

SUMMARY OF FONTERRA'S WPC80 OPERATIONAL REVIEW



Dairy for life

FONTERRA CO-OPERATIVE GROUP LIMITED
6 SEPTEMBER 2013

This document summarises the findings and recommendations of the WPC80 Operational Review.

It was presented to Fonterra Chief Executive, Theo Spierings, on 30 August 2013.

INTRODUCTION

On 2 August 2013, Fonterra initiated a precautionary recall of 38 tonnes of its whey protein concentrate ingredient (WPC80). The decision was based on the results of independent testing Fonterra commissioned from Crown Research Institute, AgResearch, which concluded the likely presence of *Clostridium botulinum* in bacteria sourced from product containing the whey protein concentrate. Subsequent independent testing by New Zealand's Ministry for Primary Industries, reported on 28 August 2013, definitively confirmed that the Clostridia was *Clostridium sporogenes*, which is harmless, and not *Clostridium botulinum*.

Shortly after initiating the precautionary recall, Fonterra's Chief Executive, Theo Spierings, commissioned an Operational Review to enable the Co-operative to understand the cause of the contamination, and evaluate how the business handled the incident and precautionary recall. The Operational Review team was also tasked with making recommendations on how Fonterra could prevent an event like this from happening again. Led by Fonterra's Group Director of Strategy, Maury Leyland, the Operational Review conducted interviews with employees across the business, and analysed materials including communications, reports and other relevant data. The findings and recommendations of the Operational Review were presented to Fonterra's Chief Executive, Theo Spierings, on 30 August 2013. This document is a summary of those findings and the recommendations made.

OPERATIONAL REVIEW TEAM

“A world class organisation constantly learns – it is never static and is not afraid to examine itself openly and critically. This has been the approach taken by the Fonterra WPC80 Operational Review team.” – MAURY LEYLAND

The Fonterra team which undertook the WPC80 Operational Review and compiled the findings and recommendations comprised:

Maury Leyland

Group Director of Strategy (Operational Review team lead)

Hardeep Kang

General Manager of Fonterra's Group Global Framework

Joanne Fair

NZ Milk Products Global Account Director

Dr Jeremy Hill

Chief Technology Officer

Ben Mayson

General Manager of Group Strategy

Liz O'Neil

General Manager of Commercial in Fonterra's Group Function

Andries Du Preez

Senior Internal Audit Manager

Blair Stewart

Strategic Insights and Capability Manager

MAURY LEYLAND

As Fonterra's Group Director of Strategy in the Office of the CEO, Maury Leyland is responsible for driving Fonterra to deliver on its Group strategy, following the refocus of the Co-operative's global priorities in 2012.

Having worked at Fonterra since 2005 across supply chain, strategy, Trading Among Farmers and Fonterra's Value Stream Optimisation programme, Maury has a comprehensive understanding of Fonterra's global business and significant experience in crisis management and operational excellence.

Maury was a member of the design team for Team New Zealand during the successful 1995 America's Cup campaign, and before joining Fonterra, she spent nine years with the Boston Consulting Group. She is on the Board of Telecom, a member of the Advisory Board for the Department of Engineering Science at the University of Auckland, a member of the Institute of Directors and previously was on the Board of Transpower.

She is a Fellow of the Institution of Professional Engineers of New Zealand (FIPENZ) and holds a Bachelor of Engineering with First Class Honours from the University of Auckland.

PURPOSE AND SCOPE

The purpose of the Operational Review was to ask, should a situation like this occur again, what should Fonterra do differently. The scope of the Operational Review was to:

- understand what happened with respect to events and decisions leading to Fonterra's precautionary recall, and its handling of the event;
- understand why this happened; and,
- recommend improvements to prevent an event like this from happening again.

The Operational Review's scope was focused on, and limited to, the operations of Fonterra's business. In particular, it examined what

is required in order to process milk and manufacture products to the quality and safety levels expected by Fonterra, its customers, regulators and anyone who buys its products. The review did not focus on the external organisations Fonterra worked with before and during its precautionary recall.

The Operational Review comprised a comprehensive analysis of several aspects of Fonterra's business, including commercially sensitive material.

This summary outlines the Review's recommendations and the areas requiring attention that it identified. More detailed work plans and implementation programmes have been, and are being, created separate to this document.

BACKGROUND INFORMATION

FONTERRA

Fonterra is the world's largest dairy exporter. Its New Zealand operations collect milk produced by the New Zealand dairy farmers who are both the Co-operative's suppliers and shareholders. It processes this milk to create a wide range of dairy ingredients and consumer dairy products. Fonterra's and New Zealand's food safety systems and standards are among the highest in the world. Fonterra's dairy manufacturing operations, food quality programmes, and testing regimes are recognised as world-leading within the global dairy industry.

Each year in New Zealand, Fonterra produces approximately 2.4 million metric tonnes of dairy products from around 17 billion litres of milk. To achieve this, the Co-operative has robust quality control processes and systems, and high food quality and safety standards. Any lapse in these standards is regarded by Fonterra as an extremely serious matter due to the potential consequences.

WHEY PROTEIN CONCENTRATE WPC80

Whey protein concentrate, the ingredient at the centre of Fonterra's recent precautionary recall, is an important export product for Fonterra and for New Zealand. Although Fonterra produces it in lower volumes than milk powder, whey protein concentrate is a valuable export as a base ingredient used in a wide range of products, from infant formula to yoghurts and sports drinks. Fonterra manufactures 19,500 metric tonnes of whey protein concentrate each year, at five of its New Zealand sites.

CLOSTRIDIA TESTING

Sulphite Reducing Clostridia (SRC) testing is used in dairy manufacturing to ensure products are low in Clostridia such as *Clostridium sporogenes*, which isn't a food safety hazard but at high levels can cause food to spoil. SRC testing is not intended for *Clostridium botulinum*, which is almost unheard of in dairy products and which poses a potential food safety risk. Of the seven types of *Clostridium botulinum*, three can cause botulism, but these three types have never been detected in New Zealand.

THE PRECAUTIONARY RECALL

Although it proved to be a false alarm, Fonterra's precautionary recall was complex and global, and a major food safety concern in many parts of the world. The whey protein concentrate ingredient was used in a wide range of products, including infant formula, by eight of Fonterra's customers in a number of countries.

SEQUENCE OF EVENTS

The Operational Review determined that the following sequence of events led to Fonterra's precautionary recall.

- Between 10 and 22 March 2013, routine testing conducted at Fonterra's Darnum site in Australia identified high Clostridia levels in finished product made for a customer.
- As a result, Fonterra immediately initiated two parallel work streams:
 - Work stream one:
A trace-back through its manufacturing processes to determine where and when the product was manufactured, and what the conditions of the product's manufacture were.
 - Work stream two:
Further microbiological testing to confirm that the high Sulphite Reducing Clostridia test levels indicated harmless Clostridia such as *Clostridium sporogenes* and ensure there was no potential food safety risk.

MANUFACTURING TRACE BACK

- The WPC80 ingredient was traced back to Fonterra's Hautapu whey plant in the Waikato region in New Zealand's North Island.
- Three batches of whey protein concentrate had been reprocessed in May 2012 due to concerns about possible foreign matter contamination during original manufacture. The original product was suspected to contain a small piece of plastic.
- The reprocessing of the whey protein concentrate occurred on 17, 18 and 22 May 2012 to ensure the product was appropriately filtered.
- The method of reprocessing used in this instance was non-standard. It was during this reprocessing that the Clostridia contamination occurred. To complete the reprocessing, an item of non-standard equipment was used – a transfer pipe.
- Although standard cleaning procedures were followed, including those for the transfer pipe, before and during reprocessing, subsequent analysis of the plant shows that the source of Clostridia was likely to have been this transfer pipe. The pipe has since been decommissioned.
- The reprocessed WPC80 passed all testing requirements for general use whey powder at this point. Testing regimes for 'base' ingredient products are less stringent than those for finished products which is why the Clostridia levels were identified only when the product was manufactured into a finished product state.
- 37.8 metric tonnes of the whey protein concentrate were sold to eight customers:
 - 20.7 tonnes were sent direct to customers for use in products such as UHT beverages. This occurred between July 2012 and February 2013.
 - 3.6 tonnes were sent to Fonterra's Waitoa site, in Waikato, New Zealand in January 2013 to be used as an ingredient in nutritional base powder.
 - 13.5 tonnes were sent to Fonterra's Darnum site in Australia in October 2012 to be used in the manufacture of nutritional base powder for infant formula. This manufacturing was undertaken in March 2013.

MICROBIOLOGY TESTING

- At the same time as the manufacturing trace-back, Fonterra began microbiological testing to confirm that the Clostridia which had been identified at Darnum were *Clostridium sporogenes* to ensure there was no potential food safety risk.
- The microbiological testing involved a series of tests at Fonterra's research centre in Palmerston North, New Zealand.
- On 8 May 2013, a MALDI-TOF test (a sophisticated mass spectrometry technique) that was conducted at the research centre indicated that the Clostridia were most likely *Clostridium sporogenes*, but the findings were not definitive.
- The research centre's further testing was unable to rule out the presence of *Clostridium botulinum*. As a result, Fonterra decided to commission further independent testing.
- Fonterra commissioned Crown Research Institute, AgResearch, to conduct further testing, to confirm that the identified strain was *Clostridium sporogenes* and to rule out any potential presence of *Clostridium botulinum*.
- On 2 August 2013, Fonterra received AgResearch's test results, which confirmed the likely presence of *Clostridium botulinum* in bacteria sourced from product containing the whey protein concentrate.
- Fonterra immediately advised the Ministry for Primary Industries, on 2 August 2013, of the test results, initiated a precautionary recall of the WPC80 with the eight customers that had received it, and publicly communicated the test results and potential food safety risk.
- Subsequent to this precautionary recall, New Zealand's Ministry for Primary Industries commissioned further testing from four laboratories – two in the United States and two in New Zealand. These tests definitively confirmed that the whey protein concentrate contained *Clostridium sporogenes*, and was clear of *Clostridium botulinum*.
- The Ministry for Primary Industries made the test results public at a press conference on 28 August 2013.

CONTRIBUTING FACTORS

The Operational Review concluded that no single occurrence led to the precautionary recall and the events that ensued, and that no single issue was the sole contributor. Instead, the Review determined that the recall, and events that followed, were the result of a series of separate and unrelated incidents that occurred in an unforeseen sequence.

While the root cause of the contamination was an item of non-standard equipment used in reprocessing the WPC80, a computer systems upgrade, as well as lapses in escalation and communication each played a part in contributing to the event.

In summary, the key contributing factors were:

- The decision to reprocess the original WPC80 and not downgrade the product, in combination with the use of an item of non-standard equipment.
- A one-off lapse in information sharing across two parts of the business which led to delays in testing.
- The issue should have been escalated to CEO-level earlier.
- A major upgrade of the computer systems at Fonterra's Australian sites, immediately prior to the recall, which resulted in product tracing taking longer than it should have.
- Although Fonterra has clearly established domestic and international product recall systems, the size and complexity of the WPC80 recall was a factor, particularly given the product had itself become an ingredient in the products of multiple customers.

RECOMMENDATIONS

To prevent an event like this from happening again, the Operational Review identified 20 recommendations, which cover four elements of Fonterra's business:

- **People** – the focus on food safety by Fonterra employees
- **Products** – quality control and testing regimes during manufacturing
- **Systems** – traceability capability
- **Response** – internal and external transparency, and speed of escalation

The Operational Review's recommendations are intended to:

- Ensure that Fonterra's world-class food production standards continue to be maintained at all times, across all sites, in areas such as quality control, testing, and product specifications.
- Further increase Fonterra's focus on quality and safety across its end-to-end supply chain.

- Further increase Fonterra's transparency, internally and externally, to improve information flows and the speed of escalation.
- Ensure that Fonterra strengthens its product recall and supply management systems which allow the tracing of all product in its control, and that Fonterra collaborates with its customers on how to effectively link different supply chains to quickly trace products.

ACTIONS

Based on the findings, and to achieve the intended outcomes of the recommendations, the Operational Review recommended 20 actions that were subsequently adopted by Fonterra Management. The graphic on the following page, and list that follows, shows these actions, and the status of each, at the time of writing this summary.

PLAN OF ACTION

	COMPLETE	IMMEDIATE ACTIONS	FURTHER ACTIONS
OUR PEOPLE FOOD SAFETY	<ul style="list-style-type: none"> • Creation of a Group Director of Food Safety and Quality role • Strengthen Food Integrity Council 	<ul style="list-style-type: none"> • Food safety in new and senior level employment agreements 	<ul style="list-style-type: none"> • Enhance the process for managing quality complaints • Amend performance objectives across the organisation • Comprehensive suite of people initiatives to lift focus on food safety and quality
OUR PRODUCTS MANUFACTURE	<ul style="list-style-type: none"> • Closure of Hautapu site for review • Quality audits at all sensitive plants 	<ul style="list-style-type: none"> • Identification and risk assessment of temporary lines and equipment 	<ul style="list-style-type: none"> • Address authorisations and compliance for non-standard processing and testing • Focused quality audits of all global plants • Full review of standards, with initial focus on infant formula and sensitive applications • Explore options to more proactively align with customers and regulators on standards
OUR SYSTEMS TRACEABILITY	<ul style="list-style-type: none"> • Complete training for traceability protocols for Australia 	<ul style="list-style-type: none"> • Strengthening our crisis management capability 	<ul style="list-style-type: none"> • Wider review and overhaul of Fonterra-wide product traceability capability including products in customer control
OUR RESPONSE TRANSPARENCY	<ul style="list-style-type: none"> • Global Food Safety & Quality hotline launched 	<ul style="list-style-type: none"> • Ensure we have a live, fit-for-purpose, rehearsed crisis management capability 	<ul style="list-style-type: none"> • Review and overhaul communication protocols with respect to third parties (customers, industry and government) in a crisis

SUMMARY OF RECOMMENDATIONS

PEOPLE – A FOCUS ON FOOD SAFETY

- Recommendation 1: Create a Group Director of Food Safety and Quality reporting directly to the CEO (complete)
- Recommendation 2: Strengthen the remit and scope of Fonterra's Food Integrity Council, chaired by the Group Director Food Safety and Quality (complete)
- Recommendation 3: Incorporate food safety expectations in all new employment agreements.
- Recommendation 4: Improve the management of customer complaints and export non-conformances with respect to escalation, root cause analysis, response and continuous improvement opportunities.
- Recommendation 5: Amend people's performance objectives across the organisation to reinforce the emphasis on food quality and safety as a mandatory objective.
- Recommendation 6: Develop a comprehensive suite of people initiatives to lift the focus on food safety and quality.

PRODUCTS - MANUFACTURING

- Recommendation 7: Reset of Hautapu site (complete)
- Recommendation 8: Establish interim Sulphite Reducing Clostridia testing programme (complete)
- Recommendation 9: Conduct a specialised audit of Fonterra's most sensitive plants (complete)
- Recommendation 10: Identify and audit any non-standard or temporary manufacturing set-ups in Fonterra's New Zealand plants.
- Recommendation 11: Introduce more robust systems to authorise and ensure compliance of any non-standard processing (including rework) and testing.
- Recommendation 12: Conduct specialised quality audits for all Fonterra sites including offshore businesses, third party manufacturing and Joint Ventures.
- Recommendation 13: Conduct a full review of product standards with clear focus on when product is placed on hold and authorisations around release.
- Recommendation 14: Explore options to more proactively align with customers and regulators on standards.

SYSTEMS - TRACEABILITY

- Recommendation 15: Define, document and communicate traceability protocols for all areas of the business.
- Recommendation 16: Conduct an immediate review of significant system changes planned for product traceability and customer complaint management to ensure adequate change and risk management.
- Recommendation 17: Conduct a wider review and overhaul of Fonterra-wide product traceability capability, including product outside of Fonterra's control.
- Recommendation 18: Institute a Quality hotline for Fonterra staff and contractors to encourage early escalation. (complete)

RESPONSE - TRANSPARENCY

- Recommendation 19: Ensure Fonterra has a well-rehearsed crisis management capability.
- Recommendation 20: Review and clarify communication protocols with respect to third parties (including customers, industry bodies and government) in a crisis.

CONCLUSION

Although the initial likely identification of *Clostridium botulinum* proved not to be a food safety risk, the significant impact of the recall stress-tested a great many systems across Fonterra's business.

The Operational Review concluded that:

- Fonterra's quality and care systems in its manufacturing and testing are robust, and underpin its reputation for leadership in the global dairy trade.
- Transparency of information, internally and externally – despite the lapses in information sharing and escalation noted in the review's findings – and commitment to public safety, were reflected throughout this event.
- Notwithstanding the shortcomings identified by the review, Fonterra's staff, on most occasions, acted conscientiously on new information, and generally sought to do the right thing. This is not to overlook the identified lapses in information flows, and failures to escalate the issue, but it is to note that, despite the harsh stresses of this event, Fonterra's staff, along with the business' processes and systems, proved generally resilient, and able to improve and learn.

The recommendations of the review represent a significant programme of work, which is intended to not only embed lessons and improvements from this event, but to enable Fonterra to take a leadership position in product traceability and food safety and quality in the global food and dairy industries.

ENDS