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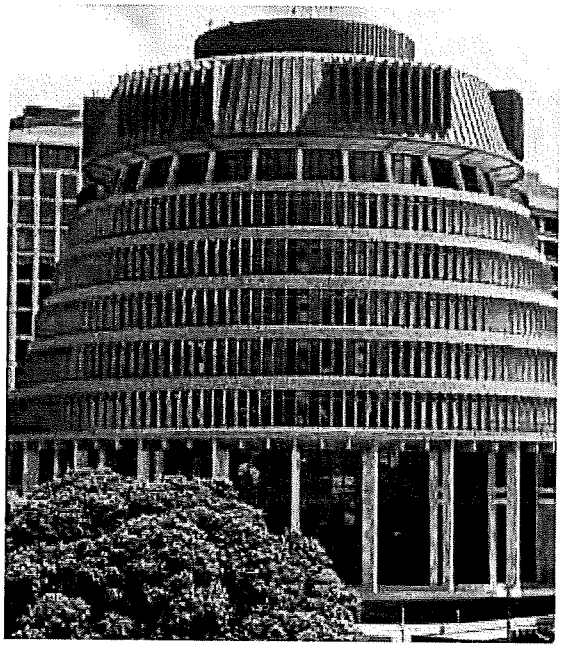

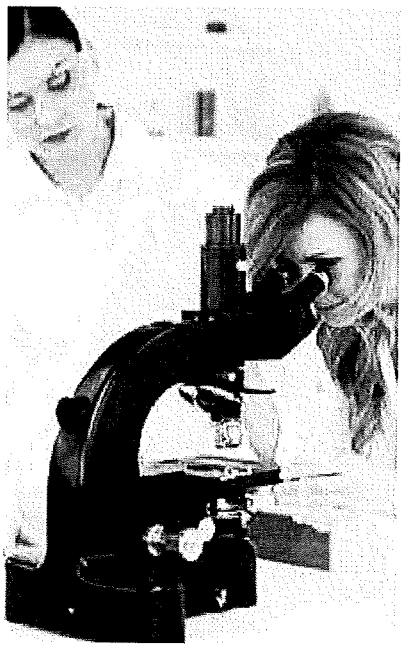

THE WPC80 INCIDENT: CAUSES AND RESPONSES

GOVERNMENT INQUIRY INTO THE WHEY PROTEIN CONCENTRATE CONTAMINATION INCIDENT

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Preface

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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Overview

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.

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."[1]

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

Findings

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 not AsureQuality, 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.

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 inform AsureQuality 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

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

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.