the incident occurred in August 2013. And there had been no systematic staff training (other than on-the-job training) in the protocol, although some staff were aware of the protocol or its predecessors from previous positions at NZFSA, or from actual incidents. No job cards or quick reference guides were available to staff. Nor had there been any effort to ensure other government agencies and industry groups were aware of MPI's protocols.

Overall, familiarity with the food protocol was variable. The response to an outbreak of listeriosis in Canada in 2008 suggests the ministry is not alone in this experience. Few involved in dealing with that outbreak were familiar with the relevant protocol, according to an official report: see inset at 68.<sup>144</sup>

<sup>142</sup> The protocols deal with three categories of incidents: those with purely local implications; those requiring a joint-agency response; and those that need a whole-of-government approach.

<sup>143</sup> Ministry of Agriculture and Forestry, *Food Incident Response Protocol*, June 2010 (food protocol), inherited from the NZFSA when the two departments amalgamated.

<sup>144</sup> Fn 108 at 63.

**Listeriosis outbreak, Canada, 2008**

**Human cost:** Twenty-three dead and 57 seriously ill; four out of five victims were elderly people in hospitals or long-term care homes

**Financial cost:** The temporary closure of the plant and the recall of affected products cost the company \$20 million; lawsuits added another \$27 million

**Disease:** Listeriosis, most commonly contracted from delicatessen meats and unpasteurised milk; a bacterial disease that poses greatest risks to pregnant women, newborns and those with weakened immune systems

**Source:** Investigators traced the outbreak to the slicing machines of Maple Leaf meat company's Toronto plant

**Causes:** Poor hygiene, quality control and compliance monitoring, as well as the highly risky practice of giving delicatessen meats to those with lowered immune systems

**Lessons:** Need for an updated, clear and well-recognised protocol to deal with foodborne illness outbreaks; a ready-to-implement communications plan (to avoid the slow, fragmented response that eventuated); more mock exercises by regulators; stricter cleaning procedures and more rigorous enforcement

The ministry described the trade protocol as a “module” that can be linked to the food protocol, but the relationship between the two is ill-defined and lacks explicit guidance for staff about when to follow one rather than the other. The choice is made all the more difficult because of the amount of overlap between the two documents.

In MPI-only incident responses, the principal distinguishing feature is that the trade protocol requires the formation of a response strategic leadership team (RSL) to set the strategic direction of the response.<sup>145</sup> A trade response manager, in charge of a response management team (RMT), manages day-to-day operations and reports to the RSL. The food protocol has no single body equivalent to the RSL. Rather, it provides for an incident controller to co-ordinate and implement the response, reporting to the “commander” or “key decision-maker”, either a deputy Director-General or the director of the compliance and enforcement

group (now the compliance directorate at MPI). When a food incident requires the involvement of other agencies, both protocols rely on the Officials Committee for Domestic and External Security Coordination (ODESC), set up by the Department of the Prime Minister and Cabinet (DPMC).

*Underlying framework*

The food protocol, and to a lesser extent the trade protocol, follow the principles of the New Zealand Coordinated Incident Management System (CIMS), the definitive framework for successful incident management.<sup>146</sup> The framework is sufficiently flexible to be adapted to large or small-scale incidents and to agencies' individual needs.<sup>147</sup> CIMS calls for a governance body (taking a strategic view) that has ultimate responsibility, but leaves operational control to a controller.<sup>148</sup> The controller heads an incident management team and he or she directs the overall response, sets priorities, initiates action, allocates resources and briefs the governance body.

Under the CIMS framework, there is a group to collect and analyse information to support informed, risk-based decision-making. This planning group oversees preparation of action plans. An operations group executes responses (including liaison and co-ordination work). Another group communicates with the public, monitors reactions and provides a media spokesperson. CIMS emphasises testing and rehearsals to ensure operational readiness, along with debriefs for continuous learning and development.

Some ministry staff had received formal training in CIMS and others were familiar with the framework in a very general way, but the Inquiry's overall impression was that CIMS expertise was, at best, variable. The ministry's new single response model will also be based on CIMS principles.

Guidance on food incident emergency planning is available from food safety authorities around the world, as well as from the Food and Agriculture Organization (FAO) and World Health Organization

145 Ministry for Primary Industries, *MPI Trade Response Guide*, October 2012 (trade protocol) at 8.1.

146 Domestic and External Security Group and Officials Committee for Domestic and External Security Coordination, *The New Zealand Coordinated Incident Management System (CIMS)*, 2nd edition, April 2014.

147 CIMS was developed in 1998, based on a United States model. A number of agencies, including MPI, revised the model in 2014.

148 CIMS manual at 27-30.

(WHO).<sup>149</sup> These organisations emphasise that preparedness is the fundamental building block of an effective response to food safety emergencies: “[Creating] various tools such as templates for data gathering, situation report templates and decision trees, as well as clear and concise reference materials for use during emergencies, can limit the number of decisions that the emergency risk managers will have to make under time constraints.”<sup>150</sup> The ministry has told the Inquiry it is taking this considerable body of guidance into account in developing its own new model.

### Rehearsals

The ministry had not conducted any simulations or rehearsals of food safety incidents since the merger of MAF, NZFSA and the Ministry of Fisheries. The nearest it got was a biosecurity exercise in March 2012, code-named Exercise Taurus, that simulated a large-scale outbreak of foot-and-mouth disease.<sup>151</sup>

After the exercise, an independent evaluation recommended: updating the biosecurity protocol; creating a proper command centre; cutting back the size of the strategic leadership response team, which had proved unwieldy; ensuring the team kept its strategic focus and avoided straying into operational matters; and giving ministry scientists, and science generally, a larger role in the decision-making process. It also highlighted insufficient trained staff and inadequacies in documenting information flows. Nonetheless, the evaluation team was “impressed with MPI’s general emergency management approach”.

Less than a year later, the Auditor-General issued a report, *Ministry for Primary Industries: Preparing for and responding to biosecurity incursions*, which examined the effectiveness of the ministry’s biosecurity response system. The Auditor-General considered that overall the ministry was “under-prepared” for potential incursions and that, despite work under way, “serious weaknesses” remained.<sup>152</sup>

A programme had commenced to implement the recommendations of both reports, but nothing had been completed by August 2013. One participant in the Taurus exercise rightly pointed out that food safety and biosecurity incidents are different. This is a valid point. But had the recommendations been acted on, the ministry might have been better prepared to respond to the WPC80 incident.

Overall, there was a general lack of commitment to ensuring readiness to deal with a food safety incident. As more than one senior official candidly acknowledged, no one had “taken ownership” of food safety. That appeared to be due, in part, to pressures and other priorities stemming from the merger. Importantly, lack of ownership is a gap that has since been closed.

## 16. Performance

### First 24 hours

The first 24 hours after a crisis reaches the public eye are critical to the success or otherwise of any organisation’s response. The reason is simple: key decisions are made and public perceptions are often cemented during that first phase of a crisis. Early, effective management of events can greatly reduce the duration and impact of a crisis.

### Initial response

The ministry’s response in the hours and days after Fonterra’s call did not follow either of its protocols exclusively. Instead, the ministry adopted (or so it said) elements of both (while formally invoking neither) and added its own improvisations. As a result, there was not the swift, automatic response that could have been expected if staff had used a single protocol they understood (and, better still, been familiar with through training exercises).

After the ministry’s director of market assurance took Fonterra’s call at midday advising confirmed *C. botulinum*, he immediately notified the acting Director-General and began contacting other officials

149 FAO/WHO, *FAO/WHO Framework for developing national food safety emergency response plans*, Rome 2010.

150 FAO/WHO, *FAO/WHO Guide for application of risk analysis principles and procedures during food safety emergencies*, Geneva 2011 at 13.

151 MPI, *Exercise Taurus 2012 Final Evaluation Report*.

152 Auditor-General, *Ministry for Primary Industries: Preparing for and responding to biosecurity incursions*, February 2013 at 5-6.

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whom he thought would be part of a response team. Fonterra's PowerPoint presentation, detailing products "at risk", arrived at 12.35pm.<sup>153</sup> At 1.20pm, the market assurance director sent an email (attaching the PowerPoint) to 19 ministry officials, recommending that the ministry initiate a "trade/food" response.

At 1.30pm, the ministry convened a meeting described to the Inquiry as a "practical session to allocate work streams to get things done". The ministry was anxious to move quickly. This meeting, in effect, decided the composition of the seven-member response management team (RMT).<sup>154</sup> The meeting decided to appoint a senior ministry official responsible for the dairy regulatory system to be the response manager. Although he had not previously managed a food safety incident, he had extensive experience in biosecurity incidents. Many interviewees – both within and outside MPI – complimented him on his capable leadership.

The meeting also decided to establish a technical team (dealing with science-related questions), an operations team (dealing with tracing and recall), a trade and market access team (managing trade implications), a liaison team (handling commercial food producers and other stakeholders) and communications and logistics teams. A separate reporting committee helped with ministerial briefings and provided policy and legal advice to the response team. In total, more than 100 ministry staff were involved in the response.

At 3.30pm, 25 officials, predominantly from MPI, gathered. The meeting agreed to set up an RSL and endorsed the structure set in motion at 1.30pm. At the top would be a 10-member RSL comprising six MPI officials and one representative each from the Ministry of Foreign Affairs and Trade (MFAT), Ministry of Health, New Zealand Trade and Enterprise (NZTE) and DPMC.

The response's objectives would be first to "protect consumer health", second to "protect New Zealand's reputation for safe product and maintain market access in dairy products" and third to "keep

ministers, the ministry senior leadership team and RSL fully informed for effective stakeholder liaison".<sup>155</sup>

The acting Director-General chaired the initial RSL meetings, but within a few days rightly stepped aside to concentrate on other crisis-related demands on his time. A deputy Director-General experienced in biosecurity incidents took over.

The ministry described this structure to the Inquiry as a hybrid of the two protocols, although the Inquiry found it hard to identify precisely what came from which. The Inquiry does not criticise the decision to take the RSL concept from the trade protocol because the ministry was familiar with this from biosecurity incidents.

The ministry's view was that the RSL fulfilled the same role as ODESC, particularly given that DPMC was consulted on 2 August about the response and represented on the RSL. But as several interviewees observed, given the incident's broader implications on "New Zealand's reputation, potential loss of markets and impact to the economy", it might have been appropriate to invoke ODESC.

In any future multi-agency incident, it is important for the ministry to address this point explicitly, both at the time the response structure is set up and as the crisis develops. Indeed, the discussions and reasons should be documented to avoid any uncertainty about the structure chosen.

The Inquiry also considers a separate intelligence and planning group would have been very useful, as required by the food protocol and the CIMS manual in force at the time. Such a group has the "core role" of risk identification and profiling, as well as gathering, evaluating and presenting information on food safety and trade risks.<sup>156</sup> This is especially important because good risk assessment is critical in managing any food crisis.

In short, the ministry's planning and preparedness fell short of best practice: it should have had a single, coherent food incident protocol that could simply have been picked up and put into effect at midday.

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<sup>153</sup> Discussed earlier in part four, section 10.

<sup>154</sup> Other officials attended these meetings, particularly the deputy work stream leaders.

<sup>155</sup> Three further objectives were "document systems, process, records and reports"; "investigate circumstances and any liability"; and "learning and preventing any recurrence".

<sup>156</sup> Food protocol at 16.

### Key dates

<b>3 August, 12.12am</b>	Ministry issues first media release: products made from WPC80 “appear to contain” <i>C. botulinum</i>
<b>3 August, 2.45pm</b>	First Director-General statement: Karicare Stage 2 Follow On may contain affected WPC80
<b>4 August, 8.30pm</b>	Second Director-General statement: potential contamination of stage 1 infant formula cannot be ruled out
<b>6 August, 3pm</b>	Third Director-General statement corrects wording error of second statement
<b>12 August, 12pm</b>	Fourth Director-General statement narrows scope of consumer advice to infant and follow-on formula made between 21 May and 2 August 2013
<b>28 August</b>	Ministry receives and announces final test results from US laboratories
<b>28 August</b>	Ministry releases its tracing and verification report

### Relevant food incident experience

As emphasised by many interviewees, senior staff involved in the response (either in the RSL or RMT) had extensive biosecurity and incident management experience, but little direct experience in food incidents. Incident management skills are important but, as one participant pointed out, “food safety incidents have unique features”. It is obviously desirable for the ministry to deploy suitably trained people with food incident response experience. The Exercise Taurus evaluation highlighted a lack of sufficient trained or experienced staff, and a number of interviewees made the same comment about those participating in the first few days of the response effort.

### Access to AgResearch report

In spite of the flurry of emails and phone calls with Fonterra, MPI did not, in the Inquiry's view, show sufficient urgency in gaining access to AgResearch's preliminary report. Admittedly, part of the delay was due to the time taken for Fonterra to release

AgResearch from confidentiality restrictions. But the result was that the ministry did not have access to the report until 7pm on 4 August, more than 48 hours after notification.

Could it have made a difference to how the ministry responded? Quite possibly yes. The “confirmed” *C. botulinum* in the PowerPoint presentation that arrived soon after Fonterra's notification on 2 August became, in AgResearch's preliminary report received two days later, “likely” *C. botulinum*. The results of the “initial investigation” were hedged by other qualifications, too: they were for “research purposes” only; they came from a laboratory that was not a “registered diagnostic facility”; and the possibility of close relatives to *C. botulinum* could not be ruled out.

Indisputably, the ministry should have access to all relevant information at the earliest possible opportunity (ideally immediately on notification) in order to make prompt, informed risk assessments. The ministry has some general powers to compel the release of documents held by risk management programme operators, but a specific statutory power would be useful, enabling the ministry to demand all relevant material.<sup>157</sup> This power should explicitly override any conflicting obligations, such as confidentiality requirements.

It was not until 13 September that Fonterra gave Nutricia the preliminary AgResearch report. Yet the report contained information vital to Nutricia's ability to carry out a risk assessment. The Inquiry has previously observed that affected parties should receive scientific or test results, particularly if relevant to recall decisions, and the Inquiry invited the ministry to consider such disclosure.<sup>158</sup> Any statutory power to compel relevant material should also include the ability to disclose such material to affected parties.

A final point: it is important during a crisis that as much information as possible is shared among participants to assist a well-co-ordinated response. Information should not be withheld unless there are compelling legal or other reasons preventing this.

<sup>157</sup> For example, s 88(1)(b), Animal Products Act 1999 – power to examine.

<sup>158</sup> First report at 58.

*Initial risk assessment*

Both ministry protocols (in line with international principles) demand that officials begin, and document, a risk assessment within two hours of initiating a response, which, in this case, would have been by 3.30pm at the latest on 2 August. The food protocol recognises that a complete assessment may not be possible within that time, but that a start must be made, even in draft form. The trade protocol adds that the assessment should be “laid out clearly and tabled at the incident team meetings”.<sup>159</sup> Similarly, the ministry requires a “rapid risk assessment” in biosecurity incidents.

The requirement exists for a very good – almost self-evident – reason: making decisions in a crisis demands an accurate assessment of the crisis, and the sooner the better. Indeed, without a good grasp of the facts, good decision-making will be difficult. And any risk assessment must be continually updated as new information comes to light or assumptions change.

No structured and documented risk assessment took place. Questioned about this, officials in charge said the very nature of their decision-making was risk-based (one interviewee described it as “an intelligent and risk-driven response”) and a lack of documentation did not diminish their performance, particularly on 2 August. The Inquiry accepts that staff acted in response to the risks as best they understood them, but does not consider this a sufficient argument to counter the need for a formal assessment, as required by the protocols.<sup>160</sup> For example, such an assessment would in all likelihood have highlighted:

- The need to obtain the underlying scientific data from Fonterra, including the AgResearch preliminary report, as quickly as possible
- The lack of certainty in the scientific position, contrary to Fonterra’s PowerPoint presentation
- The rarity of *C. botulinum* in manufactured dairy products, particularly infant formula.

Undoubtedly, the ministry was influenced by Fonterra’s standing as a multinational with a considerable body of in-house scientific expertise, and assumed that the notification of “confirmed” *C. botulinum* was accurate. But a formal risk assessment at the outset would have subjected every assumption to scrutiny and also given due weight to other non-scientific risks, such as the loss of infant formula supply – which later became a potential problem – and the possible health risk from inappropriate changes to infant diet.<sup>161</sup>

Danone (Nutricia’s parent company), argues that its own scientists should have been consulted early on and contributed to a risk assessment. After all, it was the party most affected by the incident, ultimately recalling 7.5 million cans and pouches of infant formula. Those scientists, it says, would have included microbiologists with expertise in Nutricia’s infant formula manufacturing processes, as well as in *C. botulinum*. The scientists could also have provided information about Nutricia’s testing regime and the lack of reported illnesses, despite potentially contaminated products being on sale for some time.

The Inquiry agrees that the ministry should always consider seeking scientific advice from those with first-hand knowledge of both the product and the potential hazard in question. That would not bind the ministry to act on such advice – or blind it to possible conflicts of interest. But there can be no harm in obtaining information from those closest to the relevant product so the ministry can make decisions as objectively as possible. Nutricia’s scientists could also have helped in assessing infant diet-related risks.

This also raises the question whether the ministry used outside scientific advice soon enough. The answer is no. An RMT meeting at 10.30am on 3 August discussed setting up a group of external scientists, known as a technical advisory group. But the ministry did not establish the terms of reference until 9 August, and the group did not meet until 12 August, 10 days after the notification. By that advanced stage, the only remaining question of any significance was the scope of the recall.

<sup>159</sup> Trade protocol at 9.2.

<sup>160</sup> For other overseas protocols: see United Kingdom Food Standards Agency, *Incident Management Plan*; Food Safety Authority of Ireland, *Code of Practice No 5: Food Incidents and Food Alerts*. See also the WHO risk analysis guidelines:fn 150. These guidelines emphasise the importance of documenting both initial steps and the entire process of risk analysis during a crisis.

<sup>161</sup> It is acknowledged that the ministry identified various scenarios, in response to new and emerging information from Fonterra, and how it would react to each of these at its 3pm meeting on 4 August.

Previously, the NZFSA Academy comprised about a dozen or more experts available on retainer to assist with scientific questions. The Inquiry considers there would be merit in re-establishing such a panel for use on an as-needs basis.<sup>162</sup> The ministry cannot realistically be expected to maintain sufficient in-house scientific expertise to deal with all possible food safety incidents. But with such expertise to call on, it could rapidly and appreciably boost its scientific capability.

None of this is to call into question the obvious expertise of senior scientists within the ministry. Many were brought into the response, although some with particularly relevant experience were not during the critical first 72 hours. Nor did the ministry call on the experience of some senior MPI staff with extensive food incident experience. Many interviewees were perplexed by this. That point aside, and even allowing for internal scientific expertise, there is an obvious benefit in bringing in outside scientific advice at such times.

### *First media release*

On 2 August, and during subsequent days and weeks, ministry staff – particularly RSL and RMT members – worked round the clock. At the height of the crisis, both teams met twice a day or more. The RMT met first to review and finalise a “situation report”, essentially summarising the information to hand and priorities for the day. These reports went to the RSL, which used them to agree to the day’s actions. Non-MPI participants generally agreed that the RSL and RMT meetings worked reasonably well.

As in all food incidents, the ministry had to decide what information to give the public and overseas regulators and when. At 10pm on 2 August, the ministry, via MFAT, notified New Zealand’s overseas posts of the suspected contamination to allow them to advise foreign regulators.

At the earlier 3.30pm RSL meeting, the group noted work was under way on a media release. Just after midnight, the release went out. It was brief – hardly more than 200 words. It spoke of “a food safety

issue” at Fonterra and said in a qualified way that the products in question “appear[ed] to contain” *C. botulinum* (compare Fonterra’s advice that this was “confirmed”). As to which products were contaminated, the statement said only that these were “a range of products including infant formula, growing-up milk powder and sports drinks”. It did not say what specific products consumers should avoid; what the risks of contracting botulism were; what medical advice should be followed; or how widely the problem might have spread.

### **FAO/WHO: communications**

Communication about a food safety emergency should not underestimate the gravity of the situation, but indicate as clearly as possible to the public:

- What is known about the food safety emergency
- The food products involved
- What the risks are and whether they are known
- What levels of exposure could be harmful
- What the public should do if they have consumed or obtained affected products
- How to access additional information

Many interviewees, including food safety experts, were critical of both the timing and content of the media release. As many pointed out, the lack of detail provoked an array of questions. Journalists and the public predictably enough searched the internet. The absence of any reassuring information, together with the words “botulinum” and “infant formula”, was guaranteed to result in alarm and international coverage. One interviewee described the situation at this point as a “time bomb”. The statement was firm in one respect: the first priority was to track down any contaminated products in New Zealand.

The media release fell short of the principles set out in the FAO/WHO risk guidelines, which make clear that any communication to the public must indicate the facts as clearly as possible: see inset. MPI’s explanation was that it had no option but to release a public statement at this time. It knew Fonterra

<sup>162</sup> Such an academy would give the ministry access to experts here and around the world. This contrasts with the role of the New Zealand Food Safety Science Centre: first report at 25.

had already advised customers so there was every possibility the news would become public.

Given that the ministry had made public health its primary consideration and the media release gave the public no guidance about what steps to take, a better course of action would have been to wait until the ministry had more facts at its disposal before going public. It could then have issued its first media release in conjunction with the first Director-General statement and Nutricia's recall about 24 hours later.

Future incidents will involve considerations of food safety, trade and reputation, which may at times compete. The ministry's work to develop a new response model should include guidance on when and how to communicate with different audiences.

### Director-General statements and voluntary recalls

There are three ways for the ministry to bring about a product recall: first, it can encourage manufacturers to undertake a voluntary recall; secondly, it can issue a Director-General statement, an advisory declaration protected by qualified privilege that will typically recommend consumers not eat particular products;<sup>163</sup> and thirdly, it can issue a statutory recall compelling companies to withdraw the products in question.<sup>164</sup> Neither the food nor trade protocol contains guidance about how the ministry should approach the use of any of its statutory powers. This gap should be filled.

MPI, Fonterra and Nutricia exchanged a series of phone calls and emails on 2 August about the location of affected products. At 7pm, Fonterra told the ministry that five batches of Nutricia follow-on formula (a type also referred to as stage 2 formula) were potentially contaminated with nutritional powder made at Darnum.

About 9.30pm on 2 August, the ministry spoke to senior Nutricia executives in Sydney. The information then available to both the ministry and Nutricia suggested the affected follow-on products were not on sale in New Zealand. That evening, however,

Nutricia put a hold on follow-on products within its supply chain as a precautionary measure.

### *First statement: 2.45pm, Saturday 3 August*

By 9am on 3 August, the ministry considered it did not have enough certainty whether Nutricia's follow-on products containing affected WPC80 were in New Zealand. Nutricia continued to trace affected production as it received more information from Fonterra (and kept the ministry informed). The RSL decided the consequences were potentially serious enough to warrant "action today". A small group, including legal advisors and a market access manager, began work on the wording of a Director-General statement as a "precautionary measure". As the morning progressed and the ministry continued its endeavours to verify the location of affected production, the situation became more confused rather than clearer.

At 2.45pm, the first Director-General statement was issued. It provided the public with five new pieces of information:

- The ministry had received advice at 7pm the previous day that certain batches of Nutricia's Karicare Follow On for infants six months and over might contain affected WPC80.
- Those batches were not, as best it could tell, on sale in New Zealand, but it was seeking to verify that.
- No other products in New Zealand, to the ministry's knowledge, contained the affected Hautapu WPC80.
- To be on the safe side, parents and caregivers should switch from Karicare Follow On – the only product in the company's range affected and usually sold locally in 900-gram tins – to either formula for infants up to six months, ready-made liquid formulas or other brands.
- Anyone with health or other concerns should ring one of three helplines listed at the end of the statement for more information.

<sup>163</sup> These statements are issued under the Animal Products Act 1999, Food Act 2014 and Wine Act 2003.

<sup>164</sup> In 2013, the Animal Products Act 1999 power rested with the Director-General, and the Food Act 1981 power with the Minister for Food Safety. As recommended by the Inquiry, both recall powers now rest with the Director-General.

The ministry did not consult Nutricia over the wording. Nutricia later criticised as not medically sound the statement's recommendation to switch to formula intended for infants up to six months (known as stage 1 formula). It also found fault with the statement's lack of detailed information for parents and caregivers, pointing out that telling a parent to stop using a particular formula product (or to move to another) does not provide sufficient guidance for parents who rely entirely on infant formula as their baby's food source.

Some interviewees, particularly food safety experts, noted that this first statement did not follow the typical regulatory approach in situations of uncertainty, namely to begin broadly and gradually scale back the recall as more confirmed information comes to hand. Such an approach avoids the need to broaden the scope of a recall, which can create more uncertainty by fuelling the suspicion that authorities are scrambling to catch up with, rather than being abreast of, events. However, MPI's view was that when the acting Director-General issued the first statement, the information available did not justify a broader statement. The Inquiry agrees.

About three hours after the first statement, MPI's understanding changed considerably. At 5.30pm, there was a telephone conference call involving Fonterra representatives and officials from the ministry, MFAT and NZTE. During the call, Fonterra revealed that the problem might extend to infant formula (not merely follow-on formula). After the conference call, the ministry asked Nutricia whether it could provide information to confirm or deny Fonterra's news, saying the matter was urgent and that the acting Director-General was considering a second Director-General statement. Nutricia said it would seek what information it could that night.

The acting Director-General sought expert advice from the Ministry of Health because it needed to balance the very low risk of exposure to botulism against the risks of leaving parents and caregivers with very few options to feed their infants. The acting Director-General decided to allow Nutricia time to reconcile its information with that provided

by Fonterra. The Inquiry considers this appropriate, and it is helpful that the underlying basis for the decision was recorded in writing.

At about 9pm, MPI learned of the first suspected case of infant botulism, which, although quickly ruled out, emphasised the high stakes involved.

#### *Second statement: 8.30pm, Sunday 4 August*

At 1.30am on Sunday 4 August, Nutricia issued a voluntary recall of two of its products, one for babies up to six months old (infant formula) and the other for babies over six months (follow-on formula, specifically Nutricia Karicare Gold+ Stage 2 Follow On). Batch numbers on the base of tins allowed customers to identify affected products. Nutricia did not provide the ministry with advance notice of the recall, or a draft, but considered it was consistent with their previous discussions.

Nutricia's recall applied to stage 1 infant formula. This was the very product the Director-General statement recommended less than 11 hours earlier that parents give to their babies in place of follow-on formula. This lack of co-ordination caused confusion. It could have had disastrous consequences if the incident had not proved to be a false alarm.

At 12.15pm, the ministry issued a media release, prominently labelled "precautionary advice" and noting the following changes:

- The ministry now thought some contaminated infant formula "may be on sale".
- Nutricia had begun a precautionary recall of specific batches of infant and follow-on formula.
- Nutricia had given MPI information that would lead to another Director-General statement.

At 8.30pm, eight hours later, a second Director-General statement noted the Nutricia product recall, but added:

- Nutricia had not been able to identify all potentially contaminated product items and their location.

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- The ministry was still verifying which products contained the contaminated WPC80 and their location.
- The acting Director-General had decided to expand his precautionary advice to include Karicare Stage 1 formula (as well as Karicare Stage 2 Follow On formula). Parents and caregivers should switch to alternative brands.

This statement conflicted with Nutricia's voluntary recall in two ways. First, Nutricia's recall was confined to specific batches, whereas the Director-General statement included all batches. Secondly, the second statement contained a potentially important, but subtle, error. It referred to "Nutricia Karicare Stage 2 Follow-on formula products for children from six months old". The Nutricia recall notice referred to "Nutricia Karicare Gold+ Stage 2 Follow On formula products for children from six months old". Despite the similarity in wording, these were not the same products. This was a simple case of poor attention to detail – but detail with serious ramifications if the incident had not been a false alarm. Such lack of attention also extended to the ministry's website where the change was not clarified.

The ministry said that there were two reasons for the broader scope of the second Director-General statement. First, it had begun to doubt the accuracy of Fonterra's information. Secondly, because of the ever-changing information from Fonterra, Nutricia was unable to confirm to the ministry that the contamination was confined to specific batches. The Inquiry agrees that both these left the acting Director-General with little alternative but to issue the further statement for all batches of the relevant products as a precautionary measure.

As it happens, the very next day (Monday 5 August) Fonterra advised the ministry it had supplied Nutricia with a further 17 bags of contaminated WPC80. As a result, MPI told Nutricia the acting Director-General would initiate a statutory recall of all Nutricia products if it failed to broaden its recall. At 7pm, NZMP's managing director incorrectly told

television viewers that all Nutricia Karicare products were contaminated.

At 8.30pm, Nutricia extended its voluntary recall to all batches of Karicare infant formula Stage 1 and Karicare Gold+ Stage 2 Follow On formula.

*Third statement: 3pm, Tuesday 6 August*

The third Director-General statement rectified the wording error of the second statement (by referring to the correct follow-on products) and brought the ministry's position into line with Nutricia's after its recall. After more than three days, the Director-General statements and Nutricia's recalls finally referred to the same products.

Two points apply to all three Director-General statements. First, there was an unfortunate lack of co-ordination between the ministry and Nutricia over the statements and Nutricia's voluntary recalls. MPI and Nutricia had different views on why this was so, but both agreed on this much: that the situation was urgent and deadlines were short.

Of course, this will often be the case with any food safety scare. The lesson to heed is the importance of effective co-ordination between the ministry and any company recalling a product to avoid consumer confusion. By Tuesday 6 August, as one of the ministry's situation reports noted, a large supermarket chain reported the retail situation was an "absolute disaster" and "farcical" because of the inconsistency between the second Director-General statement and Nutricia's recall on the Monday night.

In hindsight, it would have been better if both had liaised with each other to ensure consistency in information. The lack of co-ordination highlights – as the Inquiry notes later – the importance, wherever possible, of an early face-to-face meeting of the main participants. In future, it is important the ministry considers how best to achieve this. In some cases, it may even be appropriate to exchange the draft wording of key public statements.

Secondly, the ministry did not document the basis on which the first three Director-General statements were issued, including the information on which it relied; the underlying risk assessment; or other options considered. The Inquiry accepts that the ministry was acting under pressure, but considers such written advice would have formalised and lent added rigour to these key decisions.

Also, it would have enabled the Inquiry to establish precisely and more easily just what information the the ministry relied on in issuing the statements, particularly the first. Nutricia perceived that the ministry placed too much reliance on Fonterra's information, when it rightly pointed out that, as the manufacturer, it had the best information about the whereabouts of its own products. In the absence of a documented decision-making process, the Inquiry has been unable to establish whether this was so.

In contrast, the ministry recorded extensive notes in situation reports and meeting minutes regarding other activities. The Inquiry is confident the ministry will keep a record of the decision-making process preceding any future Director-General statements.

#### *Fourth statement: 12pm, Monday 12 August*

On 7 August, the RMT agreed to take three steps in planning subsequent stages of the response: to seek input from the technical advisory group it had formed; to ensure Fonterra and Nutricia worked jointly on the scope of any further Director-General statements; and to act in "one step, recognising that we only have one chance to get it right". The next day, the MPI made a commitment to Nutricia that the scope of Director-General statements would narrow once the acting Director-General was satisfied this was appropriate.

Over the next four days, Nutricia, Fonterra, MPI and AsureQuality worked to achieve these goals. Their tracing and verification work included physically checking all inventory in stores and examining records. MPI also completed a carry-over risk assessment, giving it the confidence to narrow the scope of the recall.

On 12 August, the acting Director-General issued a final statement limited to specific batches of infant and follow-on formula made between 21 May 2013 and 2 August 2013. Notably, on this occasion the decision was based on a 10-page briefing paper from the response manager to the acting Director-General. The paper contained a specific recommendation and detailed justification, as well as the results of a risk assessment. Here was the accompanying documentation missing in relation to earlier statements.

The issuing of the statement was timed to coincide with an updated recall notice from Nutricia – midday the same day. This previously unseen co-ordination reassured consumers, retailers and the public that both organisations were acting with precision and certainty. Had such co-ordination existed from the outset, the Inquiry believes much of the public confusion could have been avoided.

#### **Tracing**

The Inquiry has already discussed in part five the bewildering complexity of the tracing work that had to be done. The ministry faced an enormous task in confirming information provided by Fonterra and Nutricia. Fonterra's constant amendments to figures meant the ministry had to repeatedly reconcile the information from Fonterra and Nutricia with official assurance certificates, including physically checking product labels in warehouses. For example, on 4 and 5 August, six verifiers checked product information at six sites in Auckland and the Waikato.

It was only by ensuring that all information was absolutely accurate that the ministry could meet its objectives of protecting consumer health and maintaining New Zealand's reputation as a source of safe food. Many staff put long hours into the tracing and verifying effort.

Fonterra's frequent changes to information greatly contributed to the confusion that prevailed during the weekend of 3-4 August. For example, it was only three hours after the first Director-General statement on 3 August (confined to follow-on formula)

that Fonterra revealed that infant formula might also be contaminated. Then on 5 August, Fonterra's incorrect statement on television led to a barrage of media inquiries, a distraction that had the potential to undermine MPI's credibility as a source of accurate information.

### Other aspects of the response

#### *Carry-over*

Carry-over complicates tracing. The ministry took a precautionary approach to carry-over. Based on Fonterra's estimate that one spore in infant formula could cause illness, and information from Nutricia about the amount of carry-over between production runs (calculated as up to 6.7 per cent), MPI considered it would be necessary to recall three batches made after every contaminated batch. Nutricia's information was provided under urgency, reflecting a worst-case scenario.

On 12 August, the technical advisory group met and questioned the 6.7 per cent estimate, suggesting one per cent was more likely. This would have meant recalling two rather than three subsequent batches. The Inquiry does not criticise the conservative approach taken by the ministry, but this highlights the need for much earlier involvement by the technical advisory group. If it had queried the estimate earlier, the scope of the recall could have been reduced. By 13 August, when the group provided its report, Nutricia's tracing was all but over.

#### *Further testing in the United States*

From the outset of the response, no one doubted the need for further testing of the Fonterra samples. Having obtained AgResearch's preliminary report, MPI engaged suitably qualified laboratories to confirm AgResearch's results. In less than a week, the first of the samples was on its way to the United States, and the second was dispatched the following day. Samples went to the Centers for Disease Control and Prevention (CDC) and the National Veterinary Services Laboratories (NVSL).

On 23 August, the ministry received preliminary results emailed from both laboratories indicating no evidence of botulinum toxin. MPI regarded the results as "very preliminary" and did not want to make them public until confirmed. Over the next five days, however, news began to spread. The Inquiry heard criticism of this decision, the argument being that an early disclosure might have helped defuse the situation. But the ministry preferred to wait for final results, rather than risk yet more inconsistent information if the preliminary results changed. The Inquiry agrees.

The Inquiry dealt in part five with the criticism that the ministry should have immediately released the final results received on 28 August.<sup>165</sup> It has no objection to the ministry's approach and has already noted the lack of trust that developed between the ministry and Fonterra and impeded co-ordination.

#### *Communications*

Some interviewees criticised the ministry for failing to emphasise the precautionary nature of the recall more clearly in public communications. They said that highlighting the rarity of botulism in dairy products would also have alleviated much unnecessary public concern. The Inquiry has already emphasised, in its discussion of the first media release, the importance of clear communication about risks and the measures consumers should take.

Others, however, emphasised that no matter what language the ministry used, the combination of "botulism and infants was guaranteed to cause alarm". The Inquiry agrees. Media releases need to give the clearest of directions. A mention of the rarity of *C. botulinum* in dairy products and the minuscule number of infant botulism cases worldwide might have risked sending mixed messages. The ministry's website was the place for such information. While helpful background on botulism was posted at the time of MPI's first media release, the above facts were not included.

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165 At 64.

Numerous aspects of MPI's website communications were less than ideal. Most significantly, the ministry did not immediately update the website after a media release or Director-General statement. Out-of-date information on the site created obvious (but easily remedied) potential for confusion. Nor did the ministry effectively co-ordinate its own material with publication of information on the Ministry of Health website. This led to inconsistency between the two ministries over the scope of the recall following the third Director-General statement, which lasted more than a day – a long time in a crisis of this scale.

Finally, the question arises whether the ministry should have appointed a media communications spokesperson other than the acting Director-General. Under the CIMS framework, the time-consuming and demanding media engagement role is typically undertaken by someone other than the key decision-maker. There were mixed views. Some emphasised the importance of having the acting Director-General appear before the media; others favoured an alternative spokesperson.

In the Inquiry's view, it was entirely appropriate the acting Director-General was the public spokesperson regarding Director-General statements. But it would have been better if the ministry had appointed a suitably trained and experienced spokesperson to deal with the numerous – and often challenging – media conferences called during the incident. The acting Director-General performed very well in the role, but, as a matter of best practice, a dedicated media spokesperson should have assumed that function.

### Other matters

The incident highlighted a variety of miscellaneous functions, operations and features that either worked well or were in need of improvement. In the former category were:

- *Market access updates:* Many interviewees said the joint MPI-MFAT trade and market access team was particularly effective, especially with

its overnight status updates, which the Inquiry examined and found concise and helpful.

- *Co-ordination:* MPI and other ministries and governmental agencies generally co-ordinated well during the crisis. The ministry was supported in various aspects of its response. As but one example, DPMC arranged for additional communications resources to be made available from other ministries to MPI when MPI's staff became severely stretched.
- *Liaison:* Industry groups such as the Dairy Companies Association of New Zealand were complimentary about the way the ministry kept them fully informed of developments. Liaison with all stakeholders was reported to have been effective.
- *Ministerial briefings:* Having sighted MPI's daily briefings to relevant ministers, the Inquiry can vouch for the fact they were timely and comprehensive.
- *Alternative supplies:* Several interviewees praised the way the ministry, with the assistance of the Minister for Food Safety, stepped in to ensure adequate quantities of infant formula were available from other manufacturers. Plaudits also go to Nestlé and Heinz Wattie's, which ensured that New Zealand shelves were sufficiently stocked.
- *Publication of reports:* Many appreciated the prompt and public release of the ministry's reports on tracing and verification,<sup>166</sup> and testing by the United States laboratories.<sup>167</sup>
- *On-site co-ordinators:* The presence of Fonterra and Nutricia representatives at the ministry's head office helped with communication and co-ordination, and the Inquiry suggests this should be standard practice in any serious food incident. In hindsight, the presence of a Nutricia representative a day earlier (3 August) would have been preferable.
- *Separation of roles:* The ministry deserves credit for ensuring a clear demarcation between its response effort and compliance investigation.

<sup>166</sup> MPI, *Whey Protein Concentrate Incident Tracing and Verification Report*, 25 August 2013.

<sup>167</sup> MPI, *WPC 2013 Response Report: Laboratory Identification of the Fonterra bacterial isolates*, 29 August 2013.

Areas where the ministry should consider making improvements include:

- *Clarification of roles (teams)*: Individuals gave conflicting accounts about whether the RSL, as had been emphasised in Exercise Taurus, strayed from a strategic focus into the operational activities of the RMT. Perhaps this happened on occasion. The RSL chair said he was aware of the need to ensure the group resisted this understandable temptation. It is important in any future incident that MPI ensures the RSL sticks to its strategic role.
- *Clarification of roles (Director-General)*: The Director-General statements can be made only by the Director-General. But given the RSL's strategic focus and the potential for overlap in decisions concerning the Director-General's use of this statutory power, clear distinctions are needed about the respective roles of each in making strategic decisions. A food incident protocol spelling out these matters was essential from the outset of the response.
- *Unrealistic deadlines*: The situation, especially in the early days, was urgent, but many tasks – notably tracing – needed time. The Inquiry heard concerns that the ministry imposed unrealistically short deadlines on its own staff and Nutricia to provide tracing information. A balance must be struck between the need to act decisively and allowing companies time to trace their products.
- *Impact on other businesses*: Some believed that the ministry gave too little weight to the interests of other manufacturers and exporters caught up in the incident – particularly small and medium-sized operators. On 9 August, MPI issued a "To whom it may concern" letter – posted on a secure website – listing products not affected by recalls or suspected of containing contaminated WPC80. This was a positive step, but several interviewees said it could have happened sooner. The ministry said the letter could not go out until it was confident that the recipients did not have contaminated products. But the Inquiry notes

that many of the products had been heat-treated and could have been excluded within the first 48 hours of the crisis. The important point is that MPI does all it can for the legitimate interests of producers, without compromising public safety.

- *Better data presentation*: The ministry received, as one interviewee put it, an "avalanche of data", but it was often not easy to grasp. Experienced data analysts and tools are needed to ensure the presentation of information in an easily understandable form.
- *Liaison with overseas regulators*: At least one overseas regulator noted misunderstandings in the first few days about who was the contact person – a confusion that reinforces the need for job cards and for ministry personnel to know their roles from the outset.

### *Stand-down and incident debriefing*

The ministry stood down its main operational teams on 26 August, just before the release of the United States test results. The RMT debriefing that day amounted to an evaluation of the RMT itself and those reporting to it. All international food protocols emphasise the importance of a prompt evaluation to make the most of any lessons emerging from an incident, a point the Inquiry endorses.

No formal review of the RSL performance has taken place. Nor has there been any debriefing with other government agencies or external stakeholders to assess the overall response. The ministry's position was that this Inquiry constituted an external review and no ministry-led review was necessary. In addition, the ministry said, the preparation of submissions for the Inquiry at both stages gave it the opportunity to evaluate its performance and draw lessons. Nonetheless, the Inquiry considers a structured internal debriefing of RSL operations should have occurred promptly, as happened with the RMT. The ministry should also have sought the views of all stakeholders while the incident was fresh in people's minds.

### Horsemeat scandal, European Union, 2013

**Human cost:** None, since horsemeat is not harmful to health (although there was a risk of the veterinary drug phenylbutazone entering the food supply)

**Financial cost:** When the Food Safety Authority of Ireland announced that horsemeat (and some pig meat) had been found in beefburgers, multinationals, including Burger King and Tesco, were hit hard; Tesco's share price fell €360 million in a day; sales of frozen hamburgers collapsed; frozen ready meals fell sharply

**Source:** A Polish slaughterhouse

**Cause:** Deliberate adulteration for financial gain

**Lessons:** Need for improved food traceability, especially labelling related to origin of processed meat

Ministry representatives participated in a type of debriefing during a meeting of the Bi-national Food Safety Network on 19 May 2014 in Melbourne.<sup>168</sup> Recommendations included that the New Zealand and Australian governments amend the scope of the bi-national food incident protocol to include New Zealand government agencies, and that the agencies agree on the principles for effective co-operation (including information sharing).

### Overall assessment

A review of food incidents worldwide shows they are typically complicated and difficult to manage: see insets. There are often fine judgements to make, particularly about when to go public. The Canadian listeriosis report acknowledges this difficulty and notes two competing approaches: sometimes it is right to wait for "conclusive evidence", including laboratory confirmation, before alerting the public to any health threat. Other times "it is better to err on the side of caution", with a lower "reasonable and probable grounds" threshold.<sup>169</sup> In the end it is a matter of judgement.

In this instance, MPI was presented with an extremely challenging scenario. Fonterra's notification of "confirmed" *C. botulinum* was inexcusably late. The combination of infant formula and botulism – albeit at a very low risk – was certain to cause widespread apprehension. Fonterra notified several overseas customers ahead of MPI, which caused the

ministry to go public earlier than might otherwise have been the case. Tracing proved very demanding. Finally, the ministry itself was still settling into post-merger structures.

Nevertheless, the ministry deserves credit for its overall effectiveness in helping to remove such a large quantity of affected production from sale or distribution. On the information available to the Inquiry, the ministry's actions helped to maintain the high regard of international regulators, as in a post on the FDA website on 5 September: see inset at 82.<sup>170</sup> The Inquiry acknowledges these positive comments, but also areas in need of improvement.

### Belgian dioxin crisis, European Union, 1999

**Human cost:** None

**Financial cost:** US\$1.54 billion, half borne by the agriculture sector, half by the food industry

**Contaminant:** Dioxin, high levels of which were found in the eggs and meat products of chickens, pigs and cattle that ate contaminated feed

**Source:** Suspected to have been oil from electrical transformers, added to recycled cooking oil, in turn added to animal feed supplied to Belgian, French and Dutch farms

**Cause:** Deliberate adulteration for financial gain

**Lessons:** Need to notify the public as soon as possible; the Belgian government delayed going public with the news for at least a month, greatly complicating tracing efforts and adding hugely to the financial cost

### A different outcome

How might events have turned out if Fonterra had acted differently and the ministry had co-ordinated more effectively with the parties most directly affected within the first 24 hours? The Inquiry posed a scenario in which the following took place:

Fonterra:

- Notified the ministry first before contacting any customers
- Supplied (or was made to supply) the draft preliminary report by AgResearch at the time of notification, and

<sup>168</sup> The network facilitates collaboration and information sharing among officials from Australian and New Zealand jurisdictions.

<sup>169</sup> Fn 108 at 69-70.

<sup>170</sup> [blogs.fda.gov/fdavoices/index.php/2013/09/fda-systems-recognition-ensuring-imported-foods-are-safe](http://blogs.fda.gov/fdavoices/index.php/2013/09/fda-systems-recognition-ensuring-imported-foods-are-safe)

The ministry:

- Began a structured risk assessment within two hours of notification
- Invited Fonterra, Nutricia and other affected parties to meet with it promptly to seek their input into the risk assessment and discuss a single co-ordinated response
- Sought immediate advice from independent scientific experts.

In the view of the Inquiry (and that of the vast majority of interviewees to whom this scenario was put), a recall would still have been necessary because of the risk, however slight, of *C. botulinum* in infant formula. But the recall could have been more co-ordinated, more targeted and more orderly. Public communications would have emphasised to a greater degree both the precautionary nature of the Director-General statements and the need for further testing.

In all likelihood, MPI would have delayed its first media release, and the acting Director-General his first Director-General statement, pending agreement with Nutricia about the scope of the initial recall. The response could then have developed from this firm footing with less confusion among consumers.

## 17. MPI improvements

The WPC80 incident has been a salutary experience for the ministry – as it would be for any regulator. Its performance has come under the glare of public scrutiny, and that has been followed by the Inquiry's investigations, which have shown up areas in need of improvement.

Since the incident, the ministry has begun a series of organisational changes to lift its response capability. The Inquiry commends the priority given to this work, but it cannot emphasise enough the need for the ministry to commit itself to the other side of such reforms: regular staff training and simulation exercises, without which it is impossible

for the ministry to test and evaluate its readiness to respond to potential incidents. Many improvements have been made to date.

*Single model:* The ministry is now developing a single scalable response model to standardise its management of all incidents, but with customised modules to reflect the diverse range of incidents that it may have to deal with. (A biosecurity risk, for example, will pose quite different challenges to those connected with, say, a drought.) The customised modules recognise that a one-size-fits-all approach will not work and the Inquiry endorses that approach. One module deals exclusively with food safety incidents. MPI is working closely with other government agencies, including DPMC, on the new response model.

### Praise from the FDA

“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 US, 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 US 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.”

A new planning and preparedness team will complete development of the model by December 2014, with implementation to start in 2015. Food response incidents will use the RSL and RMT structure, although the severity of the incident will decide the size of these groups. In some cases, there may be a single-person RSL. Similarly, the RMT may comprise only the controller. The appropriate structure will be determined at the beginning of the response, although reviewed – scaled up or down – as the incident progresses.

The Inquiry is pleased to note that the ministry, in preparing the food safety module, has been working with Food Standards Australia New Zealand to ensure consistency with its own food incident response model.<sup>171</sup> Pleasingly, too, interested parties will have an opportunity to give feedback. The ministry also intends to publish online all its new response plans, including those for food safety incidents – an approach in line with that taken by many food safety authorities overseas.

The Inquiry notes with interest that MPI is also working with industry organisations to ensure it is ready for any outbreak of foot-and-mouth disease. A national response network of more than 100 organisations will work together on any outbreak. This initiative, despite its very specific biosecurity focus, contains elements that may be helpful in preparing for food safety incidents.

*Incident management team:* The ministry has formed an incident management team, comprising five personnel with a mix of food safety, public health, science and general crisis response skills and experience. The deputy Director-General of the ministry's regulatory and assurance branch will make the decision to mount a food safety response and determine who will be part of the response team. But the incident management team will assist by helping establish the response structure, identify staff and other resource needs, develop incident management plans and liaise with stakeholders.<sup>172</sup> It could also be responsible for training and simulations of food incidents.

It is too soon for the Inquiry to offer any definitive comment, but there can be no doubt that the incident management team should enable the ministry to be better prepared for another food safety crisis of the same scale as the WPC80 incident. The vital thing, however, will be to ensure that the ministry has good co-ordination and avoids any duplication between what should be the high-level, advisory work of the incident management team and the operational work of the actual response team.

*Restructure:* The ministry has restructured itself during the past 12 months into three core areas: biosecurity, food safety and policy and trade (by a process it calls "alignment"). It has formed a new regulation and assurance branch, headed by a deputy Director-General, that is devoted largely to the second of these. The ministry has set up governance boards to act as formal mechanisms for setting priorities, directing strategic planning, providing guidance and ensuring the integrity of regulatory systems. A food safety board comprising deputy Directors-General and managers is charged with ensuring the integrity of New Zealand's food safety system so as to protect all consumers, whether local or overseas.

With the changes now made, staff and stakeholders alike have, to quote the ministry, "absolute clarity as to who is accountable for food safety". The new branch will also raise the profile of this critical area, in line with the first report's recommendation.

*Capability:* MPI's new capability programme aims to ensure it has the right people in the right roles doing the right things at the right time in all ministry responses. The ministry has an especially keen eye – appropriately in the Inquiry's view – on emerging risks. In particular, it is attempting to identify potential food safety issues and their possible impact on domestic and overseas markets. The ministry has made progress in identifying capabilities and core competencies for the key roles in all responses. Only staff with training in the CIMS approach will be part of any food safety response.

<sup>171</sup> This model is a guide for co-operation between Commonwealth and state agencies during food incidents, but does not override response protocols of individual agencies or jurisdictions.

<sup>172</sup> The incident controller may be drawn from the team.

Such staff will have role cards for use during any response, specifying reporting lines and tasks for each role. More widely, the ministry recognises capability will be critical to effective implementation of parts of the Food Act 2014, including recalls.

*Simulations:* The ministry recognises the pivotal place of simulations in testing and evaluating readiness. It already has an exercise planned for February 2015 involving the Ministry of Health. This will test how effectively the two ministries can co-operate in a food safety response. The Inquiry cannot overstate the importance of carrying out simulation exercises from desktop tests to full-scale drills involving other government and industry bodies. These should be a regular feature and not one-off activities.

Exercises need resources – over and above day-to-day business – to ensure readiness for large-scale incidents such as WPC80. All participants, including overseas food safety authorities, emphasised the importance of these, both large and small. The Inquiry recommends targeted funding to ensure that the ministry is in a position to conduct such a programme of exercises.

*Escalation:* As noted elsewhere, the ministry is working with industry bodies and verifiers to agree on appropriate escalation processes. The ministry intends to ensure that industry participants are quite clear about where and when to report a potential food safety problem. Undeniably, escalation processes need some formality, but this should not go so far as to undermine the informal, yet highly valuable relationships between industry participants and key MPI staff. Such relationships, observed one interviewee, “are, for a small country like New Zealand, critical to the edge it has: informality is a strength”. An escalation protocol is consistent with the Inquiry’s emphasis in its first report on the need for a broad range of compliance tools; as well as the importance of generally regarding enforcement as a measure of last resort.<sup>173</sup>

*Crisis communications:* The ministry is drafting a communications framework, which will be the subject of industry consultation. A related – and much-needed – improvement is the streamlining of the ministry’s website to improve accessibility and readability, particularly those areas that provide guidance to the industry and consumers about food safety.

*Logistics:* The ministry acknowledges that simple logistical difficulties obstructed its response over the weekend of 3-4 August. These included the absence of a dedicated, decent-sized crisis room, restricted access to MPI’s offices and computers by other agency staff, and the initial inaccessibility of the ministry’s sole A0-size printer (which was so essential for complex trace-back diagrams). Even seemingly minor details must be eliminated to ensure a seamless operation in the event of a crisis. Again, this is where simulations can assist.

*Other reforms:* Pre-empting any potential for food safety incidents to occur in the first place was a central lesson of the WPC80 incident. This can be done by ensuring robust monitoring of the dairy regulatory requirements;<sup>174</sup> improving the analysis of, and response to, audit information to identify emerging issues, risks and trends;<sup>175</sup> and developing a broader, more transparent set of compliance tools.<sup>176</sup> None of this is to suggest any need for more prescriptive regulation. The Inquiry has already endorsed the outcome-based approach of the current framework and acknowledges the valid concern of the industry that excessive regulation can lead to unnecessary complexity.<sup>177</sup>

It is pleasing to note that the ministry has now strengthened the systems audit team to deliver improved, and more visible, monitoring. The Inquiry cannot emphasise enough the importance of dairy capability in this team. It also welcomes the production of quarterly reports outlining dairy sector performance and trends for the industry.<sup>178</sup>

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173 First report at 51.

174 Including the need to monitor timely notifications of product disposal requests and the like: at 39.

175 First report at 42: many interviewees last time considered the ministry could do more in this area.

176 First report at 51. The ministry has accepted the Inquiry’s concern about the blurring of functions stemming from its dual roles as trade facilitator and food safety enforcer. It has established a compliance liaison position to co-ordinate audit and compliance work and avoid industry confusion.

177 Fn 49 at 42.

178 MPI has provided the reports since May 2013 to the Dairy Products Safety Advisory Council, which is free to distribute them. MPI has agreed in principle to also share the reports with DCANZ.

All these reforms, and undoubtedly others MPI can develop together with the industry and verifiers, should strengthen its ability to detect potential food safety problems early. A greater evaluation component to third-party verification has already been discussed in part four.<sup>179</sup> Even the most practised and co-ordinated response to any food safety incident is no substitute for effective and preventive action.

However, the Inquiry is concerned at the limited progress made regarding well-overdue simplification of the regulatory framework governing the dairy industry, particularly the tertiary layer.<sup>180</sup> The first report recommended that the ministry accelerate its standard integration programme, using, from the outset, specialist drafters, technical industry experts and recognised agencies. This work is pressing because simplified risk management programmes can only follow simplified regulations.

The detailed examination of the WPC80 incident has reinforced the Inquiry's view that risk management programmes have gone well beyond their original aim of helping businesses manage hazards and risks specific to their operations. As the Inquiry previously recommended, such programmes should be limited to food safety and related regulatory matters. Some run to hundreds, if not thousands, of pages. It is telling that a full review of Fonterra's risk management programme for Hautapu took the ministry three months.

The process of reviewing the dairy regulatory framework – particularly the 12,000 pages of tertiary instruments – has proved a more mammoth task than the ministry or Inquiry envisaged. The task is no less urgent, though. The Inquiry heard numerous examples from the industry of what it perceives as conflicting advice from MPI about interpretation of particular regulations. This is no surprise, given the complexity and incoherence of these instruments.

Further resources are needed to ensure there are enough ministry dairy technical experts (including secondees if necessary), as well as drafters to

complete the task in a timely manner. Accordingly, the Inquiry recommends that the ministry receive targeted funding to ensure completion of the much-needed reform of dairy regulations within the two years (realistically now requiring another six months) recalled in the first report. The ministry should provide the Government with a budget for this work as a matter of priority.

If the regulatory review does not occur, particularly when simplified risk management programmes rely on this work, the potential for another dairy incident increases. The extra funding needed to help the ministry will be trifling compared to the magnitude of the potential loss of reputation and revenue associated with an incident even approaching the scale of this one.

### Recommendations

The Inquiry recommends:

- The ministry should continue its work to ensure readiness for a food safety response, including:
  - Finalising its food incident protocol (as part of its single scalable response model), ensuring it is consistent with CIMS and benchmarked against international models. A draft should be provided to the food industry and other key stakeholders for comment before final publication
  - Undertaking regular exercises/simulations of its food incident protocol ranging from smaller desktop exercises through to large-scale, multi-agency rehearsals
  - Ensuring staff are fully trained to respond to food incidents.
- In any food incident, the ministry should:
  - Start, and document, a risk assessment addressing both scientific and strategic risks as soon as practicable and update the assessment as the incident develops

<sup>179</sup> See earlier discussion at 39-40..

<sup>180</sup> First report at 31.

## PART SIX: THE MINISTRY'S RESPONSE

- Document the use of statutory powers, particularly Director-General statements, including written advice from officials about available options and the underlying scientific and risk assessment information on which recommendations are based
  - Co-ordinate with all relevant parties to ensure a single integrated response.
  - The ministry should re-establish a group of scientific experts along the lines of the previous NZFSA Academy.
  - The law should be amended to give MPI a specific statutory power to compel disclosure of any relevant information (including test results) needed to respond effectively to a food safety incident. The power should include the ability to disclose such information to any affected party.
  - The ministry should receive targeted funding to ensure it:
    - Has the resources – over and above those needed for day-to-day operations – to conduct a regular programme of simulations
    - Completes the much-needed reform of dairy regulations.
  - The ministry should, in consultation with the dairy industry and verifiers, continue to strengthen its monitoring and auditing activities to ensure early detection of potential food safety problems.
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## PART SEVEN: TESTING

AgResearch played a central role in the later stages of the incident when Fonterra sought help to clarify the nature of the suspected WPC80 contamination. Inevitably, that role has raised questions – especially from scientists – about laboratory competency, the tests that took place, their effective limits and the interpretation and communication of the test results. Valuable lessons for food companies and laboratories arise from these questions.

### 18. Capability and competency

AgResearch conducts a range of scientific research and development work. Its food and bio-based products group, which is of particular relevance to the Inquiry, conducts food microbiology and safety research. It is also involved in research projects with other government agencies and industry groups, including Fonterra, the ministry, Massey University, Plant & Food Research and Environmental Science & Research (ESR).

AgResearch's more than 500 scientific staff include experts in genetic fingerprinting, toxicology, food quality research and microbiology. They have many years' experience in research organisations in New Zealand and overseas. Their expertise commands wide respect and some are considered leaders in their fields. AgResearch carries out only a very small amount of diagnostic testing in accredited laboratories for clients (equal to barely five per cent of revenue).<sup>181</sup>

The Inquiry is in no doubt that the toxicologist and microbiologist at the heart of the WPC80 testing had the necessary expertise and experience to carry out the testing commissioned by Fonterra. The microbiologist has more than 20 years' experience. Her specialty is molecular genetics and detection of microbial populations. In previous work she developed molecular-based tests for detecting and identifying highly pathogenic bacteria – tests for which she holds patents.

The toxicologist who conducted the mouse bioassay is internationally recognised in his field, with more than 40 years' experience in such areas as toxicity trials on food additives and contaminants. He has collaborated with regulatory authorities in Australia, Brazil, Canada, Germany, Italy, Spain and the United States on various aspects of toxicology and risk assessment. He is a former member of the Toxicology Expert Panel on Seafood Toxins 2005 for the European Food Safety Authority, as well as other international expert panels.<sup>182</sup>

AgResearch has previously undertaken research testing for *C. botulinum* in meat, seafood and cheeses. In 2005, the pair were involved in an AgResearch study into whether *Clostridia* species could grow in refrigerated meat during transport to export markets. Both individuals were involved in research in 2011-2013 on behalf of Fonterra, in which AgResearch scientists examined the ability of *C. botulinum* to grow under different salt concentrations in cheeses.<sup>183</sup>

<sup>181</sup> In 2013-2014, diagnostic testing accounted for 3.2 per cent of AgResearch's science revenue. Most of this was gene marker testing for animal breeding purposes and tuberculosis testing.

<sup>182</sup> FAO/WHO, Intergovernmental Oceanographic Commission Expert Panel on Biotoxins in Molluscs 2004. The toxicologist has published 115 peer-reviewed papers on toxicology.

<sup>183</sup> Independent experts reviewed the proposed research, known as the Fonterra cheese challenge trial, before it began and had no concerns about methodology.

AgResearch has rigorous processes in place to monitor and maintain standards. The food assurance team, for example, which carries out much of the institute's testing, operates in accordance with a laboratory procedures manual at its Ruakura and Hopkirk facilities.<sup>184</sup> Based on good laboratory practice, the manual incorporates many of MPI's laboratory approval scheme practices and ISO accreditation requirements.

Other measures to maintain standards include peer review of research proposals and reports; publishing research in scientific journals; setting publication targets; reviewing the quality of its scientific work through an advisory panel made up of international experts; and regularly reviewing the quality and appropriateness of scientific work.

Overall, the Inquiry considers that AgResearch had the capability, capacity and competency at the time to undertake the work it conducted for Fonterra.

## 19. Workplace culture and communication

Staff in a research institute work and think in subtly different ways to their industry counterparts. Appreciating those differences in approach – some a matter of style, some a matter of substance – is essential to understanding how AgResearch and FRDC sometimes came to work and talk at cross-purposes.

### Using research facilities for diagnostic testing

As previously noted, diagnostic testing – in relation to food safety – is essentially routine product testing carried out for regulatory purposes to ensure all products, domestic and export, are safe to consume. Generally, it must be undertaken in an accredited laboratory.

Research-focused testing and diagnostic testing are fundamentally different. Research focuses on experimentation, using different methods to obtain more information or test theories. Typically, research experiments are individual projects; diagnostic testing uses established methods regularly and repeatedly to arrive at a defined answer.

Scientists at diagnostic laboratories are skilled at interpreting equivocal results, especially having seen thousands of positive and negative results with the repetitive nature of their work. Also, tests can be standardised, an important feature in assurance and quality control systems. Researchers, by contrast, may conduct the same tests carried out in a diagnostic laboratory, but will experiment with methodology.

One advantage of research laboratories is that new techniques that produce faster – and in some cases more accurate – results can be employed. Often, however, such techniques are not yet fully developed.<sup>185</sup> Another advantage is that research scientists have a deep understanding of a particular organism (for example, *C. botulinum*) or field of work (for example, toxicology). And when serious risks emerge, it often falls to research laboratories to develop tests for subsequent use by diagnostic laboratories. Until such tests are cleared for use by diagnostic laboratories, regulators must rely on research laboratory results to help with decisions about whether a product undergoing testing is safe and suitable for sale or consumption.

Differences in scientific behaviour, methodologies and culture also come into play. For Fonterra and other industry participants, “testing” and “diagnostic” are largely inseparable; for AgResearch and other research institutes, the same can be said of “testing” and “research”. In both cases, the workplace context shapes the meaning of the words.

The Inquiry has no doubt that, had AgResearch been asked to undertake testing of infant formula products already in the marketplace for food safety purposes, it would have said no. It would have regarded this as diagnostic testing. This point, repeatedly emphasised by AgResearch, is one the Inquiry accepts.

Furthermore, AgResearch's testing could not have produced the results needed for a diagnostic outcome. Conclusive results would only have been possible if AgResearch's polymerase chain reaction (PCR) testing had employed appropriate controls

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<sup>184</sup> The food assurance team forms part of the food and bio-based products group.

<sup>185</sup> Techniques must be validated before diagnostic laboratories can routinely use them.

(see genotypic analysis at 91), or if it had followed the mouse bioassay methodology to its full extent.<sup>186</sup> But, as could be expected of research scientists, the AgResearch staff engaged in the testing made modifications that, while appropriate for the testing and the resources available in New Zealand, precluded a definitive diagnostic result.<sup>187</sup>

Plainly, as discussed in part four, the purpose of the testing was not communicated clearly enough. Yet clarity of purpose is vital when considering an approach to a research laboratory for testing that is, or could be considered to be, diagnostic. And it is equally apparent that the research laboratory, for its part, must make clear to the client that use of a method still awaiting validation for diagnostic purposes is likely to produce results which may be uncertain or ambiguous.

One way to aid communication and ensure both the laboratory and client have a common understanding of the purpose of any proposed tests is to use a testing plan. This sets out the agreed purpose, scope and methodology, including any expected or agreed deviations from specific methods. For example, a diagnostic testing plan for *C. botulinum* commonly involves phenotypic and genotypic testing before conducting any mouse bioassay. If these methods do not identify toxin genes, no mouse bioassay is necessary or, for animal ethics reasons, desirable.

### Accreditation

The media made much of the fact that AgResearch lacked accreditation to conduct *C. botulinum* testing. Some industry and regulatory voices were adamant that Fonterra should have chosen an accredited laboratory, while others insisted the question was a red herring. Accreditation is a way to demonstrate the necessary technical competence and experience to conduct tests performed on a regular basis. An independent agency checks that this is so.<sup>188</sup> It is a common feature of food safety regulation.

A lack of accreditation does not necessarily imply a lack of competence and experience to conduct tests. Research laboratories are seldom accredited because their work is largely concerned with breaking new ground. Testing in this context cannot be evaluated against known standards. Research laboratories may, however, choose to be accredited for those occasions when they perform regular diagnostic testing services using known methods.

Is the decision, then, about when to approach an accredited laboratory for diagnostic testing and when to approach a research laboratory for research testing as clear-cut as the above would suggest? It seems not. From questions asked by the Inquiry, enough differences of opinion emerged to conclude that requirements should be clearer in this regard, particularly when non-standard testing might have food safety implications.

For example, some thought an accredited laboratory was necessary only when a specific test is required by law. Others believed an accredited laboratory was necessary for any test that might influence product release decisions (for example, tests for “products on hold”), or any test that demonstrates the safety (or otherwise) of food for human consumption. Differences of opinion existed within Fonterra, too. FRDC scientists who helped arrange AgResearch’s involvement did not believe that the testing required an accredited laboratory. On a more general level, however, colleagues later told the Inquiry any testing of a product ultimately destined for human consumption requires an accredited laboratory.

In almost all cases, the position is clear: diagnostic testing for a regulatory purpose (for example, to show compliance with the relevant food standards or dairy processing criteria) must be in an accredited laboratory. But ambiguity may arise when testing occurs, as here, after the normal regulatory approvals have been obtained and the product has been exported. Testing products that have been placed on hold may also create ambiguity.<sup>189</sup>

186 For a brief description of PCR and other relevant tests, see the ministry’s *WPC 2013 Response Report Laboratory Identification of the Fonterra bacterial isolates*, 29 August 2013.

187 New Zealand does not hold all necessary reference cultures for *C. botulinum*, a point acknowledged in MPI’s report.

188 International Accreditation New Zealand (IANZ).

189 The ambiguity arises, in part, because the obligation to use a “recognised laboratory” is triggered when testing is done “to demonstrate regulatory conformance”: cl 6(1) of the Animal Products (Dairy Processing Specifications) Notice 2011. However, this will not always be clear.

Any ambiguity in this area is undesirable, when food safety, export earnings and New Zealand's reputation are at stake. In the Inquiry's view, the law should be clarified to ensure all participants know exactly when it is necessary to use an accredited laboratory. The Inquiry has examined the relevant legislation and tertiary regulation and considers it to be unclear, at least for situations such as this one involving products that had already met standard regulatory tests. It would have been equally unclear if the products in this incident had, in reality, been on hold. In the Inquiry's view, the law should be clarified as part of the current project to complete reform of the dairy regulations.<sup>190</sup> A ministry guideline would assist, too. It also emerged from discussions with parties that it is far from clear when a client requires approval from the regulator to undertake diagnostic testing using a non-validated method.<sup>191</sup>

The Fonterra board inquiry report suggested that, in the absence of a New Zealand laboratory accredited for *C. botulinum* testing, Fonterra should have gone to a laboratory accredited for the genotypic tests carried out by AgResearch, even if the laboratory lacked accreditation specifically for *C. botulinum* testing. In general, the Inquiry agrees that accredited laboratories should be used when available, but there is nothing to suggest that any other laboratory using the same genotypic tests would have arrived at different results. The Inquiry is confident, however, of a different outcome had Fonterra advised MPI when it decided to test for *C. botulinum*, especially if it had sought advice about which tests to conduct and which laboratory or laboratories to use. MPI would almost certainly have directed Fonterra to use accepted methods of accredited testing.

## 20. Tests and their limitations

Different tests achieve different results with different degrees of certainty. Sometimes, a combination of tests is necessary, as the following sequence shows, to try to reach a conclusion with any certainty (here, the identification of bacteria). And sometimes,

as the sequence also makes clear, the conclusions can not only be uncertain, but also contradictory.

The combination of tests Fonterra and AgResearch employed were:

### The three tests

*Phenotypic tests:* these narrow identification to a class of organisms based on observable physical or biochemical characteristics of an organism

*Genotypic tests:* these involve use of DNA sequences to define biological populations using molecular tools

*Specific identification tests:* these are tailored to distinguish between very similar organisms

Many organisms require only phenotypic and genotypic tests. *Clostridia* species require all three. For example, phenotypic and genotypic tests that indicate an organism may be *C. botulinum* are presumptive only. A mouse bioassay is the specific identification test to confirm or refute a tentative finding.<sup>192</sup> The Fonterra and AgResearch testing that led to the notification to MPI of confirmed *C. botulinum* included all three tests.

### Phenotypic tests

Fonterra selected the three isolates it sent to AgResearch on the basis of phenotypic analysis. Accredited laboratories at its Clandeboye and Te Rapa plants confirmed that the bacterial growth in Darnum and Waitoa products was consistent with *Clostridia* species.<sup>193</sup> FRDC (a non-accredited research laboratory) then analysed isolates from Darnum and Waitoa products using a mass spectrometry technique known as MALDI-ToF. Essentially a fingerprinting method, it produces a protein profile for each organism that is compared against a database containing profiles of known organisms. Three isolates from Waitoa production, with profiles also seen in Darnum production, were selected for further analysis by AgResearch.

190 First report at 31.

191 Clause 9, Animal Products (Dairy Recognised Agency and Recognised Persons Specifications) Notice 2011 No 2.

192 Many experts regard a mouse bioassay as the only reliable test to confirm the presence of BoNT, the toxin produced by *C. botulinum*, although attempts have been made to find other tests.

193 That growth, on differential reinforced clostridial agar (DRCA) plates, requires oxygen-free conditions, plus reduced sulphite, to produce black colonies.

## Genotypic analysis

AgResearch then conducted genotypic analysis by four methods.<sup>194</sup> Three generated a DNA fingerprint to compare with those of known organisms. Each method cuts, or fragments, the DNA and visualises the resulting fragment pattern in a slightly different way.<sup>195</sup> The fourth method was real-time PCR. This focuses on toxin genes (again comparing the results with reference samples). The presence of one or more toxin genes is a strong indicator that the organism is *C. botulinum*. But to complicate matters, the toxin genes may be present but inactive, or may produce an inactive toxin, so that a mouse bioassay is still necessary for a positive identification of the organism.

In all four methods, AgResearch used reference DNA samples for *C. sporogenes* and *C. botulinum* types A, B, D, E and F.<sup>196</sup> A reference DNA sample for type C was not available.

The first three methods suggested that Fonterra's isolates were similar, but the results did not sufficiently align with any of the reference samples to allow positive identification. Comparisons of the fingerprints identified which of the reference samples the isolates most closely resembled. This gave a preliminary indication that the isolates were closer to *C. botulinum* types A (toxic to humans) and D (toxic to animals) than *C. sporogenes*.

The fourth method – real-time PCR – produced uninformative results. For a number of scientifically complex reasons, AgResearch was unable to draw conclusions about whether the Fonterra isolates contained genes for *C. botulinum* toxin types A, B, E, or F. (AgResearch did not carry out PCR assays for types C and D.)

The Inquiry found AgResearch followed accepted practice in conducting the genotypic tests while recognising its inability to verify the results. The principal impediment to this was the lack of

appropriate reference samples or controls, a point AgResearch scientists recognised but did not make clear in their preliminary report.<sup>197</sup>

## Mouse bioassay

AgResearch's mouse bioassay work has been the subject of controversy within scientific circles. In its preliminary report, AgResearch said it conducted the mouse bioassay in a manner approved by the FDA.<sup>198</sup> But the Inquiry, and many international experts, noted deviations from the FDA's published methodology, raising questions about the reliability of the results.

Criticism falls into three categories: the number of mice tested; the observation and interpretation of symptoms; and the failure to test for toxin neutralisation. The later United States testing also came in for criticism, particularly the transporting and viability of samples.

### Number of mice

The FDA method requires 18 mice per sample to carry out multiple dilutions of test samples in duplicate. Fonterra gave AgResearch three cultures (samples). Thus, AgResearch needed at least 54 mice. But it had only 14 available. Critics say the shortfall influenced how AgResearch conducted its testing and compromised the soundness of the results. AgResearch rejects this and argues the modifications it made to the FDA method made no difference to the outcome. (The Inquiry has already noted in part four the dispute about whether Fonterra knew AgResearch had limited mice.)

Some critics said the three samples should have been pooled, or alternatively one sample selected, given AgResearch knew, from the phenotypic tests, that the three samples appeared to be similar. This could have given greater confidence in the results. But as the AgResearch microbiologist noted, the contract required AgResearch to test all three cultures. Also, the toxicologist said he was unaware

<sup>194</sup> To use the common scientific acronyms, these were ERIC, ARDRA, AFLP and RT-PCR.

<sup>195</sup> All the fingerprinting techniques AgResearch used are under development with the aim of providing accurate diagnostic identification of *Clostridia* species, including of *C. botulinum*.

<sup>196</sup> AgResearch sourced these reference samples from its own collection, as well as from another New Zealand research facility. It expressed some uncertainty about the accurate identification of the toxin types within the reference samples (particularly types B, D and F), but they were the best examples it had available at the time.

<sup>197</sup> AgResearch hopes to begin research to overcome limitations in genotypic testing, through research projects aimed at the risks of *Clostridia* contamination in food.

<sup>198</sup> [fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070879.htm](https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070879.htm)

of the genotypic relationship between the samples, having received the samples blind – his standard practice to avoid any bias.

AgResearch used only undiluted samples because there weren't enough mice (the FDA method requires testing an undiluted sample and three diluted samples). However, the two United States Government-accredited agencies (CDC and NVSL) that subsequently confirmed there was no *C. botulinum* contamination, also used only undiluted samples in the screening phase.<sup>199</sup>

The lack of duplication also concerned experts. The FDA requirement was, in their view, central to ruling out unknown variables in the two deaths. This was especially important because the testing was on biological specimens, which left open the scope for other causes of death.<sup>200</sup> AgResearch's toxicologist said the absence of duplicate results had no bearing on the outcome. He was confident of that view, supported by his four decades of toxicology experience.

### Observation and interpretation

Experts noted that the description of symptoms in AgResearch's preliminary report contained nothing about the expected sequence of symptoms leading to a conclusion of botulism poisoning. These are ruffling of fur followed in sequence by laboured abdominal breathing, weakness of the limbs and total paralysis with gasping for breath. Death is caused by respiratory failure that manifests as a wasp-like narrowed waist. In reply, the toxicologist said he did observe these symptoms and that his observations were supported by his notes.

The Inquiry found the notes provided good evidence of lowered respiration, an absence of movement and abdominal breathing. There is also one reference to a mouse being "hunched".

The toxicologist explained that he interpreted lowered respiration as indicating laboured breathing; the "hunched" mouse had ruffled fur; the lack of movement was either partial or full paralysis; and his references to abdominal breathing equated to the wasp-waist symptom.<sup>201</sup> In hindsight, this highlights the benefit in using the language in the FDA protocol at all stages.

In interpreting the results, some experts suggested that more deaths were necessary to indicate the presence of *botulinum* toxin. It will be recalled that two mice died, and AgResearch reported another three showed the effects of toxin.<sup>202</sup> The FDA method offers no advice about how to interpret a result in which mice receive undiluted samples, show symptoms, but do not die. It simply emphasises that deaths can confirm the presence of toxin.

The toxicologist's reply was that death was not necessary to confirm the presence of *botulinum* toxin because at low doses, mice may recover as toxic effects decrease. Rather, he said it was more important to observe the classic symptoms of low respiratory rate and lack of movement and then to test with heat-treated samples as a control. Experts the Inquiry consulted generally considered that a positive result required the observation of the wider range of classic symptoms as noted above, as well as death itself.

### Toxin neutralisation

The final step of a mouse bioassay is to treat mice with antitoxins to each of the *C. botulinum* types, then dose them with samples containing toxin of the same type. Mice so protected show no toxic effects. This step is called neutralisation. It has two purposes: to identify the particular *C. botulinum* type and to provide a final confirmation of the presence of toxin.

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199 The modification applied by CDC and NVSL to screen using undiluted samples only is documented in the *CDC Handbook*: [cdc.gov/ncidod/dbmd/diseaseinfo/files/botulism.pdf](https://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/botulism.pdf)

200 Other causes of death include injection of the food product or growth media, metabolic by-products produced in cultures and damage to vital organs during inoculation. The toxicologist told the Inquiry these causes could be ruled out.

201 The abdominal breathing was noted as first occurring on, or shortly after, injection.

202 Of the other three results that showed non-fatal toxic effect, AgResearch reported one result was strongly positive, one positive and another equivocal. The mice showed initial lowered respiration rates that then increased, but their appearance and behaviour returned to normal within 24 hours.

AgResearch had no antitoxin. Regulatory controls introduced in 2002 in response to the threat of terrorism have made it extremely difficult to obtain reference *C. botulinum* strains and antitoxin for neutralisation assays. In any event, it considered this step necessary only if the client wanted to know the specific toxin type. Otherwise, a sufficient positive control was to inject mice with samples that had been heat-treated to destroy the toxin.<sup>203</sup> FRDC staff acknowledged that they knew AgResearch would not be testing for toxin neutralisation.

### Concluding comments

The Inquiry does not need to resolve such disagreements as exist about the outcome of the mouse bioassay results. Its concern is only to understand what happened from a food safety perspective so that all involved, along with the wider industry, can draw instructive lessons and avoid a repetition of the incident. The chief lessons of this incident, as seen through the food safety lens, concern how and why the testing was commissioned and the results communicated; less so, the differing scientific views of experts about the results themselves. These questions will always be influenced by context, especially whether testing is research, diagnostic or somewhere between the two.<sup>204</sup>

### United States testing

Some scientists questioned the work undertaken by the United States laboratories, particularly the transporting and viability of samples, the loss of the toxin genes through subculturing, and the possibility of false negative results.<sup>205</sup> The samples the laboratories received were in transit for about five days. Both laboratories confirmed that, despite the length of time, all cultures were viable and grew well. Some *C. botulinum* toxin genes can be degraded if the organisms become stressed or are

repeatedly subcultured. Some scientists questioned whether the same subcultures were tested overseas as at AgResearch. The ministry's report shows that they were.<sup>206</sup> The possibility of a false negative result arose after NVSL's observation of mild non-specific symptoms. Subsequent testing ruled this out.<sup>207</sup>

### Results

AgResearch submitted two reports to Fonterra, a preliminary version (with a "draft" watermark) prepared at Fonterra's urgent request on 2 August and a final version on 30 August (essentially after the event). They differ, but reach essentially the same conclusions.

The final report recommended further examination of the isolates – this was a notable difference from AgResearch's preliminary report, which made no firm recommendation for further analysis. The preliminary report noted that identifying the toxin type produced by the isolates would require AgResearch to enhance its capability for enzyme-linked immunosorbent assay (ELISA) and PCR testing. AgResearch told the Inquiry that the 31 July meeting with FRDC representatives discussed further testing, but the main focus was on testing more samples rather than more analysis of existing isolates (as Fonterra representatives acknowledged).

The preliminary report's lack of detail about testing methods has drawn criticism among scientific circles. However, the Inquiry does not find this surprising: issuing a preliminary report is not standard practice and a lack of such details would not be considered unusual. In any case, the final report set out the methodology in full.

203 Botulinum toxin is destroyed when heated to 100°C for 10 minutes.

204 The Inquiry also wishes to avoid any suggestion of influencing questions of liability in light of the Fonterra-Danone litigation.

205 Subculturing is the process of making a new cell or microbiological culture by transferring some or all cells from a previous culture to a fresh growth medium.

206 Fn 186.

207 Mild non-specific symptoms were observed when testing samples incubated for 24 hours. NVSL repeated its test with samples incubated for seven days (to allow for more toxin to be produced). The seven-day samples were negative for botulinum toxin.

AgResearch's microbiologist, mentioned earlier, compiled the preliminary report, drawing on her work and that of the toxicologist and others. Her immediate manager reviewed this draft before it went to Fonterra. AgResearch microbiologists who had had no involvement in the Fonterra work reviewed the final report, as did the institute's chief executive.

Neither report uses the word "confirmed" about the findings, raising questions about why Fonterra reported confirmed results to MPI on 2 August. Until receipt of AgResearch's preliminary report, communication between Fonterra and AgResearch about the results was by phone and email (with the exception of the 31 July meeting mentioned above). Fonterra said it based its decision to report confirmed *C. botulinum* to MPI on the information provided through these informal channels. The preliminary report, setting out AgResearch's findings, reached Fonterra only shortly before it notified the ministry at midday on 2 August.

Asked by the Inquiry whether they had critically reviewed the preliminary report, Fonterra scientists (including its two microbiologists) replied no. They expressed a lack of expertise in the area and a corresponding trust in AgResearch's expertise. But Fonterra said nothing in the report suggested that AgResearch was other than confident in its findings. Scientists consulted by the Inquiry also considered that, despite the qualification of "likely", AgResearch's language implied a strong belief that the organisms identified were *C. botulinum*.

Nevertheless, the AgResearch preliminary report was clear that, although the samples were "shown to be toxigenic" and were "likely to be *C. botulinum*", AgResearch could not "rule out other close relatives". As previously noted, MPI did not receive a copy of the report until the evening of 4 August – two days after notification.

## Lessons

The need for clearer communication emerges as the pre-eminent lesson of this section of the report, whether in reference to the role of particular types of laboratories, the purpose and limitations of particular tests, or defining expectations about what tests will achieve.

The Inquiry has already noted the changes that Fonterra (including FRDC) has since made in relation to testing, especially non-standard testing, elsewhere in this report.

AgResearch, too, has made changes, particularly related to communication and clarification of roles. Contracts now include a statement making clear whether results are suitable for diagnostic or research purposes. Risk assessment principles have been revised so scientists can have a greater appreciation of the possible risks of a proposed test. AgResearch scientists are also now encouraged to elicit as much information as possible from clients in order to be clear about the purpose of any testing before entering into a contract.

Wider lessons for the industry relevant to this section have already been outlined in part four, that is, the need for clear purpose (by both clients and laboratories) and proper scientific risk assessment relating to the reason for, and possible outcomes of, commissioned testing. Other lessons learned include:

**Accreditation:** The law and guidance material need to spell out explicitly when diagnostic testing must take place in accredited laboratories using validated methods. Accreditation is a proper requirement for diagnostic laboratories, which are equipped to carry out food safety testing. Laboratories have a responsibility to inform themselves of the purpose of any testing, but the obligation to select the appropriate laboratory remains with the client.

*Testing plans:* These deserve greater use because they crystallise both parties' assumptions and expectations and, properly prepared, leave an unambiguous record of their intentions. Laboratory and client should agree on a testing plan setting out the purpose for each method to be used, the order in which the laboratory will conduct the tests and the criteria (where possible and appropriate) determining whether each test will proceed. These measures would not stand in the way of research alongside diagnostic methods. In such instances, the plan could outline what influence, if any, the research results are likely to have on the diagnostic results.

*Variations to testing:* Communication remains important throughout the various stages of testing, and this extends to variations to testing, such as, here, the number of mice. Even in research testing involving a validated or reference method, laboratories should discuss in advance any variations from the method and obtain client agreement. Contracts should list known variations and their likely influence on the interpretation of results, such as, here, the absence of antitoxin. Contracts should also outline reporting procedures that the laboratories will follow, should variations become necessary as testing proceeds.

*Non-validated methods:* If a laboratory accepts a commission to undertake diagnostic testing using a non-validated method, it must make clear to its client, as well as in subsequent reports to its client, that the non-validated methodology may introduce uncertainty into the results.

## Recommendations

The Inquiry recommends:

- The ministry, the New Zealand Food Safety Science and Research Centre (in the process of being established) and laboratories should collaborate to establish, test and maintain:
  - Mechanisms for sourcing controls (such as reference cultures and antitoxins), if required for non-standard testing in New Zealand
  - A global register of accredited laboratories and scientific experts able to undertake, or advise on, microbiological testing, especially for pathogenic and uncommon organisms
  - Arrangements (including customs and biosecurity clearances) that ensure minimal effects on cultures during transport to overseas laboratories for tests that cannot be conducted in New Zealand.

- The law should be amended to make clear what tests must be conducted in accredited laboratories.
- Industry participants should be required to seek approval from the ministry when no accredited laboratory or validated method is available for diagnostic testing, or a significant variation to a validated method is unavoidable.

## Appendix 1: Terms of reference

Extract from *New Zealand Gazette*, 12/9/2013, No. 126, p. 3512

### Establishment of the Government Inquiry into the Whey Protein Concentrate Contamination Incident

Pursuant to section 6(3) of the Inquiries Act 2013, I, The Honourable Nathan Guy, Minister for Primary Industries, and I, The Honourable Nikki Kaye, Minister for Food Safety, hereby establish the Government Inquiry into the Whey Protein Concentrate Contamination Incident (“Inquiry”).

#### Membership

The following persons are appointed to and constitute the Inquiry:

- Miriam Rose Dean, CNZM QC (chairperson);
- Dr Anne Marie Astin, PSM (member); and
- Anthony John Nowell, CNZM (member).

#### Terms of Reference

##### Background

New Zealand has a reputation as a credible and trusted supplier of safe and suitable food to both domestic and international markets. This well-deserved reputation is a vital element in the continuing growth and productivity of the food industry.

Exporting food is critical to New Zealand’s economy, with the food industry making up half of New Zealand’s merchandise export value. New Zealand has an excellent track record of exporting safe food, and our food safety system is considered world-leading.

The whey protein concentrate (“WPC”) contamination incident risks damaging the reputation we have worked hard to gain.

This Inquiry is about strengthening an already strong system, to ensure that New Zealand food products retain their status as among the world’s safest and most desired.

##### Appointment and Order of Reference

This Inquiry will inquire into and report (making any recommendation it thinks fit) upon the following:

*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).

This part of the Inquiry will not be undertaken until the Ministry for Primary Industries’ (MPI) compliance investigation is completed, subject to any views the Inquiry reaches on the application of section 16 of the Inquiries Act 2013.

This part of the Inquiry will rely on findings of fact from the MPI compliance investigation and supplement this as required.

##### *Inquiry into regulatory and best practice requirements*

- (b) The requirements of any Acts, Regulations, or other laws, or of any recognised practices, that govern the following aspects of food safety against the background of this incident in relation to the dairy industry, including how those legal and practice requirements interact with each other:
  - (i) Quality and integrity of product testing;
  - (ii) traceability requirements, including the requirements across the supply chain to retailers;
  - (iii) reporting and risk management decision-making;
  - (iv) implementation of food safety standards;
  - (v) contingency plans for food safety and food quality;

- (vi) role of regulators, including any recognised agency; and
- (vii) potentially affected products, including infant formula.
- (c) How the matters referred to in paragraphs (b) (i)–(vii) above compare with similar matters in other comparable jurisdictions.

#### **Matters Upon or for Which Recommendations Required**

The Inquiry will report on and make any recommendations it considers fit on:

- (a) the adequacy of legal and best practice requirements with regard to product testing, traceability, reporting, implementation of food safety standards, contingency planning and role of regulators (refer to paragraphs (b) (i)–(vii) and paragraph (c) above);
- (b) any legal or regulatory changes or additions necessary and desirable to prevent or minimise similar incidents; and
- (c) any changes or additions to operational practices for product testing, traceability, reporting, implementation of food safety standards, contingency planning and response of regulators, to address the lessons from this incident.

#### **Exclusions From Inquiry and Scope of Recommendations**

The Inquiry is not to inquire into, determine, or report in an interim or final way, or otherwise prejudice any of the following matters:

- (a) The Ministry for Primary Industries' investigation into the compliance with any legal or practice requirements;
- (b) whether any questions of liability arise; and
- (c) the legislative structure of the New Zealand dairy industry.

#### **Definitions**

"Practice" or "practices" includes, without limitation, each of the following:

- (a) Decision-making;
- (b) procedures;
- (c) processes;
- (d) services; and
- (e) systems.

#### **Reporting Sequence**

The Inquiry is to report findings and opinions, together with recommendations, required and otherwise, that it thinks fit to make in respect of them, to the appointing Ministers in writing in the following sequence:

- (a) Inquiry into regulatory and best practice requirements:
  - (i) An interim report is to be provided by no later than three months after notification of the Government Inquiry in the *New Zealand Gazette*;
  - (ii) a final report is to be provided at a date to be specified by the appointing Ministers, following the conclusion of the Ministry for Primary Industries' investigation and any subsequent Court action;
- (b) Inquiry into how the potentially contaminated whey protein concentrate entered the New Zealand and international markets, and how this was subsequently addressed, at a date to be specified by the appointing Ministers, following the conclusion of the Ministry for Primary Industries' investigation and any subsequent Court action.

#### **Consideration of Evidence**

The Inquiry may begin considering evidence on and from **12 September 2013**.

Dated at Wellington this 10th day of September 2013.

HON NATHAN GUY, Minister for Primary Industries.

HON NIKKI KAYE, Minister for Food Safety.

Notice No: 5757

**Appendix 2: Categories of interviewees involved in the Inquiry (stages one and two)**

**Who we interviewed:** In total the Inquiry has conducted interviews with over 220 individuals from 55 organisations, including experts. In addition, 36 formal written submissions were received with a number of contributors providing substantial additional information. The Inquiry panel also visited field sites in New Zealand and had the benefit of international expertise to inform its investigation and analysis.

**INTERNATIONAL AUTHORITIES**

- » Food Safety Authority of Ireland
- » Canadian Food Inspection Agency
- » US Food and Drug Administration
- » NSW Food Authority
- » Codex
- » Health and Consumer Protection European Commission

**CUSTOMERS**

- » Danone (Nutricia Limited)
- » Nestlé New Zealand Limited
- » Vitaco Health (NZ) Limited

**SCIENCE, RESEARCH AND VERIFICATION**

- » AgResearch Ltd
- » Institute of Environmental Science and Research
- » Riddet Institute
- »ASUREQuality Ltd
- » Eurofins New Zealand Laboratory Services Limited
- » The New Zealand Institute for Plant and Food Research Limited
- » MilkTestNZ
- » Chief Science Advisor, Office of the Prime Minister
- » Institute for Food, Nutrition and Human Health

**EXPERTS**

- » Public health
- » Food safety
- » Infant nutrition
- » Risk communications
- » Agribusiness
- » Science

**DAIRY COMPANIES**

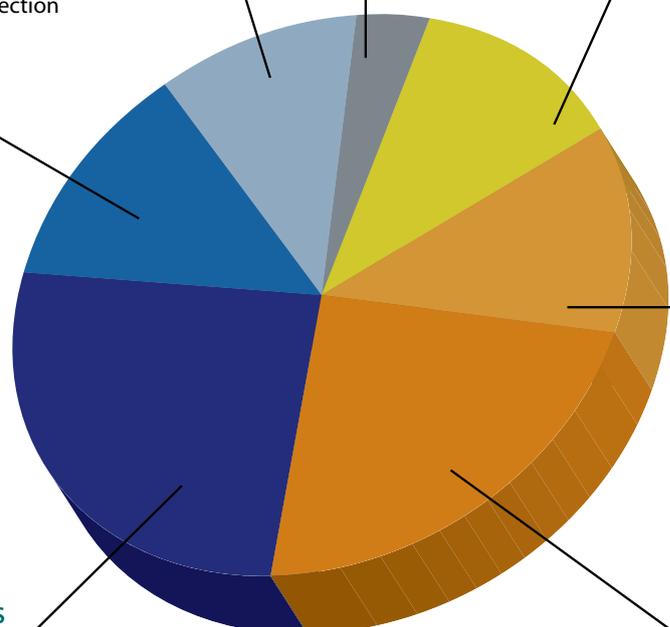
- » Fonterra Co-operative Group Limited
- » Sutton Group
- » Westland Co-operative Dairy Company Limited
- » Synlait Milk Limited
- » Dairy Goat Co-operative (NZ) Ltd

**INDUSTRY REPRESENTATIVES**

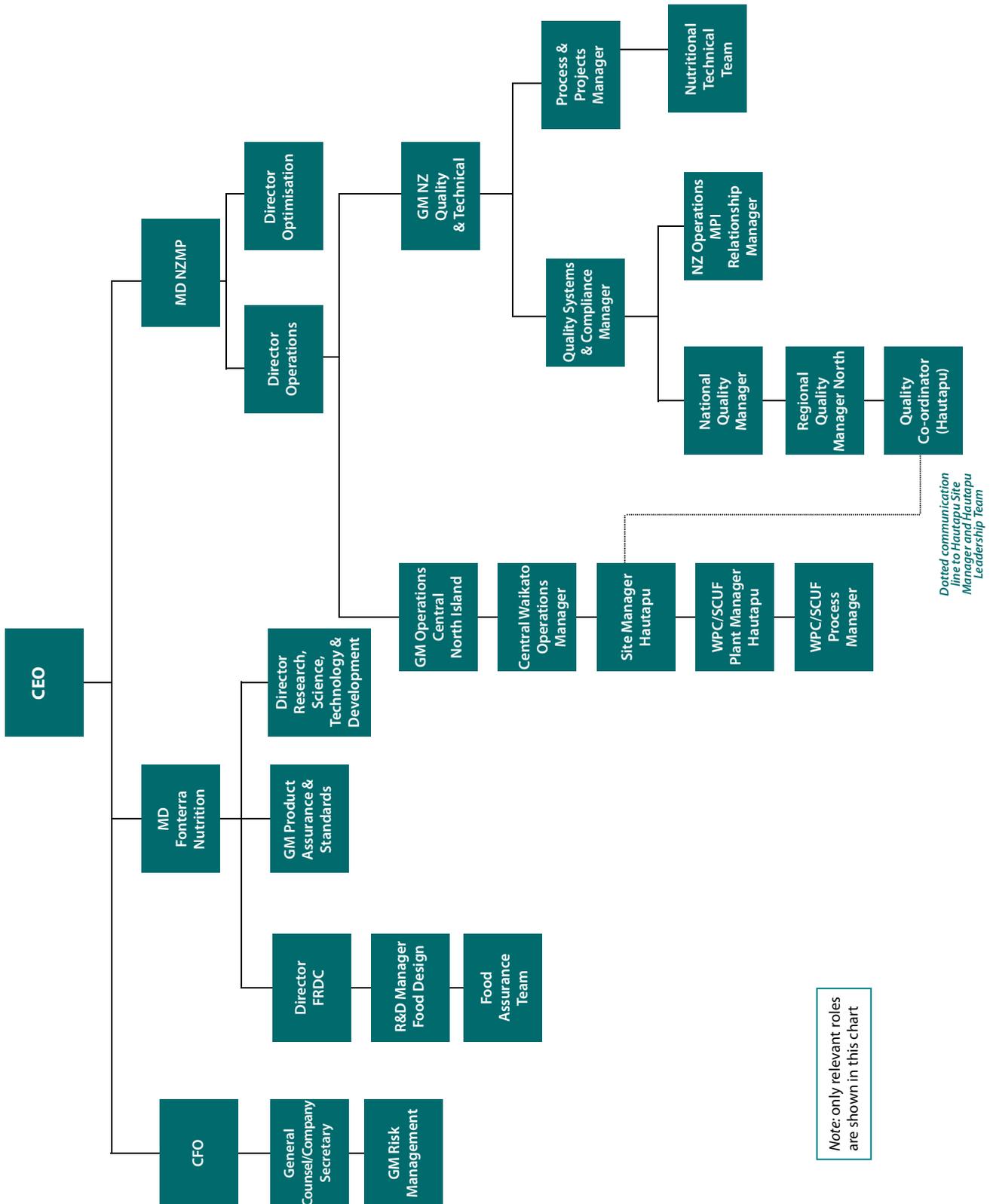
- » Food Standards Australia New Zealand
- » Food and Grocery Council
- » Infant Formula Exporters Association
- » Dairy Companies Association of New Zealand
- » Infant Nutrition Council
- » Federated Farmers
- » Global Standards 1
- » Dairy New Zealand
- » New Zealand Seafood Council
- » International Dairy Federation
- » New Zealand Veterinary Association

**GOVERNMENT AND REGULATORS**

- » Ministers for Trade, Food Safety and Primary Industries
- » Members of Parliament
- » Department of the Prime Minister and Cabinet
- » Ministry for Primary Industries
- » Ministry of Foreign Affairs and Trade
- » Ministry of Health
- » Ministry of Business, Innovation and Employment
- » New Zealand Trade and Enterprise
- » State Services Commission
- » Productivity Commission
- » Electricity Authority
- » Tertiary Education Commission
- » International Accreditation New Zealand
- » Joint Accreditation Systems of Australia New Zealand



Appendix 3: Fonterra's group reporting structure as at 1 August 2013



Note: only relevant roles are shown in this chart

Dotted communication line to Hautapu Site Manager and Hautapu Leadership Team

**Appendix 4: Fonterra’s new procedures, as applied to this incident**

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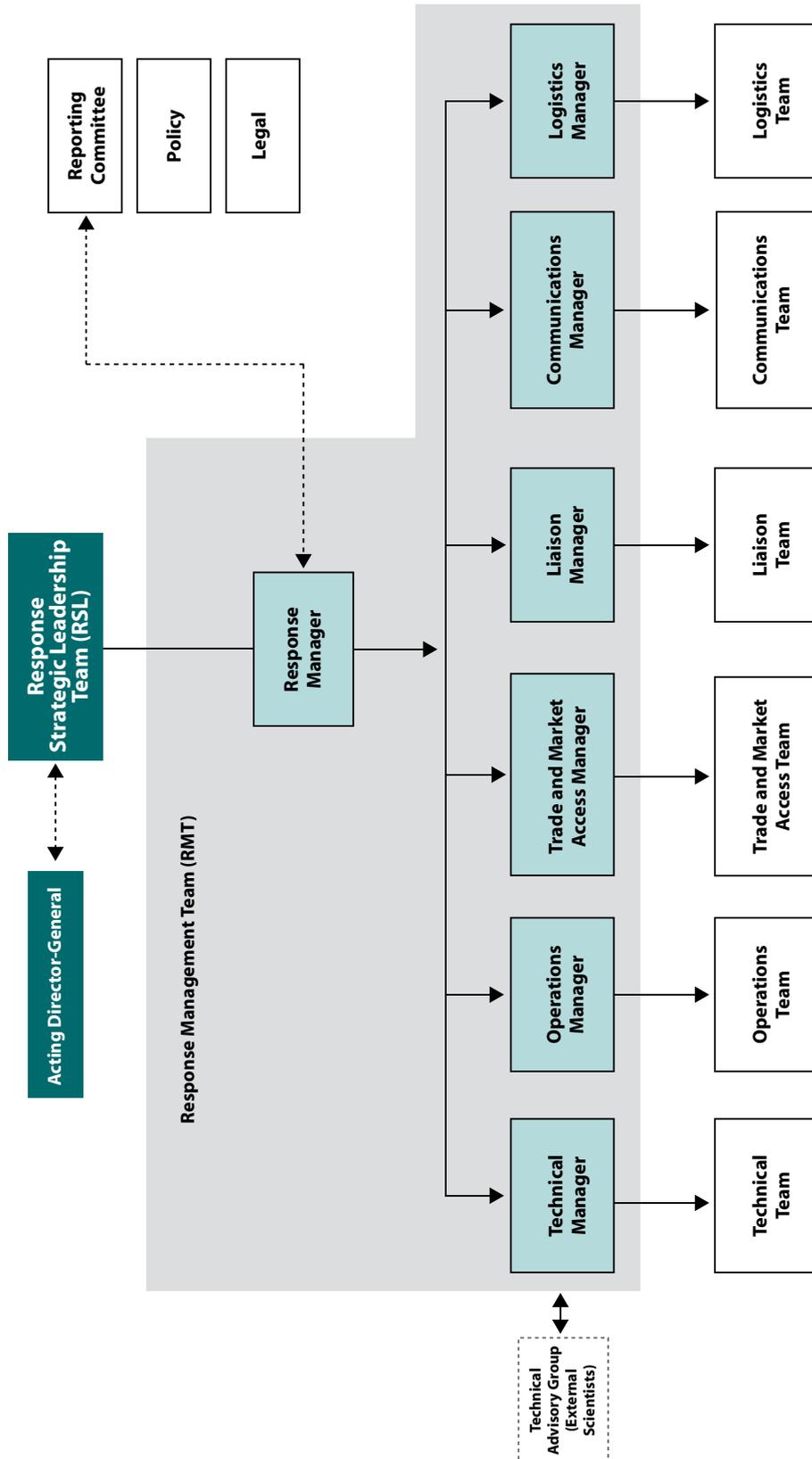
**How new Fonterra procedures would prevent a repeat of the WPC80 incident**

**Then**

**Now**

- |   |  |
|---|--|
| <p><b>1</b> Reworking using improvised method outside Hautapu’s risk management programme and without risk assessment</p>       | <ul style="list-style-type: none"> <li>• Reworking options limited for products intended for sensitive population groups</li> <li>• Non-standard equipment removed</li> <li>• Idle equipment washed with acid solution</li> <li>• Training within a strengthened food safety culture ensures risk management programmes are followed – including, where applicable, change control and risk assessment procedures</li> <li>• Quality co-ordinator has final say on reworking – and may also, after assessing any food safety concerns against set criteria, refer matter to critical event team</li> </ul> |
| <p><b>2</b> Testing of WPC80 shows extremely high SRC levels, indicating significant failure in good manufacturing practice</p> | <ul style="list-style-type: none"> <li>• High SRC levels treated as potential food safety problem</li> <li>• All food safety risks trigger assessment for escalation to critical event team</li> <li>• Business unit critical event team either manages response or, if deemed serious enough, refers matter to group’s incident management team</li> </ul>  |
| <p><b>3</b> <i>C. botulinum</i> testing approved</p>  | <ul style="list-style-type: none"> <li>• Request for <i>C. botulinum</i> testing, like any non-standard testing, requires approval of business unit’s quality and compliance manager and group’s product assurance and standards manager</li> <li>• Request must identify product to be tested and reasons for test, plus contain hazard analysis</li> <li>• Either manager can, if concerned, refer matter to critical event team</li> <li>• Both managers – and possibly also critical event team – monitor tests, communicate results and, if necessary, refer matter higher</li> </ul>                 |

Appendix 5: MPI's WPC80 incident response structure



## Appendix 6: Events after 2 August 2013

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### 2 August

- 12pm** Fonterra notifies ministry of “confirmed” *C. botulinum*
- 12.35pm** Fonterra’s PowerPoint presentation to ministry says 871 tonnes affected (or “in market product impacted”); amount includes 590 tonnes to Danone
- 1.20pm** Internal ministry email recommends “trade/food” response
- 1.30pm** Meeting of top officials decides composition of ministry’s response management team (RMT), appoints a response manager and establishes various teams  
Ministry alerts ministers and other government agencies
- 2.40pm** Ministry asks AsureQuality to seal off Hautapu equipment identified as source of contamination and help with tracing work
- 3pm-4pm** Fonterra gives ministry details about affected exports
- 3.30pm** First meeting of response strategic leadership team (RSL) sets seven priorities, including protecting consumer health
- 6pm** Fonterra gives ministry more details about affected products
- 7pm** Fonterra tells ministry five batches of Nutricia follow-on formula (one on sale in New Zealand) are potentially contaminated with nutritional powder from Darnum
- 9.30pm** Ministry talks to Nutricia, after which company puts internal hold on follow-on products
- 10pm** Ministry begins notifying overseas regulators via MFAT

### 3 August

- 12.12am** Ministry issues first media release: “a range of products” (not specified) made from WPC at one Fonterra site “appear to contain” *C. botulinum*
- 8am** Overseas markets suspend imports and some markets require SRC testing  
Ministry gives advice to district health boards, sets up helplines, liaises with WHO, markets, Fonterra, Nutricia and other manufacturers and responds to media  
Ministry asks Fonterra for details about strain of *C. botulinum* and testing methodologies  
Fonterra scientists and ministry officials hold conference call
- 2.45pm** First Director-General statement: Karicare Stage 2 Follow On may contain affected WPC80
- 5.30pm** Fonterra tells ministry contamination may extend to Stage 1 infant formula; ministry asks Nutricia to confirm
- 9pm** First suspected case of infant botulism ruled out

### 4 August

- 1.30am** Nutricia voluntarily recalls specific batches of Karicare Gold+ Stage 2 Follow On formula and Stage 1 infant formula  
Ministry asks AsureQuality to send staff to Nutricia in Auckland to help with tracing  
Ministry rules out risk of botulism in heat-treated products
- 12.45pm** Ministry media release says Stage 1 infant formula may be contaminated and “may be on sale”, and adds that Director-General statement will follow

- 7pm** Ministry gets AgResearch preliminary report after Fonterra lifts confidentiality restriction
- 8.30pm** Second Director-General statement says potential contamination of Stage 1 infant formula cannot be ruled out
- 5 August**
- 7.15am** Fonterra tells ministry it supplied Nutricia with another 17 bags of contaminated WPC80  
Ministry tells Nutricia it will initiate statutory recall if Nutricia does not broaden recall  
Ministry sends auditors to Fonterra head office and Darnum to help with tracing
- 7pm** Fonterra executive wrongly tells TV viewers all Nutricia Karicare products are potentially contaminated
- 8.30pm** Nutricia extends voluntary recall to all batches of Karicare Stage 1 infant formula and Karicare Gold+ Stage 2 Follow On formula
- 6 August** Ministry sends first samples to United States for testing  
Fonterra commits more resources to help with Australian tracing effort
- 3pm** Third Director-General statement corrects wording error of second statement and brings ministry into line with Nutricia
- 7 August** Fonterra chief executive publicly apologises for anxiety caused by incident
- 8 August** Fonterra media release wrongly says “almost all products” have been found and recalled  
Fonterra announces board inquiry  
Fonterra completes tracing in New Zealand (837.5 tonnes)
- 9 August** Ministry sets terms of reference for technical advisory group comprising external scientists  
Fonterra advises ministry bag of WPC80 given to Palmerston North school; ministry assessment concludes no health risk
- 12 August** Technical advisory group meets
- 12pm** Fourth Director-General statement narrows scope of consumer advice to infant and follow-on formula made between 21 May 2013 and 2 August 2013; coincides with updated Nutricia recall  
Ministry announces compliance investigation under way
- 13 August** Fonterra advises further change to affected product quantities
- 14 August** Fonterra advises further change to affected product quantities
- 15 August** Fonterra advises further change to affected product quantities
- 18 August** Fonterra completes tracing of Danone production in Australia (1,759 tonnes); advises further change to affected product quantities
- 20 August** Ministry announces interim changes to dairy regulatory system
- 23 August** Ministry receives preliminary results from United States laboratories indicating no evidence of botulinum toxin
- 25 August** Ministry releases *Whey Protein Concentrate Incident Tracing and Verification Report* to Fonterra, Danone and overseas regulators
- 27 August** Ministry receives final product reconciliation from Fonterra
- 28 August** Ministry receives and announces final results from United States laboratories and also makes public the tracing and verification report
- 31 August** Ministry makes public *WPC 2013 Response Report: Laboratory identification of the Fonterra bacterial isolates*