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

- **Operation Alpha: Fonterra WPC80 Investigation (Reasonable Grounds Paper)**

This document has been proactively released to supplement the final report of the Government Inquiry into the Whey Protein Concentrate (WPC) contamination incident and the Government's response to that report.

Some information in these documents is withheld in line with the following sections of the Official Information Act (as applicable):

- s.6(a) – prejudice of international relations;
- s.6(c) – prejudice of the maintenance of the law, including investigating offences;
- s.9(2)(a) – to protect the privacy of natural persons;
- s.9(2)(b)(ii) – prejudice of the commercial position of the subject of the information;
- s.9(2)(ba)(i) – protect information which is subject to an obligation of confidence;
- s.9(2)(c) – prejudice the role of the Government Inquiry as a measure to protect health and safety of the public
- s.9(2)(h) – legally privileged information

Operation Alpha:

Fonterra WPC80 Investigation (Reasonable Grounds Paper)

12 December 2013

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This is an internal MPI document and is not for public release or release under OIA.

This report contains legally privileged information, and other information provided in confidence to the MPI investigation.

It is prepared for the purpose of informing an active compliance investigation, and this report and its contents are not for release outside MPI, without the approval of the Deputy Director General Compliance and Response and the Chief Legal Adviser.

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EXECUTIVE SUMMARY

The Hautapu Torch Incident

On 2 February 2012, during the manufacture of WPC80 at the Hautapu Whey factory, a dryer operator investigating a high static fluid bed pressure reading shone his torch up the air intake and the torch was sucked in breaking the plastic lens of the torch.

Most but not all of the lens was recovered but factory staff believed that the fan clearance, radiator and SFB bed would prevent the missing pieces getting into the product and the dryer was restarted.

The following day the incident was reviewed and reconstruction of the lens determined that two pieces were missing. The dryer was stopped and inspection found one of the two missing pieces. The other piece was not located.

This left the possibility that the missing piece had ended up in the powder although this was deemed to be unlikely. A decision was made to continue manufacture and the remaining 41 tonnes was run so adding a further 41 tonnes to the 1 tonne of product possibly contaminated. The decision was to pack and put the powder on hold, and check the radiator again at the next end of run. Accordingly, the product was given 'Product Hold' status and the issue was reported through the daily incident report.

On 3 February 2012, the contaminated WPC80 was packed under cipher codes GW02 and GW03 and full details of the incident were recorded in the Fonterra Product Safety Risk Management Programme (PSRMP) Exception Detail Report 562.

Exception Report Submitted to RA

Fonterra submitted the Exception Report ID562 to the RA (AQ) on 8 February 2012 and the RA submitted it to MPI on 9 February 2012 for review. MPI logged this as a Critical Exception Report (CER) number CER6266.

Fonterra then submitted a Product Disposition request PD2550v1 to the RA on 20th February 2012 seeking approval to release the product to markets identified as 'restricted' i.e. not Japan, suggesting re-classing the product to a looser specification for general market release, including use in rework, reclassification, stock food, and restricted release to the domestic market.

On 13 March 2012, the RA advised MPI that having reviewed the product disposition request PD2550v1; they did not support the proposed option, but rather, considered release to further processing and filtration as more appropriate. On 16 March 2012 MPI declined PD2550v1.

On 12 April 2012 the RA provided MPI with a revised version of the Fonterra Product Disposition request PD2550v2. They were now satisfied that regulatory conditions had been met and recommended MPI approve release for reprocessing/rework in the Fonterra Whey plant (1239) including a filtration step.

On 13 April 2012 MPI closed CER6266.

Contaminated WPC80 Reworked

The rework approved under PD2550v2 had not been done before and was unique. The Hautapu Plant Manager designed a new one off process by which ciphers GW02 and GW03 could be reprocessed using both the SCUF (1282) and Whey (1239) plants.

The rework instruction documented the fitting of temporary flexi hoses and the use of a 25 metre long permanent pipe that is used infrequently (and hadn't been used for 2 years) to bypass unnecessary steps in the plant/s. The instruction required reconstitution of the powder into a liquid form in the SCUF plant (1282) and then be run through the Whey plant (1239), filtered and then dried into powder form.

The re-work was not audited or reviewed by the RA (AQ)

The plant, temporary flexi hoses and the 25m fixed stainless steel pipe were subject to Clean In Place (CIP) cycles, an automated chemical wash flushed through the plant and pipes before and after each re-work run.

On 17, 18 & 22 May 2012 the WPC80 was re-worked in accordance with the instruction and packed under ciphers JW17, JW18 and JW22. No supervision of the re-work was conducted by either MPI or the RA.

Testing was undertaken to ensure the re-worked product met regulatory specifications but this did not include SRC testing as it is not a regulatory requirement.

JW17, JW18 and JW22 were then sent to warehousing where it was ultimately shipped to a number of domestic and international customers.

WPC80 Used at Darnum

On 22 October 2012, 190 25kg bags of JW17 and 349 25kg bags of JW18 were shipped from NZ to the Fonterra Altona warehouse in Melbourne. The WPC80 was then progressively shipped to the Fonterra Darnum plant between 27 February and 14 March 2013 to meet manufacturing schedules.

The WPC80 was used as a macro ingredient in 39 manufacturing mixes (19 batches) of nutritional formula between 1 and 21 March 2013, all of which was destined for Danone. The

finished product was sent back to Altona for storage awaiting testing results prior to release to Danone.

In accordance with standard procedures, retention samples from the 39 mixes manufactured, were sent to Dairy Technical Services (DTS) in Melbourne for testing for regulatory specifications (doesn't include SRC testing) and Danone Customer specifications (includes SRC testing)

For macro and micro ingredients used at Darnum, they, as do all dairy plants, rely upon certificates of analysis (COA) provided by the source manufacturing plant of those ingredients as proof that those ingredients met regulatory specifications. The COAs for JW17 and JW18 were confirmed as meeting regulatory specification.

No product is released to customers until the technical team has reviewed and approved the COA's and the test results from DTS.

On 21 March 2013, DTS advised Darnum of positive test results for SRCs exceeding Danone customer specifications in 7 of the 19 batches. Darnum immediately commenced an internal investigation to identify the source of the SRCs and analysis of ingredients showed that the 7 failed batches contained WPC80 from JW17 and JW18, the 12 batches that passed did not.

Darnum then contacted Fonterra NZ Technical Services regarding the SRC failures, Darnums ongoing involvement is outlined in the Fonterra section of this report.

The Danone Group

The Danone Group is a food-products multinational corporation based in France producing fresh dairy products including baby foods. 99% of the production at Darnum is for Danone. The supply agreement between Danone and Fonterra includes customer microbiological testing and specifications including SRC limits.

On 18 April 2013, Danone personnel in Singapore received a teleconference invitation from Fonterra scheduled for 23 April 2013, to discuss product that had failed Danone's SRC product specification limits.

On 23 April 2013, Fonterra sent a summary of the issue prior to the call entitled "Investigation Report – SRCs in Danone Nutritional Products" and was dated 22 April 2013. It stated that Fonterra had traced the source of the elevated SRC levels to two batches of WPC80 manufactured by Hautapu and had very high loadings of SRCs, up to 8000 cfu/g.

Fonterra advised that tests, including the use of MALDI-TOF, had confirmed no clostridium perfringens and that the contamination was from a "non-pathogenic" strain of clostridium sporogenes and therefore not a food safety risk. Danone were asked to accept the out of specification product based on Fonterra's assessment that there was no food safety risk.

On 23 April 2013, Danone and Fonterra held a teleconference where Fonterra reiterated these points and encouraged Danone to accept delivery.

On 25 April 2013, Danone, after having received advice from their microbiologist, advised Fonterra that the main concern in relation to their SRC specification is the possibility of infant botulism caused by toxicogenic strains like *C. botulinum* (and others) They told Fonterra that they would not accept any batches of nutritional powder that had failed their SRC specifications for its Infant Formula (babies 0-6 months) or Follow On formula (6 months – 1 year) products, although it might be acceptable for Growing up Milk powder (GUMP) but required further investigation. Danone ultimately agreed to accept nutritional powder from Darnum that exceeded their SRC specification on the basis that this would only be used for GUMP.

On 29 April 2013, there was another teleconference in which Fonterra submitted to Danone a preliminary report that outlined a number of options to recover the out of specification nutritional powders.

On 1 May 2013, a paper was provided to Danone by Fonterra recommending recovery options for reducing SRC levels to within specification. They requested Danone agree to this option and a small scale recovery trial. On 8 May 2013, Danone agreed to the trial with some conditions.

Danone then heard nothing further from Fonterra until a teleconference on 2 August 2013 at which time Fonterra made a presentation regarding the *C. botulinum* incident.

Fonterra Group

Darnum first advised Fonterra of the SRC issue upon advice from DTS that 7 of 19 batches of infant powder destined for Danone had failed customer specifications.

On 21 March 2013 the Technical Manager, Powders and Nutritionals, Darnum, advised Fonterra Research and Development Centre (FRDC) NZ they were undertaking an investigation to identify the source of the SRCs and to determine whether the source was raw milk. The following day FRDC advised that it was unlikely that raw milk was the issue and was likely to be related to an ingredient.

FRDC requested a sample be sent to them for identification work and at that time Darnum also sought advice whether the source might be WPC80 as that ingredient was not currently tested for SRCs at manufacture.

Darnum then contacted the NZ Products Technical Team (NZPTT) and requested the testing of retention samples from Hautapu for WPC80 ciphers JW17 and JW18 for the presence of SRCs and on 3 April 2013 NZPTT advised Darnum that the test samples returned SRC counts ranging between 400cfu/g and 8,200cfu/g for JW17 and JW18.

On 4 April 2013 samples of the affected Darnum powder was sent to the Clandeboye laboratory to investigate rework and recovery options for discussion with Danone. Also aligned with this work was a request from Darnum for FRDC to conduct testing for *Clostridium perfringens.* Shortly after these requests Darnum also raised the issue of introducing SRC testing in WPC80 specifications as it was used in infant powders.

On 11 April 2013 the FRDC advised Darnum that preliminary test results, confirmed by MALDI-TOF, indicated the presence of *Clostridium sporogenes.* Four days later the FRDC advised final test results indicating that the SRCs were largely *C. sporogenes.*

On 17 April 2013 additional samples of JW17 and JW18 were forwarded to FRDC and Clandeboye for further testing and strain identification. This was preparatory work for discussions with Danone in wanting to confirm there was no appreciable presence of *C. perfringens,* that the SRCs were predominantly *C. sporogenes* and if the two dendrograms matched it would provide further evidence to support the already compelling case that the WPC80 was the source.

On 19 April 2013 the final recovery options report was presented to Darnum. Two options were recommended, reconstitution, heat treatment, drying and re-work or reconstitute and provide spore germination conditions, and then pasteurisation and re-work.

On 7 May 2013 FRDC confirmed the JW17 & JW18 dendrogram WPC80 samples indicated several variants of *C. sporogenes* with similar typing patterns to the Darnum product noting the MALDI-TOF was reporting unidentified strains that clustered close to *C. perfringens.* In anticipation of further testing at AgResearch, FRDC requested a quote for *C. sporogenes* confirmation testing.

On 8 May 2013 a Fonterra internal email disclosed further testing results being done as part of the recovery investigation;

- **JW17 Comp**
  ~14000/g
  ~8000/g (after 80C/10min heat treatment)
- **JW18 Comp**
  ~900/g
  ~250/g (after 80C/10min heat treatment)

The email goes on to say that there are similar typing patterns for the *C. sporogenes* and there is little doubt that there is a strong link between source (the ingredient) and the contaminant in the final product and that they 'cluster' close to *C. perfingens.*

Other statements in this email are critical;

"To clarify their identity and thus their specific pathogenicity, we have no choice but to do 16S sequencing on these to confirm whether they are significant - This will take some time to get

done. Unfortunately, nothing in microbiology is simple. So, you should also know that a C. botulinum is a simply a C. sporogenes without the toxin gene.

This being the case we are checking out whether AgResearch (at Massey University) can assay for the presence of the toxin gene. It is EXTREMELY UNLIKELY that these organisms, which Maldi identifies as C. sporogenes, as carriers of the toxin gene. We certainly don't want to be alarmist. However, we would be derelict in our duty if we did not consider the possibility. The bottom line is that the ingredient powder contained very high levels of clostridia which certainly indicated a lost process control / failure to maintain good hygienic practice"

On 9 May 2013 Darnum advised Hautapu that their WPC80 product was *unfit for purpose* because it contained grossly high SRC levels. Again this is a significant statement and one that should have commenced ENC reporting but did not.

Darnum requested a teleconference on this issue and they provided a background document prior to this teleconference that amongst other things re-iterated the WPC80 was unfit for purpose, that 468 tonnes of product was affected, JW17 & 18 were the confirmed cause of the contamination and that their loss was [redacted].

On 20 May 2013 FRDC forwarded their final SRC contamination investigation report to Darnum. In summary the report indicated;

- *The dominant Clostridium species isolated from the Darnum nutritional powder blend and the Haputapu WPC80 was C. sporogenes (identified using the MALDI-TOF method).*
- *The presence of large numbers of C. sporogenes stimulates the question about whether they might pose a health risk to infant consumers i.e. has C. sporogenes the potential to be pathogenic. Clostridium experts have stated that strains of the pathogen C botulinum Group1, which are unable to produce toxin, are referred to as C. sporogenes.*
- *Although the risk appears to be low, the Food Assurance team recommends that representative isolates of the C. sporogenes from the nutritional powder blend should be screened for the ability to produce the C. botulinum toxin at AgResearch in Palmerston North (~$2000/sample).*
- *The alternative is to withdraw the product in question from the infant food chain.*

On 24 May 2013 FRDC contacted Darnum seeking a response to the recommendation that AgResearch test the infant base powder for the ability to produce the *C. botulinum* toxin. The following day Darnum advised that the contaminated powder had been rejected by Danone and has been withdrawn from the infant food chain and downgraded for either stock food or edible disposal for general populations. With this withdrawal Darnum advised that they cannot justify proceeding with the screening work to confirm that the *C. sporogenes* are non toxin-producing.

On 27 May 2013 FRDC advised AgResearch that the suggested testing to screen for *C. botulinum* is no longer required. This effectively closed the investigation phase into the cause of the Darnum infant base powder SRC contamination.

On 29 May 2013 Fonterra Australia, followed up on the status of the initial [redacted] compensation complaint made by Darnum with the Director New Zealand Milk Product Operations and General Manager Operations. They were seeking resolution and suggested referral to Theo Spierings if not resolved.

The matter was discussed with Fonterra NZ and it was advised that they were awaiting the outcome of an investigation by the Hautapu team before reacting but suggestions were that the claim be rejected because the WPC80 had been manufactured within the required specification which did not include testing for SRCs. Escalation to the General Manager Quality and Technical was suggested.

On 31 May 2013 concern was raised within Fonterra that the ciphers were manufactured from 100% rework.

This is the first evidential indication that RMP processes were not followed.

It was indicated in these discussions that the 100% rework could be significant because it is a non-standard manufacturing process and there is the possibility that SRCs may have come from flexi hoses or demineralised water used to reconstitute the WPC80.

The Process and Projects Manager was asked to answer the following:

- Who authorised 100% rework?
- Is level limited in WPC (powders has 10% max)?
- Are rules enforced?
- Did it follow change control?
- Who approved from technical and did they do adequate risk assessment?

These questions were raised with other Technical Team people to answer and one manager was concerned that he had been given conflicting information about the rework.

Around 4 June 2013 there was again discussion regarding the [redacted] compensation claim by Darnum. NZ Milk Products (NZMP) claimed they were not liable, setting out a number of reasons. Eventually NZMP considered they might be liable because the recorded levels from JW17 and JW18 are 1,000 to 10,000 times higher than typical levels, indicating that a significant deviation from normal hygiene conditions or process had occurred and that a 100% reconstitution is not considered to be standard practice.

As a result of this decision, a serious event team was established. Work streams relating to the compensation claim and the investigation into the cause of the WPC80 contamination

were identified and allocated. Because of pressure it was considered it was a very high priority and whatever resources were needed should be used. Discussions again reiterated comments that the 100% rework was a non-standard manufacturing process as confirmed by a member of the serious event team.

One member of the serious events team expressed concern that there appeared to be no process in place to look at the risk around the rework and queried whether the product disposition (PD) should have stated a percent of rework. He also questioned whether there should have been a level of DA (decision analysis) applied to the decision.

These comments show a realisation that a non standard process had been used and one that was outside the norm.

On 6 June 2013 concern was raised that the Waitoa site also didn't have SRC in the specifications and a review of the Waitoa ingredient specifications was requested before the new season started.

On 7 June 2013, the Director NZMP, agreed to split the cost of the Darnum compensation claim so closing the Darnum matter.

That same day a meeting to allocate work streams for the serious event investigation team took place and a number of actions and responsibilities were identified. It appears that at this time concern was beginning to surface regarding the use of WPC80 for infant powders without SRC testing specifications.

On 10 June 2013 the Nutritional Technical Manager was asked to check whether the WPC80 used for nutritionals was tested before use or if there was a dedicated infant powder specification with SRCs included. This resulted in a specification change to WPC80 (material 104579) on 12 June 2013 adding SRC testing at a limit of 100cfu/g maximum.

On 14 June 2013 the Project Lead – Formulation Performance, Nutritionals Technical, was sent a comprehensive list of action points for the investigation of contaminated Waitoa Nutritionals;

- Review products which use WPC80, what WPC80 specifications are used, if they have limits in place and identify risks and mitigations
- Determine if the affected batch of WPC80 from Hautapu has been used in any Nutritionals products in NZ.
- Determine if a specific Nutritionals WPC80 specification is required with tighter SRC limit (or keep current limit on general specification), and agree a definite maximum limit with technical team that is suitable for all nutritional products.
- Determine if a risk review of other dry dairy ingredients should also be undertaken for potential contamination of SRC and of other heat stable bacteria.

- Agree if an internal SRC safety limit should be applied to nutritionals products which do not currently have SRC limit, or if current measures in place are effective enough.

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

FRDC input for testing was sought and FRDC advised that apart indicating a serious breakdown in process hygiene, other ciphers of WPC also contained elevated levels of clostridia and that Fonterra should be very careful when it sees such levels of clostridia and *C. sporogenes* specifically. They went on to say that it is important to be confident that the organisms are actually *C. sporogenes* and not *C. botulinum* which would pose a serious risk to infants (infant botulism)

The FRDC then recommended testing to differentiate *C. sporogenes* and *C. botulinum* and set out the costs of that work saying that it would rule out a food safety issue relating to *C. botulinum* leaving only the process hygiene / product quality issue.

Waitoa was advised that SRC contaminated WPC80 had been used at Waitoa and requested approval for testing which would isolate the clostridia and determine if it was toxin producing or not, and if there was a food safety risk.

On 21 June 2013 Waitoa approved the request for toxin testing by AgResearch. Waitoa was provided with a draft report with key recommendations being;

> *"Immediately initiate SRC, C. perfringens, and toxin risk analysis on Yashili FO (Follow On) powder and Abbott Saudi/Vietnam GUMP (Growing Up Milk Powder), and due to the time delay in identifying affected product all three tests to be conducted simultaneously to minimise further delays"*

On 26 June 2013 AgResearch were advised to prepare for testing to identify the strain of *C. sporogenes* and a formal requisition and financial authority for clostridium toxin testing of the Waitoa product was requested

On 28 June 2013 the serious event team reported back on the actions allocated to them on 14 June and sought approval to de-escalate (close off) the serious event. They reported that SRCs are not included in the WPC specifications and that JW17, JW18 and JW22 were made from 100% rework. Outstanding action points to be dealt with as BAU were review of plant set-up for 100% rework, adding 100% rework procedures to SOPs, identifying hot-spots for SRCs and develop testing protocol for next time 100% rework process is required

In conclusion the investigation revealed that where a unique event such as the 100% rework of the WPC80 ciphers GW02 and GW03 occurs, the RMP requires the use of the specified change control process.

In this case, the change control process was not followed.

The de-escalation of the serious event investigation was approved on 1 July 2013 and this closed the serious event escalation into the compensation claim and the problem-solve investigation into the rework. Retention samples from Waitoa were received at FRDC and tested with the results distributed on 3 July.

On 5 July 2013 the isolates that would go to AgResearch for analysis were selected and prepared over the weekend of 6-7 July.

On 8 July 2013 FRDC updated the anticipated toxin testing and potential outcomes, as follows:

- *Did get good growth and counts in the end.*
- *Key types isolated and these were very similar to those isolated from the Darnum product, ie, pointing to the whey being the most likely source.*
- *Key isolates have been taken across to AgResearch at Massey today*
- *This week they will do PCR (polymerase chain reaction) based technique to look for toxin genes. If these are found then we have an answer.*
- *If no toxin genes then do we send the representative material to AgResearch in Hamilton next week for mouse bioassays?*
- *If dead mice then we have an answer – if **no** dead mice then we have an answer.*

On 12 July 2013 updates were sent to various managers within Fonterra and specifically recommended that the clostridium toxin investigation be completed to determine any food safety risk regarding the three affected batches of nutritional products made at Waitoa.

On 17 July 2013 another request for an update was communicated asking if the PCR test for the toxin gene had been completed and when the mouse bioassay would be completed. In reply to this request it was advised that the PCR work had been completed but that there were contractual issues holding up progress.

On 19 July 2013 an update from FRDC advised that the AgResearch contract had been signed and following a visit with their senior scientist last night, the following preliminary information was shared;

- *The colony morphology of the product isolates is more comparable with C. botulinum than with C. sporogenes.*
- *AgResearch had a difficulty extracting DNA from the product isolates which is a phenomenon more often experienced with C. botulinum than C. sporogenes isolates.*
- *AgResearch's recommendation is that we should not read too much into this at this stage.*
- *The toxin gene work will proceed over the weekend*
- *This process is slow as the AgResearch team has to work in extreme containment facilities (not surprising when the control organisms are C. botulinum)*

- *Gene expression will be confirmed through the mouse bioassay in Hamilton (according to FDA this test is required to confirm absence/presence of C. botulinum). This will start towards the end of next week (governed by the condition of the mice) and the results will be available 5 days post injection.*
- *One important question we have is whether Fonterra has tracked all the whey powder*

The issue of the isolates comparison is important but also is the concern raised regarding the tracing of WPC indicating some concern about what they are dealing with.

The following Q & A communication occurred on 19 July 2013;

> Q If the test over the weekend comes back indicating the likely presence of *C. botulinum* toxin what does this mean, do we get enough information at this stage to assume there is a food safety risk?
> A *If this test is positive it implies that our contaminant is not C. sporogenes but a C. botulinum and pose a potential food safety risk for infants.*
>
> Q Or is this just a test that indicates further testing is required?
>
> A *If the test is negative we have to progress towards the FDA method (bioassay) to validate the organisms as C. sporogenes.*
>
> Q I understood initially that if this comes back positive, then the mouse bioassay is not required?
>
> A *This is correct; however the bioassay is the only regulatory approved method to confirm C. botulinum and expression of the toxin gene. If the mouse model begins end of next week we should have results back by 5th August latest?*
>
> Q Is there anything we can do to speed this up if the gene expression is positive?
>
> A *Not really, they can only start once the mice are at an adequate weight.*
>
> Q If this comes back negative (and the gene test was positive) what does this mean? No food safety risk?
>
> A *If the toxin gene is present but not expressed it implies that the organism has the ability to cause harm and should be deemed a food safety risk. However, this will depend on who the target consumer is.*

On 20 July 2013 the preliminary results of the clostridia testing were escalated within Fonterra. It was noted this would be critical if testing showed results are pathogenic. Further, tracing of contaminated WPC80 or those products that it had been used in was again raised as was business continuity planning, whether this matter should be escalated further and identification of the next steps.

The Quality and Compliance Manager, and Exception Stock Lead, NZ Operations were advised and they discussed whether the issue needed escalating to a critical event when the species and counts were known from the testing.

On 22 July 2013 an internal request for information was sent and this included the Project Coordinator, Nutritionals Technical. Information sought included identification of the ciphers contaminated, if any nutritional base powders were still in stock and the whereabouts of the ciphers in the supply chain

The Team Lead, Product Release, confirmed the presence of SRCs in a list of products manufactured by Waitoa.

Additional information also indicated that the product isolates tested negative for botulinus neurotoxin genes A, B, E and F. Preparation of the extracts for the bioassay should be completed within the next 24 hours and will go to AgResearch for the mouse bioassay commencing 28 July and will take approx 5 days.

This communication also asked for a trace back of affected WPC80 batches (JW17, JW18, JW22) to be initiated including looking at trace back options for affected GUMP product that has gone to Canpac.

It was further confirmed that regardless of the preliminary PCR results, the mouse bioassay method was the only way to confirm the presence of *C. botulinum*.

On 22 July 2013 the General Manager NZ Technical initiated the formation of a Critical Event Team.

On 23 July 2013 the General Manager NZ Technical communicated with a number of Fonterra Managers advising that FRDC WPC80 testing indicated it was suspicious for a pathogenic strain and it would be 5 August 2013 before they would get confirmation of toxin production. Until then the view/advice was that it was a non-pathogenic strain. He also indicated that ciphers from the January/February Waitoa production were impacted.

He went on to state that they would review the issue for escalation to a critical event and needed to prepare including knowing where the product is, recall processes, the decision criteria, giving communications a heads up, what risks exist and when will decisions be needed. He advised on that basis that it was highly likely they would go to a Critical event that day.

He further advised that if positive for toxins the issue would be escalated to a Crisis Event on the basis of reputation, media and possible financial impact. If negative for Toxins, it would be de-escalated.

He then requested actions from various people including giving the Director NZMP (Romano) a heads up that the critical event is to ready ourselves, including understanding risk of waiting until 5 August for toxin result.

At 4.30pm on 23 July 2013 a teleconference was held regarding the incident. During the meeting the event was escalated to "Critical".

At 1:00pm on 24 July 2013, the Critical Event Team held a second meeting and identified four key work streams that included investigating the original event and reviewing the previous investigation, identifying the location of the WPC80 and Waitoa product manufactured using it, coordinating testing and communication with stakeholders. This did not include MPI or the RA.

Subsequently the review of the re-work at Hautapu was completed and the report indicated that;

"The re-work was not standard work for the Whey Plant (1239). The process is not documented in the plant Rennet Whey or Cheese WPC HACCP plans and is not within the scope of the Hautapu site PSRMP. The re-work should not have proceeded"

This is a very significant statement.

On 26 July 2013 the Director NZMP, held the first senior stakeholders critical event meeting. One manager did not support continued testing, there were concerns about the impact of the issue if it was to be aired on "Campbell Live". The Director NZMP gave the go-ahead for the further testing with the mice.

On 28 July 2013 AgResearch began mouse bioassay testing and on 30 July preliminary results from the mouse bioassay testing were communicated indicating some type of toxin, that may or may not be *C botulinum*, was present and further testing was necessary to confirm the presence of *C. botulinum*.

On 31 July 2013 Fonterra received confirmation from AgResearch that a mouse mortality confirmed the presence of *C. botulinum* in WPC80 ciphers from Hautapu.

A crisis call occurred at 5:15pm where it was suggested that MPI should be advised, as opposed to the RA (AsureQuality) because of the seriousness of the issue.

On 1 August 2013 Fonterra began preparation of the ENC document. At 2:08pm, an email was sent to [redacted], Manager Systems Assurance, MPI and [redacted], Manager Food Assurance, MPI, requesting an online meeting at 4:30pm that day.

At 3:29pm, [redacted] replied and advised they could not make the meeting and asked if they could talk the following day at 1:00-1:30pm.

[s.9(2)(a)]

At 4:05pm, [redacted] sent a text message asking for a heads up about what they wanted to discuss. Fonterra replied that they were in meetings and would be in touch shortly. [s.9(2)(a)]

At 3:00pm and again at 8:30pm, a meeting of senior stakeholders was held.
A key agenda item of the meeting was the current location of affected product.
It was determined that most of the affected product was already in the possession of the intended customers or on hold. There was also discussion about notifying customers and finding out how the affected ingredient had been used by them.

The reporting of the issue to MPI was again raised and the Director NZMP asked what would happen once it was reported to MPI. He was advised it would go to Ministers, and would go public.

There was further discussion around notifying customers prior to notifying MPI and the Director NZMP directed that Abbott and Danone were to be advised overnight and a time of 11:00am the following day for a meeting with MPI was suggested.

At 10:30pm, the Director NZMP called the CEO Fonterra and informed him of the issue and the need for a recall and Fonterra began contacting major customers.

At no stage did Fonterra identify to MPI the issue or how serious it was.

On 2 August 2013 Fonterra requested a meeting with MPI for an 11:00am teleconference call to discuss "SRC" and at 9:39am an attempt was made to call Carol Barnao, Deputy Director General – Standards, MPI.

At 9:45am [redacted] sent a text message to Fonterra regarding the teleconference request and asked what SRC is. Fonterra replied 'Sulphite Reducing Clostridia' [s.9(2)(a)]

At 9:46am Fonterra sent a text message to Carol Barnao indicating they had an issue she needed to be aware of and that they were organising a meeting later in the morning with Tim Knox, [redacted] and [redacted].

At 10:00am a conference call headed by the Director NZMP was held and this included feedback received overnight as a result of the affected customers being advised.

He gave clear instructions not to report to MPI until he gave the approval.

After the conference call Tim Knox rang Fonterra and asked why the call had been delayed. He was told "I can't talk to you until Gary has briefed Theo."

At 10:59am a meeting request was sent to relevant Fonterra and MPI Managers stating "URGENT PLEASE NOTE CHANGE OF MEETING TIME: WPC SRC Investigation/Issue – Highly Important TO NOON TODAY".

At 11:12am Romano phoned Spierings and told him that Fonterra had not talked with MPI yet but they would be shortly.

At 11:30am, the Fonterra Chairman, and three members of the Board were briefed by Spierings and Romano about the issue. They also discussed potential withdrawal or recall of product.

At 11:49am, an internal Fonterra email indicated that they still did not have the approval from Romano to go ahead with informing MPI.

At 11:54am, Romano replied approving MPI being advised

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

MPI then commenced a formal response

Review of the Fonterra RMP

Fonterra Hautapu operates an MPI approved RMP that sets out regulatory requirements including manufacturing processes designed to ensure food safety and meet market requirements. The investigation required a review of the RMP to identify those processes and requirements associated with this incident.

This proved a complex and difficult task. Expectations that the RMP was a single document were wrong as the RMP is in fact made up of multiple documents numbering in the hundreds containing thousands of pages.

The RMP was reviewed and where it referred to Manuals, process documents and other referenced documents, they were in turn requested and reviewed. To give perspective to the complexity and volume involved, Fonterra themselves struggled to identify the documents required and it took them many attempts and months to finally provide all of the relevant documents. The complexity and spread of this RMP is staggering with many cross referenced and interlinked parts. It is questionable how any one person could know the many parts sufficiently to ensure compliance.

The review of the RMP took approximately 12 weeks to complete and looked at the parts that were relevant to the Hautapu plant and globally in relation to reworking, reporting and testing. Until MPI directed Fonterra to supply the full RMP, MPI only held a 111 page outline of the RMP (R007) and this is version 22 and was the version referred to during the MPI WPC80 response.

There are several manuals and sets of RMP documents that broadly apply across all sites and then there are specific RMP outlines, site specific manuals, HACCP plans and SOPs that apply specifically to each site, including Hautapu. There are also multiple versions of each

document over the applicable time period and the RMP outline MPI hold on file has had 6 new versions since its registration, the latest being version 28.

The relevant version for this incident is version 27. Most of the version updates were clearly not deemed significant by Fonterra as they have not attracted a significant change notification to MPI. Perhaps more concerning is that the RMP outline held by Fonterra is only half the size of the copy kept by MPI at just 55 pages. Analysis has concluded that the missing content was moved from the RMP outline and is now contained in an RMP Manual. Technically the information is still within the RMP but as MPI only hold an outline, we would have no idea that it existed or where to find it.

For the purpose of overlaying the RMP obligations with the factual information as we know it, two key topics are addressed, the first is the re-work process itself and secondly is Fonterra's RMP reporting obligations, which also covers risk assessment and elevation issues.

The rework of WPC80 ciphers, GW02 and GW03 was the result of the incident with the torch and was categorised as a foreign matter 'Category B' event. 'EXNC11: Fonterra RMP Procedure: Managing Product Safety Events' was followed by Fonterra and the exception was reported to the RA (AQ) within the required 24 hours.

The first product disposition (PD2550v1) for the affected product was declined but the second request (PD2550v2) including re-work and filtration was approved. The PD recommendation from AQ to MPI identified that the rework would take place in factory 1239, which is the WPC Plant. It is now known that the re-work could not take place solely in plant 1239 as it has no reconstitution capabilities thus the re-work plan was developed whereby reconstitution occurred in the SCUF plant 1282 and then was transferred via the 25m stainless steel pipe back to plant 1239. Whether there was or should have been knowledge of this by AQ or MPI at the time the rework was approved is unanswered at this stage.

What is known is that any rework must comply with the applicable Hazard Analysis Critical Control Point Plans ('HACCP Plan'). This is set out in the Fonterra New Zealand PSRMP Manual and PPMC06 'HACCP Management Document' which specifies that the processes in the site-specific PSRMPs are operated under HACCP. PPMC06 requires all HACCP plans to comply with the requirements of CODEX and FSOE 03 which describe how Fonterra applies CODEX.

There is a HACCP plan in place for Hautapu Cheese WPC and another for Hautapu Rennet Whey WPC and for the SCUF plant. HACCP is referred to in each plan as *"a systematic and science based method for identifying and controlling specific hazards to ensure the safety of food."* HACCP is considered crucial to the operation of a successful RMP.

A full assessment of the rework process should have highlighted the unusual practice and degree of change required in creating this new process, which follows into discussion over a further procedure also included in Fonterra's RMP. There is a systems procedure called

SYS19 'Fonterra RMP Procedure: FTO Change Control' and the applicable version is numbered 4, dated 22 July 2011. For this investigation this is a significant and relevant part of the RMP.

The purpose of this document is to describe the formal procedure for the management and control of changes and applies to all of Fonterra New Zealand Operations. It requires that any changes that have *"the potential to introduce a new, or increase an existing, health and safety hazard or could affect product quality"* to be approved using the change control system prior to the change being made.

There is nothing in the rework process or in the rework instruction showing that this change control process was followed as is required when the WPC80 was reworked.

In conclusion, the change control process contained within the RMP was not followed as required in the reworking of GW02 and GW03 because it involved a unique procedure not previously undertaken and using non standard equipment and, a fixed pipe that had not been used for approximately 2 years.

Fonterra's RMP was also analysed in relation to their obligations to report to either AQ or MPI on any food safety issue and their obligations under Section 51 APA to report exporter non-conformance ('ENC') to the Director-General.

The RMP; PPMC12 describes the product safety limits and minimum product safety testing requirements that apply to all Fonterra Limited NZ origin dairy products in accordance with Dairy Processing Criteria 1 ('DPC1'). Attachment 1 to PPMC12 outlines the limits that apply to each type of product and SRCs are not included.

This is the overall theme of Fonterra's RMP, that unless the microbiological organism is one that is referenced by DPC1, food standards or an importing country requirement, then they do not have to test for it and will only do so if it is a customer requirement.

In conclusion SRC testing for WPC80 is not a requirement under DPC1 and there are no customer specifications requiring such testing.

In regards to reporting the foreign object contamination (torch lens), attachment 17 to EXNC07 outlines preferred disposition responses and includes breaches of critical control points, foreign matter contamination events and dairy product not meeting regulatory limits. This reflects why a product disposition PD2550v1 and PD2550v2 was obtained for the torch foreign matter event.

Reporting ENCs for product that has left New Zealand is covered in procedures outlined under EXNC12 'Managing Exporter Non-conformances for New Zealand Origin Dairy Products'. Fonterra do not consider this document as part of their RMP and there are two possible explanations for this. Firstly is that reporting is required under the APA and secondly is that it involves product that has left New Zealand and therefore considered not covered by the RMP.

[redacted]

Withheld under 9(2)(h)

In conclusion the assessment of the RMP has resulted in establishing reasonable grounds to believe that two breaches, and possibly a third, have been committed by Fonterra Limited, the operator of the RMP in that;

- They failed to comply with the RMP, namely, in not having an appropriate HACCP Plan in place and failing to follow SYS19 'Change Control' process when it reworked ciphers GW02 and GW03 in the manner they did on 17, 18 and 22 May 2012.
- That Fonterra failed to comply with the RMP, namely, EXNC11 'Managing Product Safety Events', by failing to notify AQ or MPI once they became aware that the WPC80 product had not been processed in accordance with the RMP.

It is further possible, depending on the legal analysis of non-conforming product and not fit for intended purpose, that there may be reasonable grounds to suspect a third breach of the RMP by Fonterra Limited the operator in that;

- They failed to comply with the RMP, namely EXNC11 'Managing Product Safety Events', by failing to notify AQ or MPI once they were aware that they had failed to identify non-conforming product or failed to prevent that non-conformance or release product that was not, or may not be, fit for intended purpose.

This third breach is technically more difficult than the first two as it relies on the WPC80 being deemed non-conforming and based on the report of [redacted] in relation to the SRCs and the false positive for the *C. botulinum* this could prove quite difficult. [redacted]

Withheld under 9(2)(h)

Use of Accredited Laboratories

Concern has been raised as to whether Fonterra conducted the testing it did in a manner authorised using duly accredited laboratories.

The Animal Products Act (APA) provides that dairy products must be safe and suitable for their intended purpose. Food safety risks are managed through a range of measures including Risk Management Programmes, and export controls. Dairy product exported from New Zealand must meet all NZ domestic regulatory requirements, as well as any specific requirements stipulated by the overseas country.

Risk Management measures include the monitoring and testing of dairy products under a number of programmes and testing is carried out by laboratories specifically recognised by MPI for this work.

Dairy laboratories are divided into two categories:

Category 1 laboratories test dairy product and material intended for domestic and export markets and are recognised by MPI for testing to demonstrate that the product.

Category 2 laboratories are laboratories that belong to an animal product business and are recognised by MPI for testing the business's dairy material including raw milk that is intended for the domestic market.

Category 1 laboratories are required to meet the requirements of ISO17025 as they apply to the testing of dairy products and these requirements are published by International Accreditation New Zealand (IANZ)

Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body. The standard is about competence, and accreditation is formal recognition of a demonstration of that competence.

All Fonterra labs are recognised by MPI and are accredited Category 1 laboratories operating to NZS ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

Individual Fonterra laboratories are accredited to carry out a range of testing with some laboratories accredited to carry out chemical testing of dairy products, some for microbiological testing, some for micronutrient testing, and with most accredited to carry out a combination of testing.

In regards to the Clostridia testing and in particular the mouse bioassay, testing requirements are uncertain. ISO/IEC 17025 set general requirements for the competence of testing and calibration laboratories.

FRDC and AgResearch have this accreditation but not for *C. sporogenes* testing or *C. botulinum* testing. AgResearch and FRDC are well resourced research laboratories with highly competent staff. So the fact that they are doing a test that they are not accredited for does not immediately invalidate the results.

The MPI microbiologist suggested that this is a red herring in that it is more important to ensure the method used meets the criteria for the gold standard in CB testing, the 'US FDA Bacteriological Analytical Manual for CB'.

In the case of the WPC, AgResearch were found to be wanting in some aspects when the comparison was made. So the fact that they are doing a test that they are not accredited for isn't so important, more the fact that they did not follow the method properly.

In conclusion it does not appear that Fonterra Laboratories or AgResearch have breached any requirements but the work of AgResearch when compared to 'US FDA Bacteriological Analytical Manual for CB' was found wanting.

Microbiological Advice

The term SRC is an acronym for Sulphite Reducing Clostridia which is a subset of bacteria known as sulphite-reducing anaerobes and there are 21 different species of Clostridium, including *C. perfringens, C. sporogenes and C. botulinum.* Generally most SRCs are innocuous or simply cause food spoilage under certain conditions.

The detection of SRC has been used extensively in food microbiology as either an indicator of human faecal contamination, quality of raw materials and/or a process control indicator. SRC testing is not intended for food safety; rather it is an indicator for food hygiene and elevated SRC results should instigate causal investigation.

C. sporogenes is generally considered an environmental bacterium that is not pathogenic for humans

The only regulatory trade limits for SRCs are for Russian Federation dairy imports and there is an advisory maximum level for the United States and Algeria.

The New Zealand Ministry of Health (MOH) describe guidelines, but not standards, for *C. perfringens.* While there are no microbiological criteria for *C. perfringens* in dairy products, the Food Standards Australia New Zealand (FSANZ) Code sets guidance criteria. MPI administers these guidelines.

The International Commission on Microbiological Specifications for Foods recently indicated that under certain circumstances monitoring for SRCs could be used as a hygienic processing indicator proposing an SRC limit of 100cfu/g for powdered infant formula.

In most cases, test results for SRCs might be considered higher than expected rather than high. The detection of *C. perfringens* at levels >10^6cfu/g (1,000,000cfu/g) would be considered high as it is a known pathogen and the detection of *C. botulinum* at any level would be considered high.

All parameters must be established and their context understood before any decision can be made about a specific level of SRC for a specific product and New Zealand dairy companies regularly monitor thermoduric bacteria in the raw milk supply and Farmers are penalised at 100cfu/ml which translates to 1,000cfu/g in powder or 10,000cfu/g in WPC.

If a manufacturer has an established testing system for SRCs and identifies higher than expected level SRCs it would be expected that an investigation would commence to identify the cause, assess the risk, notify the regulator if there is a risk identified, or if unsure; and implement corrective actions to prevent recurrence of the cause.

High SRCs, if used as part of a suite of tests, are a trigger for an operator to then look at the specified food safety tests and the control of their process with reference to HACCP.

With the exception of Ultra High Temperature (UHT) processing it would be unusual for a dairy RMP to use the SRC test for food safety purposes. When it's used as a process hygiene test then a result showing elevated SRC levels is not evidence that product is unsafe. The obligation under the RMP would be to assess the result against any trigger limit in the RMP and take whatever actions the RMP requires.

If an SRC test is being done purely to satisfy a customer specification then a failure means that the product isn't suitable for sale to that customer.

There are a number of reasons for SRCs to be high or higher than expected. The context of the levels detected is important in determining meaning with a breakdown in manufacturing hygiene resulting in higher than expected counts.

This may indicate a failure to control environmental contamination or a change in animal feeding practices (e.g. a greater use of silage). High SRCs can only be evaluated in the context of a well validated testing system and with appropriate consideration of the product being tested. For example, an SRC count in WPC could be ten times higher than the count in raw whey or IF because of the concentration step in the former and because of the low concentration of WPC in the IF.

There have not been any documented cases of botulism associated with appropriately processed general foods. Similarly, infant botulism is associated with children <6 months of age, less so with children between 6 and 12 months, and rarely with children >1 year of age. It is therefore appropriate to consider the risk of foods prepared for children up to 1 year of age. There has never been a documented case of infant botulism confirmed as caused by consumption of powdered IF.

Most competent authorities regard *C. botulinum* as being reasonably unlikely to occur in powdered infant formula. In New Zealand, *C. botulinum* type A, the most likely to contaminate powdered IF, has never been isolated but has caused illness in two sisters eating an inadequately prepared home fermented shellfish/watercress mix. *C. botulinum* is not thought to be present in the NZ environment at levels of concern.

In the opinion of MPI scientists, the presence of SRCs cannot be considered an indicator of the presence of *C. botulinum*, although the absence of SRC does preclude the presence of *C. botulinum*.

Several sets of Hautapu SCUF plant test results reviewed recorded SRC results. It was noted that the counts greater than 20cfu/g were in a tight date/batch cluster indicating an event, although the nature of that event is not clear. It could be attributable to the raw material from a high silage use farm or a hygiene issue. Given the very low counts in the rest of the database, it would be expected that Hautapu should have questioned these results.

Notably, there were two clusters where the counts were substantially higher. On 24th March 2013, the milk coming into the drier had counts of 100cfu/g at the start and 300cfu/g at the

end; and counts after drying (concentrating) of 5000cfu/g at the start and 4000cfu/g at the end. This suggests that the milk was evenly contaminated prior to drying, although the reasons for this are not clear. It would be expected that Hautapu should have carried out an investigation to find out if there was a hygiene issue that led to these higher than usual results.

The second cluster on 29th May 2013 was similar and should have elicited a similar response from the company. MPI has not found any evidence to suggest that an investigation was undertaken.

In the opinion of MPI scientists, neither of these clusters suggested a problem with the drying process and rather, that they demonstrate uniformity of the incoming product for drying and uniformity of the concentrated dried product.

Typically food manufacturing does not aim to produce a product that is sterile, rather a product that is free from food borne pathogens or the pathogens are very low in number. Only foods that have been retorted or subjected to an UHT process will be sterile.

Monitoring for SRCs is useful for judging the efficiency of retort or UHT treatments. A manufacturer would need to decide what value SRC testing would add to a monitoring programme for their manufactured product to determine whether useful or not. In the opinion of MPI scientists, historically, there was little to be gained by testing for SRCs.

The process for confirming the presence of *C. botulinum* is complex and few laboratories in the world have the capability and are accredited for the tests. The presence of spores in the culture is verified by staining and microscopic examination, and *C. botulinum* spores are positioned at the end of the cells (i.e. the rod-shaped bacteria look like drum-sticks or tennis racquets).

Biochemical tests are used but these do not separate *C. botulinum* from *C. sporogenes* nor do the 16S tests and MALDI-TOF tests. Fonterra's response in relation to the WPC contamination issue was initially precipitated by confusion in the latter test.

There are currently only two types of tests that will separate *C. botulinum* from *C. sporogenes* based on the presence of toxin genes in the former and absence in the latter. Firstly, the molecular PCR or next generation sequencing (NGS) tests look specifically for the botulinum toxin genes and an associated gene called the non-toxic non-hemagglutinin (NTNH) gene. Absence of these genes confirms the isolate is not *C. botulinum.*

Secondly, presence of these genes requires the isolate to be confirmed as *C. botulinum* by demonstration of toxin production using the internationally accepted mouse bioassay performed correctly. In the absence of the molecular tests, the mouse bioassay can be used on its own, and historically has been.

These tests are difficult and require a high level of experience and competence. Diagnostic laboratories carrying out these tests for regulatory assurances should be accredited to ISO 17025.

In the opinion of MPI scientists, the presence of SRCs is not unexpected in WPC as they are ubiquitous in the environment, are detected in raw milk, are resistant to pasteurisation, and are concentrated during manufacture.

The presence of higher than expected levels of SRCs in a product can be an indicator of a process failure. Equally, however, it can be an indicator of seasonal variations in farming practices such as high use of silage for animal feeds.

In the opinion of MPI scientists, the simple presence of SRCs in WPC would not require an exception report to be produced nor is it indicative of a potential food safety risk.

MALDI-TOF is an acronym for Matrix-assisted laser desorption/ionization (MALDI) time-of-flight (TOF). It is a recently developed scientific analytical procedure used to differentiate the genus and species of different bacteria by comparing the patterns of proteins detected directly from intact bacteria against substantial databases of profiles of cultures of known identity. In the case of *C. sporogenes/C. botulinum*, the database supplied with the Bruker instrument is not able to differentiate between the species.

MALDI-TOF should be considered a rapid screening tool for presumptive identification rather than a confirmatory test for Clostridium species. There is still substantial uncertainty associated with identifications produced by MALDI-TOF for clostridia. It is the opinion of MPI scientists that MALDI-TOF results should not alert the user to move directly to a mouse bioassay.

Given the uncertainty of identification of *C. sporogenes* and *C. botulinum* using the MALDI-TOF, several steps can occur before initiating mouse bioassay testing. mouse bioassay tests are used when necessary to identify toxicity in food. However, while the use of the mouse bioassay for confirmation of *C. botulinum* is still considered the gold standard, there are few ISO 17025 accredited laboratories around the world that perform the bioassay for *C. botulinum.*

There are no laboratories in New Zealand accredited or even fully capable, of carrying out an internationally accepted mouse bioassay for *C. botulinum.*

Prior to initiating a mouse bioassay for *C. botulinum*, a body of scientific evidence would be expected that supports the presumptive identification of *C. botulinum*. This would include high likelihood of presence in the product, and by definition in the New Zealand environment, and confirmed molecular test results for genes specific to *C. botulinum.*

The likelihood of a clostridial spore detected as *C. botulinum* can only be determined following appropriate risk assessment. In New Zealand, while it is possible that a spore could be *C.*

botulinum, it is highly unlikely. Instead it is more likely to be *C. perfringens*, *C. sporogenes* or one of the multitudes of non-pathogenic clostridia that cause food spoilage rather than human illness.

Should the isolate be shown to be *C. botulinum*, it is more likely to be a toxin type that does not cause illness in humans. The presence of clostridial spores in liquid milk or finished product following pasteurisation of liquid milk is not unexpected and usually would not be of concern, provided hygienic manufacturing practices were intact. Even in the absence of specific regulatory requirements or provisions in a company's RMP, detection of spores at levels higher than expected and at a greater frequency than expected would be expected to result in an investigation to determine the cause, and if necessary, to implement corrective actions which might include decisions on product disposition.

There are limited studies on microbial species present in IF. IF is not a sterile product and requires adherence to manufacturer's instructions for safe preparation and storage. A 2005 study in the United States reported the presence of Clostridium spores in 31% of IF purchased. Representatives of 12 species of Clostridium were identified although neurotoxigenic species were not detected. *C. sporogenes* were found to be the most common species identified.

Despite *C. sporogenes* being the most abundant Clostridium species identified in the US study, there have not been any reported cases of infant illness directly associated with IF or *C. sporogenes*.

It is the opinion of MPI scientists that the presence of clostridial spores in IF at the levels expected would not be of concern provided the IF is manufactured under a quality system and the product is handled by the consumer as per the label instructions.

CER & ENC Reporting Trends

For the period 1 January 2012 to 31 August 2013, the investigation reviewed all Critical Exception Reports (CERs) and Export Non Conformances (ENCs) submitted to the RA (AQ) and MPI in accordance with APA and/or RMP requirements to establish whether Fonterra have been generally complying with their requirements, to understand any trends, as background to inform any future decisions and to establish whether MPI have been proactive in managing the regulatory process.

CERs are referred to by MPI as Critical Exception Reports whereas Fonterra terms them as Exception Reports. CERs contain information as required by Dairy Processing Criteria (DPC1) regarding the identification of non-conforming dairy material or dairy product; and occurrences of a critical non-compliance.

Non-conforming in relation to dairy material and dairy product is defined as any dairy material or dairy product that is suspected or known not to meet regulatory requirements or not to have been processed in accordance with regulatory requirements.

A critical non-compliance is an action, event or omission failures such as not keeping records, offences under the APA, not identifying non conforming product and other non compliance.

The procedure for managing CERs is in manual EXNC11 of the Fonterra RMP version 5, dated 27 January 2011. The purpose of the CER procedure is to ensure that all product safety events are managed in accordance with the RMP and are applicable to all New Zealand Fonterra sites. They contain information regarding the exception, the event, follow up actions planned and when the RA was advised.

DPC1 and the Fonterra RMP require the RA to be notified of any CER within 24 hours with written notification being received by MPI within 72 hours.

The Fonterra on-site department manager is responsible for investigating why the event occurred and reporting the matter to the quality team. This team is then responsible for determining the category of the event and notifying the RA.

There are two categories of events scheduled in Fonterra's RMP. Category 'A' events are managed internally by Fonterra whereas category 'B' events require a Product Disposition approval by the RA or MPI. Until January 2013, Fonterra required this reporting no later than 20 hours after the event but this was changed to 16 hours post January 2013.

Category B exceptions are required by the APA to be reported to the RA as soon as practicable, but no later than 24 hours after the occurrence of the exception, but Fonterra's process documents add; ***or after the result is known by the testing laboratory.*** This is an important statement as it may explain why the RA was not advised of the preliminary mouse bioassay test results?

Fonterra amended their RMP in January 2013, reducing the 24 hour reporting time to 20 hours and inserting the word *confirmed* to read "...or after the confirmed result is known by the testing laboratory". This amendment was not notified to MPI as they didn't deem it to be a significant change to the RMP as defined in legislation.

A review of the CERs submitted by Fonterra shows that 149 (or 38%) were not received by the RA within the required 24 hours with 47% of the CERs being received three to five days after the 24 hour notification period.

Of the 389 CERs analysed, 290 or 75% were received by MPI from the RA within the required 72 hour period but 25% were not submitted to MPI by the RA within that timeframe.

A review of MPI regulatory performance indicates that there is little correspondence on MPI files that refer to the late referral of CERs by the RA and the need for the RA to comply with the 72 hour requirement.

Of the 99 CERs submitted late by the RA, there is only one instance where the lateness was queried by MPI, there were three instances where MPI queried the RA about additional information required and there were seven instances where the RA consulted with MPI regarding CERs submitted by Fonterra that were either late, had been overlooked or where Fonterra was confused about whether they in fact needed to complete a CER.

In regards to Export Non Conformance (ENC) the Fonterra procedure for managing ENC's is covered in manual EXNC12 entitled "Managing Exporter Non-Conformances – NZ Origin Dairy Products" version 12 dated 27 January 2011 with the procedure in accordance with the Animal Products Act (APA) 1999.

304 ENC's submitted by Fonterra for the period 1 January 2012 to 31 August 2013 were analysed with 117 or 38% received by MPI later than the required 24 hour notification period stipulated in the APA. Of these, 45 or 38% of the ENC's were received more than one day outside of the required 24 hour notification period.

There is no correspondence on MPI files that refers to the late submission of ENC's by Fonterra, any follow up action and the need for them to comply with the 24 hour notification period. The assumption is that no actions were undertaken by MPI.

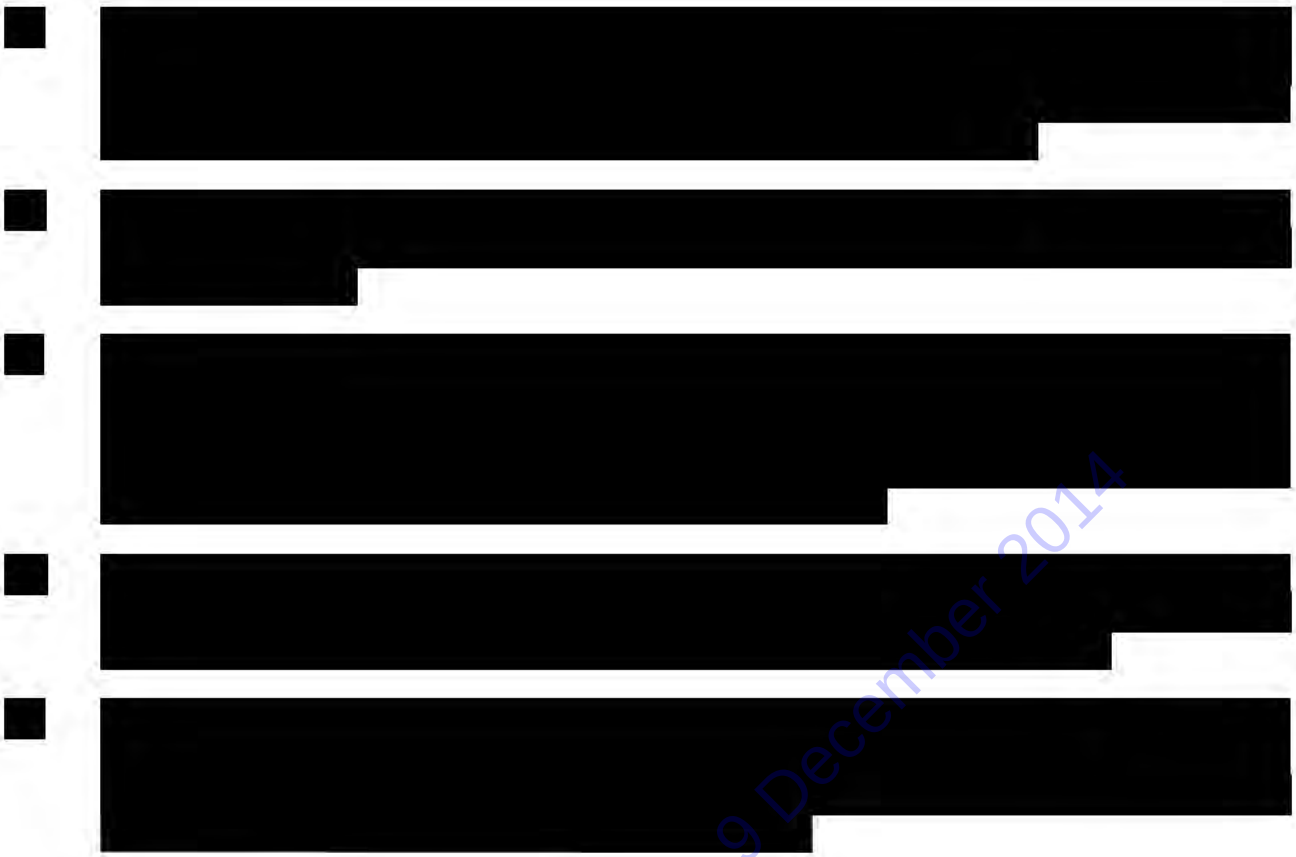
The role of the RA (AsureQuality) was also looked at. It is noted that they audit Hautapu every 3 months with one in ten being unscheduled and one in ten being unannounced. For the unscheduled audits they simply bring a scheduled audit forward a week or so but still give notice of when the audit will occur.

For unannounced audits, Fonterra insist they give 48 hours notice for OSH and logistical purposes and the RA complies with that demand. This is a bizarre arrangement which nullifies any impact of unannounced audits and one that will give Fonterra enough time to get their house in order before the 'unannounced audit' begins. This must be perceived as circumventing the intent of the regulatory system.

Legal Advice

[redacted]

Withheld under 9(2)(h)



INTRODUCTION

1 This report is intended to discuss whether reasonable grounds exist to commence a formal investigation into the Fonterra WPC80 Clostridium Botulinum incident reported to MPI on 2 August 2013.

2 As guidance for the reader, this report will be set out under a number of headings that cascade logically as the events occurred. Discussion will support the conclusions and final recommendations made and will give the reader a full understanding of all events, actions and reactions as they sequentially occurred.

3 These first sections summarise the end to end events, actions and reactions of all relevant parties from the original manufacture of the WPC80, the re-work, supply and remanufacture of products using the contaminated WPC80, and the testing conducted by Fonterra New Zealand and AgResearch;

- **Fonterra Hautapu**
- **Fonterra Darnum**
- **Danone Group, *and***
- **Fonterra Group Ltd**
  - Technical
  - Strategic

4 The next sections discuss the outcome of the review of the Fonterra RMP for compliance, whether accredited laboratories were or should have been used, microbiological expert advice and historical reporting trends;

- **RMP**
- **Use of Accredited Laboratories**
- **Microbiology**
- **Reporting Trends**

5 The final sections will discuss and outline legal advice regarding any reasonable grounds that have or have not been established, the conclusions drawn based on the information and evidence obtained and will make recommendations to the Director Compliance for his consideration as to whether a formal Investigation should proceed.

- **Legal Advice**
- **Conclusions**
- **Recommendations**

6 It is to be noted that if 'reasonable grounds' are established a formal investigation will be required to gather the required evidence to support charge/s being laid. If a formal

investigation is commenced an evidential review will be required to determine if the evidence supports any charges intended.

COMPLIANCE INVESTIGATION

7 On the 5th of August 2013, the Compliance Directorate was directed to conduct an investigation into the actions of Fonterra and others in regards to the reported WPC80/Clostridium Botulinum incident.

8 An Investigation Team was established under the direction of the Manager National Programmes but reporting to the Director Compliance. The Investigation Team consisted of some 18 – 20 staff including Compliance General Investigators, Forensic Investigators and Analysts supported by other MPI groups such as Systems Audit, Legal, and Microbiological experts. The services of the Wellington Crown Solicitor were also used due to the complexity of the incident.

9 The mission for the investigation was agreed as follows;

> *To ascertain whether Fonterra, or any other New Zealand food manufacturer that used the contaminated WPC, has complied with their regulatory obligations under their RMP and to hold any person or company to account if any liability is established under the Animal Products Act 1999, the Food Act 1981 or other relevant legislation.*

Investigative Approach

10 An early appreciation of the investigative requirements to meet the mission was conducted by the Manager National Programmes. That appreciation quickly identified considerable complexity in that Fonterra is a large multinational company having some 17,500 employees. The investigation would need to look at the actions of a large number of Fonterra staff across multiple sites within New Zealand and Australia and also look at the actions and involvement of the Danone Group, another multinational Company operating in France, Singapore, Australia and New Zealand. Adding to this complexity was the fact that the contaminated WPC80 product had been moved into multiple international and domestic markets.

11 The approach adopted was to follow the WPC80 through the supply chain and then identify the subsequent events, actions and reactions from the date of original manufacture on the 3rd of February 2012 through to when Fonterra advised MPI on the 2nd of August 2013. This approach would allow and end to end event timeline to be created that would identify all events, actions, reactions and decisions made during this incident.

12 Concurrently the Fonterra RMP would be reviewed identifying their requirements under that RMP.

13 Once completed the event timeline would then be compared to the RMP so identifying if compliance was maintained or not.

14 To keep the task manageable a multiple scene approach was adopted. This approach broke the totality of events down into smaller parts (work streams) each of which could be managed by smaller teams led by an appointed work stream lead.

15 The scenes (work streams) adopted were;

- **Hautapu** – all those events during manufacture, re-work and post event including identifying if possible how the alleged contamination occurred

- **Darnum** – The Fonterra Australia plant that received some of the WPC80 and used it as macro ingredients in manufacturing nutritional infant powders, and then subsequently identified the high SRC counts that ultimately led to the microbiological testing undertaken

- **Danone** – the multinational company that the Darnum nutritional powders were manufactured for, what communications they had with Darnum and Fonterra, what did they know

- **Fonterra** – there are two work streams in regards to Fonterra;

  - *Technical* – what events occurred, what testing was done, why was it done and who was informed

  - *Strategic* – identify decisions made within management structures, what were those decisions, what did they know, what did they suspect or believe the situation was, did they meet legislative requirements

- **Microbiological** – what do SRCs mean, did Fonterra follow international best practice in regards to food safety, what should the high SRCs have meant to testers and decision makers in Fonterra, what were the risks, were their actions/decisions consistent with good practice

- **Critical Exception Reports and Export Non Conformance Reports** – identify compliance by Fonterra over the last 18 months in regards to compliance with APA requirements, are they complying, what is the trend. Also to look at MPI performance in regards to these reports, have we dealt with lateness, is there a problem

- **Risk Management Plan (RMP)** – identify and confirm the Fonterra RMP, review the RMP against the event timeline, did Fonterra comply with their requirements under the RMP

- **Legal** – review RMP outcomes and evidential timeline to establish if there are reasonable grounds to suspect offences have been committed, if so what are those offences, what evidence supports any recommendations, what would be required to prove any charge/s and establish likelihood of a successful prosecution

16 Having identified and adopted the scene approach, it was then critical to consider the investigative approach itself.

17 There were two approaches possible in this case;

- Conduct a formal Investigation, *or*
- Use the powers set out under the APA 1999 to examine compliance

18 In considering the relevant investigative approach, the evidence available at the time the appreciation was conducted, was important.

19 Whilst it appeared likely that Fonterra had not complied with section 51 (c) of the APA 1999, in that they failed to advise the Regulator (MPI) within the required 24 hours when reporting the WPC80 incident, there was no information, knowledge or evidence indicating compliance or non compliance across the entirety of the events that unfolded leading up to Fonterra advising MPI of the incident.

20 The appreciation also identified that this would be a complex matter with a spread of multiple events, actions and reactions across Fonterra, Fonterra Australia and the Danone Group.

21 Unlike a normal criminal investigation there was, on the face of it, no obvious offence or offences. Instead this investigation would be required to identify an unknown number of events, actions and reactions and then compare those to the Fonterra RMP, the content and requirements of which was also unknown at the outset.

22 Until a full understanding of the events could be compared to the RMP it would not be possible to determine if compliance was maintained or not.

23 The APA, like the Fisheries Act, has powers of examination. Such powers allow an Animal Product Officer to conduct enquiries under warrantless powers to ascertain compliance with the Act as follows;

87 Power of entry
(1) An animal product officer may, for the purpose of determining whether or not any person is complying with this Act or any animal material or animal product or associated thing is in compliance with the requirements of this Act, without a warrant enter any place (other than a dwelling house or marae) at, in, or from which—

(a) any primary producer operates, or any animal product business that is subject to a risk management programme or a regulated control scheme or a food safety programme that is also registered as a risk management programme is operated; or
(b) any kind of goods that is or includes animal material or product is processed for sale or sold; or
(c) any registered exporter operates; or
(d) any listed homekill or recreational catch service provider operates; or
(e) any recognised agency or recognised person operates; or
(f) the books or records, or other business information kept in writing or electronic form, of any such producer, business, service provider, recognised agency, recognised person, or exporter are kept.

88 Power to examine, etc

(1) An animal product officer may, so far as is reasonably necessary for the purpose of determining compliance with this Act at any place that the officer may enter under section 87(1),—

(a) examine all things, and open containers, packages, and other things to inspect their contents:
(b) examine, inquire about, and copy any documents or other records (including records held in electronic or other form) relating to the obligations and duties under this Act, and for this purpose may—
(i) remove documents or records to another place for the purpose of copying them, or require the person having control of the documents or other records to forward them or a copy of them to the officer by way of post, courier post, fax, or other means acceptable to the officer; and
(ii) require a person who has control of or knowledge of the documents or records to reproduce or assist in reproducing in usable form information recorded or stored in a computer or other device or system:
(c) use or require the use of any reasonable means to identify the kind or description of any animal material, animal product, equipment, package, container, or other relevant thing:
(d) identify or mark any animal material, animal product, equipment, package, container, or other relevant thing:
(e) take samples of any animal material (or take whole animals, in appropriate cases) or animal product, or any other input, substance, or thing which has been, is, or may be in contact with or in the vicinity of any animal material or animal product, and test or analyse or arrange for the testing or analysis of such samples:
(f) direct the operator or person in charge of the place to identify and hold any animal material, animal product, substance, equipment, package, container, or other relevant thing until—
(i) the results of tests and analysis have been assessed; or
(ii) any lawful direction of an animal product officer has been complied with.

24 To conduct a formal investigation at the level required in this case would be resource intensive and take considerable time. That fact coupled with a lack of information, knowledge and evidence suggesting obvious non compliance, led to the decision that this case was best initially approached using the enquiry powers set out in the APA

25 The investigation was thus structured as an examination under the APA with the aim of establishing whether or not there were 'reasonable grounds' to believe any offences had been committed. If reasonable grounds were established, then a formal investigation could be conducted to establish the liability of any party.

26 So whilst this report discusses the Fonterra Investigation, it is in fact at this time an enquiry. To ensure there was no confusion with the Government Enquiry, the title of 'Investigation' was maintained.

27 In using this approach investigating staff were made aware that they were enquiring and as such when speaking to witnesses no cross examination was to occur.

28 Finally, should reasonable grounds be established and a decision was made to proceed to a formal investigation then the investigation (enquiry) outcome would inform what and where that investigative focus would be required so reducing resourcing and time commitments.

Fonterra Cooperation

29 Having adopted this approach, a meeting was held between Senior Fonterra Managers, their Legal Representative, the Director Compliance and Manager National Programmes Compliance. At that meeting Fonterra were advised of the approach intended and their cooperation sought. Fonterra agreed the approach was sensible and pledged full support to the adopted approach.

30 Liaison was established at two levels. At a strategic level the Director Compliance and Group Director Strategy would liaise outside of the investigative process to maintain awareness and address any high level issues.

31 At an Operational level Fonterra appointed their General Manager Commercial to work directly with the Manager National Programmes. This arrangement gave the investigation team direct access to any Fonterra staff members that needed to be spoken to as witnesses and also gave access to any documents the investigation team required. The only stipulation was that Fonterra wished to have either a legal advisor or the General Manager Commercial present for support purposes when staff members were spoken to.

32 This arrangement worked well and full cooperation from Fonterra resulted. The investigation team was given access to any and all staff members and all documents sought were provided. It was evident that Fonterra did not wish to hide anything and worked hard at meeting all requests.

BACKGROUND

34 In February 2012, 42 tonnes of Whey Protein Concentrate (WPC) was manufactured at the Fonterra Hautapu plant under the cipher codes GW02 and GW03. This WPC was manufactured to 80% protein content thus known as WPC80.

35 During the manufacturing process an unusually high pressure reading in the plant caused an engineer to enter the fan room and shine a torch up into the air duct to see if there was a blockage. This duct is under suction pressure and on shinning his torch into the duct the torch was sucked into the duct breaking the plastic lens. Most of the plastic lens remained attached to the torch but when reconstructed it was discovered that two pieces were missing. It was assumed that the missing pieces had been sucked into the plant and may have contaminated the WPC80 under manufacture.

36 It is important to note that at the time this incident occurred only 1 tonne (approximately) of WPC80 had been manufactured. For reasons unknown, instead of ceasing manufacture, dumping that product and cleaning the plant, and then recommencing manufacture, Fonterra continued to manufacture the remaining 41 tonnes of WPC80 so contaminating the entire 42 tonnes of WPC80.

37 On the 8th of February 2012 Fonterra raised an Exception Report with Assure Quality (AQ) which was duly notified to MPI on the 9th of February 2012. On the 20th of February 2012 Fonterra submitted Product Disposition (PD2550v1) to AQ requesting authority to move the contaminated product to unrestricted use in restricted markets, that is, those markets with lower requirements. On the 14th of March 2012 AQ recommended to MPI that approval be given to releasing the product to restricted markets and on the 16th of March 2012 MPI declined that PD request.

38 On the 12th of April 2012 AQ advised MPI that they had received a further PD request from Fonterra (PD2550v2) and recommended that it be approved. The new request was for the release of the WPC80 for reprocessing, including filtration steps. MPI approved this PD request and on the 13th of April 2012 MPI closed the case in its database.

39 The application to reprocess (re-work) under PD2550v2 was made for plant 1239 which is the Hautapu WPC plant.

40 The contaminated WPC80 was then re-worked at the Hautapu plant on the 17th, 18th and 22nd May 2012 under the cipher codes JW17, JW18 and JW22. This re-work was in accordance with a re-work plan that had been designed by the Hautapu plant manager. It is important to note that such a re-work had not ever been conducted before and this was a one off situation requiring the design of a unique plan.

41 Whilst the re-work was approved for Plant 1239 (Hautapu WPC plant) that plant had no reconstitution capability.

42 As the re-work required reconstitution into liquid form, the re-work process actually commenced in plant 1282 (Hautapu SCUF/Lactoferin plant) and was then brought back into the 1239 WPC plant via flexible hoses. As the re-work only required filtration and re-drying various parts of the WPC plant was not required so other flexible plastic hoses were used to bypass certain parts of that plant. To further complicate matters a stainless steel feed pipe that had not been used for two years was also used in the process.

43 Prior to and during the re-work process, Clean In Place (CIP) was conducted on the plant and associated temporary pipes in accordance with standard CIP processes.

44 Upon completion of the re-work process the WPC80 JW17, JW18 and JW22 was then sent to storage. Standard specification testing was completed post re-work and the re-worked WPC80 met specification requirements. This did not include Sulphite Reducing Clostridium (SRC) testing as domestic and international specifications do not require testing for SRCs. The requirement for SRC testing is a specification set by customers only thus is only conducted when manufactured and sold directly to those customers.

45 There is an anomaly in quantities as records indicate that ciphers JW17, JW18 and JW22 totalled approximately 38 tonnes post re-work whereas GW02 and GW03 totalled approximately 42 tonnes (Pre re-work) This difference is unexplained.

46 Between May and October 2012 WPC80 from ciphers JW17 and JW18 were sent to the Fonterra Altona store in Melbourne Australia and other shipments of JW17, JW18 and JW22 was made to various other customers.

47 Between the 1st and 21st of March 2013 the WPC80 was moved from the Fonterra Altona store to the Fonterra Darnum plant situated in Southeast Victoria, Australia. The Darnum plant primarily manufactures nutritional powders for the Danone Group who uses those nutritional powders as a base for their manufacture of infant formulas.

48 Between those dates Darnum manufactured a significant quantity of nutritional powder for the Danone Group some of which used JW17 and JW18 WPC80 as a macro ingredient. Prior to release to Danone, testing is required to ensure the nutritional powder meets Danone's customer specifications. Samples are taken from each batch or during each days manufacture and sent to Dairy Technical Services (DTS) in Melbourne, this is a certified independent dairy laboratory.

49 On the 21st of March 2013 DTS advised Fonterra Darnum that some product did not meet Danone specifications due to high SRCs. Ultimately the test results for all batches manufactured between the 1st and 21st of March 2013 showed that some batches had high SRC levels and were out of customer specifications yet other met specifications.

50 This advice caused Fonterra Darnum to commence an internal investigation into the cause of the high SRCs.

51 They conducted internal testing thinking their own raw milk was the cause but eventually analysis indicated that the only common denominator was WPC80 from ciphers JW17 and JW18.

52 On the 22nd of March 2013 Fonterra Darnum advised Fonterra NZ Technical Services of the issue and requested testing to confirm the SRC contamination was linked to WPC80 ciphers JW17 and JW18.

53 This request then initiated a long and at times disconnected sequence of testing by Fonterra NZ that ultimately ended with AgResearch conducting Mouse Bi-assay testing.

54 AgResearch advised Fonterra of a presumptive positive test for Clostridium Botulinum on 29 July 2013 and then on the 31 July 2013 confirmed the positive results to Fonterra. As is now known these were false positive results.

55 At 2.08pm on the 1st of August 2013 Fonterra requested, via email, a meeting with MPI. No reason for the meeting was specified. Between 3.29pm and 4.09pm that day, a number of text messages occurred between Fonterra and MPI regarding availability for the meeting and MPI seeking a reason for the meeting.

56 Fonterra did not indicate any reason nor did they convey any sense of urgency.

57 At approximately 9.30am on the 2nd of August 2013, Fonterra again requested a teleconference with MPI indicating the subject matter as "SRC". MPI went back to Fonterra requesting what they meant by "SRC".

58 At 9.46am the same day, Fonterra sent a text message to the DDG Standards indicating that there was an issue that MPI needed to be aware of and that they were organising a meeting with MPI later in the morning.

59 At 10.55am on the 2nd of August 2013, Fonterra sent a meeting request to MPI via Microsoft Outlook, requesting a meeting at 11am that day. The subject matter on this request was "WPC SRC Investigation/Issue – Highly Important".

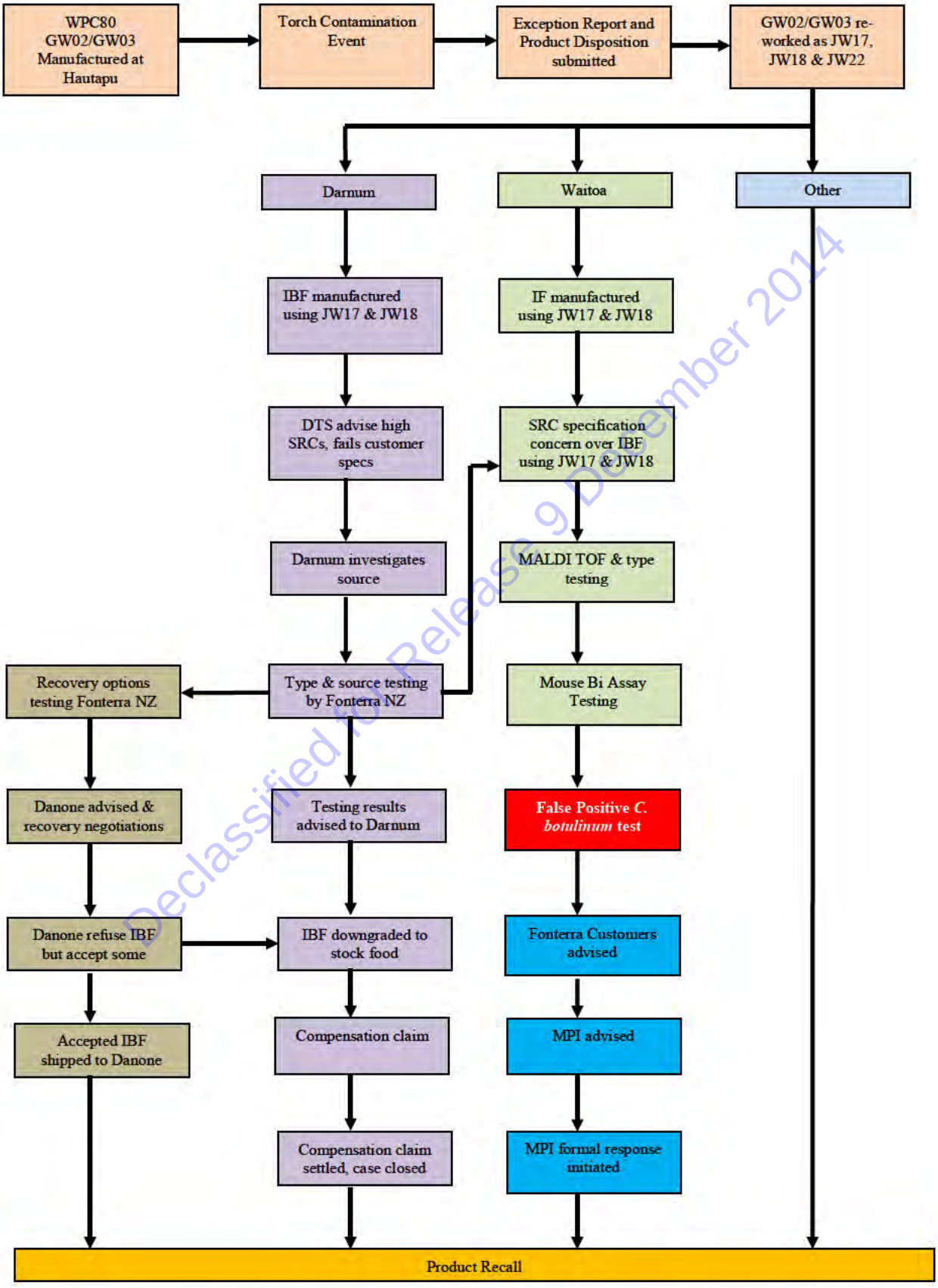
60 At 10.59am, Fonterra sought a postponement until noon that day at which time a teleconference was finally convened. Shortly before the teleconference commenced, Fonterra emailed a PowerPoint presentation to MPI.

61 It was during this briefing that Fonterra outlined the WPC80 incident and their belief that they were dealing with a Clostridium Botulinum and were advising MPI as was required of them under Section 51 (c) of the Animal Products Act (APA)

62 As a consequence of the teleconference MPI then initiated a formal response and monitored the subsequent product traceability and recall actions by Fonterra.

EVENT FLOW CHART

To assist the reader the following flow chart generally sets out the sequence events



FONTERRA HAUTAPU

Work Stream Aim

63 The Hautapu plant is where the original WPC80 was manufactured and where the foreign object contamination occurred that ultimately led to WPC80 ciphers GW02 and GW03 being reprocessed as ciphers JW17, JW18 and JW22. It was believed that the WPC80 was contaminated with high SRCs during that reprocessing.

64 The aim of this work stream was to identify and establish;

- all those events occurring from the original manufacture of GW02 and GW03
- what the foreign matter contamination was and how it occurred
- the events and decisions made that led to the reprocessing including plans and decisions
- how the reprocessing was completed and in what plant/s
- was the plant cleaning (CIP) completed as required
- identify if possible the cause or likely cause of the SRC contamination
- where JW17, JW18 and JW22 was sent to

65 These events, actions and reactions to be compared against the RMP to check compliance was maintained, whether good food manufacturing practices were maintained and whether compliance with other legislation was established.

General Information

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

67 The site operates pursuant to an MPI registered Risk Management Programme (RMP) identification number of R007. The registered operator is Fonterra Limited, Victoria Road, Cambridge and the day to day Manager is recorded as the General Manager, NZ Manufacturing.

68 The Verification Agency is AsureQuality

- The RMP authorises the following manufacturing processes for the site;
- defined heat treatment
- separation
- hydrolysation

- concentration
- evaporation
- drying
- salting
- mixing/blending
- formulation
- milling
- product development
- packing and labelling

The RMP lists for its intended use/consumer group as for human and animal consumption, sensitive populations and non-edible, for further processing, export and stock food.

69 The authorised manufacturing processes are applicable to the following factories within the site;

- 1274 Casein
- 1239 Whey
- 1270 Lactose
- 1273 Cheese
- 1275 MPC (Milk Protein Concentrate)
- 1282 SCUF (Scale Up Facility)

Whey Protein Concentrate (WPC)

70 Whey is the liquid remaining after milk has been curdled and strained during the cheese making process.

71 Whey Protein Concentrate (WPC) is a milk powder product obtained from the evaporation of Cheese or Rennet Whey using a process of mixing, blending, evaporation, and drying.

72 The Hautapu site processes 3,500 tonnes per year of WPC (1,900 tonnes of cheese WPC & 1,600 tonnes of rennet WPC) in the WPC factory (1239) situated within the Hautapu site.

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

Product Specifications

74 All products manufactured at the Hautapu site are manufactured in accordance with a documented Product Specification which describes in detail data relevant to the product such as;

- type of product
- composition (e.g. moisture content)
- packaging (e.g. pack type)
- constraints (e.g. dietary statements such as halal)
- destination, export tariff (e.g. code)
- storage (e.g. shipping type)
- logistics (e.g. typical pallet configuration)
- compliance statements (e.g. eligible for EU certification)
- ingredients (e.g. Cheese Whey)
- testing parameters including chemical, microbiological, physical, sensory, trace element, mineral composition and parameters that the product must meet
- additional data where amendments and internal comment to the specification can be made.

75 WPC is manufactured in accordance with product specifications;

- Product Specification document dated 27/6/2004 Product Number 104579 WPC80 Cheese
- Product Specification document dated 27/6/2004 Product Number 104578 WPC80 Cheese
- Product Specification document dated 27/6/2004 Product Number 104589 WPC80 Rennet

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

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

77 Thus, G references the month, W references the year and the numeric references the day of packaging. GW03 therefore can be translated to show that the packing (not manufacture) took place on the 3rd of February 2012.

The Manufacturing Process

78 Whey is transferred from the Hautapu Milk Treatment factory into one of three storage silos located in the WPC factory. The whey is then transferred to a feed balance tank which feeds directly to the ultra filtration plant which is a 'hot plant' running at 50°C.

79 The plant has two outputs, retentate and permeate. The retentate is retained and chilled down to 10°C and transferred to a temporary storage silo whilst the permeate is further processed.

80 The retentate is then passed through a pre-heat step of between 54°C to 56°C after which it passes through an evaporator and then to a fat multi-pass evaporator.

81 The retentate then goes to drier feed tanks before passing into a drying chamber. Once in the drying chamber the retentate is dried into a powder before passing out the bottom of the drying chamber. By that point in time the drying process has been completed although some secondary and final drying happens in the vibrating fluid bed. At the end of the vibrating fluid bed the powder is then cooled down slightly before it passes through a sift screen.

82 The sift screen is the Critical Control Point for this part of the process as outlined in the Hazard Analysis and Critical Control Point plan (HACCP) documentation for the factory. The sifter has a 3 millimetre square sifter screen through which the powder

passes and it retains any solids larger than that. Generally these solids are just oversized powder particles.

83 From the sifter the powder then passes through to one of a number of 20 tonne temporary storage bins. The bins hold a number of dry runs until a decision is made to send that powder for packing in the centralised packing area where it is given a cipher number which is a unique identification number.

84 The WPC powder is then packed into multi-wall 25kg bags before being palletised and wrapped. It is then sent to the dry stores on site at Hautapu.

85 The whole process is monitored by two operators, one of which is responsible for the wet process from the acceptance of the whey into the silos to the point of the retentate going into the temporary storage silo.

86 The second operator monitors the process from the point of taking the retentate out of the temporary silo and through the evaporator, drier and finally into a bin where it is eventually transferred to the Packing Centre.

WPC80 Ciphers GW02 GW03

87 On the 3rd of February 2012 WPC80 cipher GW02, using product specification 104578, and cipher GW03, using product specifications 104578 and 108638, were packed following manufacture in the Hautapu Whey factory (1239).

88 During the packing process, retention samples were taken from ciphers GW02 and GW03 as required in the specification and, following the packing process, the samples were despatched to Fonterra laboratories for analysis. Ciphers GW02 and GW03 met all requirements.

89 At that time, there was no Sulphur Reducing Clostridia (SRC) testing requirement in the specification.

90 As previously stated, all factories within the Hautapu site have an individual factory identifier number. WPC80 ciphers GW02 and GW03 were manufactured at Hautapu in factory number 1239.

91 Retention samples are held on site for products manufactured at Hautapu, for the duration of the shelf life of a product.

Foreign Matter Event

92 On the 2nd of February 2012 during the manufacture of the GW02 and GW03 ciphers, the dryer operator was investigating why the static fluid bed (SFB) pressure was too

high on the WPC dryer. The operator entered the fan room and shone his torch up the air intake of the SFB. The torch was sucked in to the inlet pipe and the hard plastic lens of the torch was broken against the damper. A number of large pieces of lens were subsequently recovered.

93 From the damper the air travels through to the fan, through a duct to the radiator and then to the SFB. The air blows in under the SFB floor which has small holes less than 2mm in size. It was believed by factory staff that the fan clearance, radiator and SFB bed would prevent any pieces of torch lens getting into the product and the dryer was restarted.

94 The following day the incident was reviewed and it was determined there were two pieces missing from the lens. The dryer was stopped and an inspection was carried out. Small particles were found on the radiator which made up the equivalent of one piece. The other piece of torch lens was not located.

95 This left the possibility that the plastic had ended up in the powder although this was deemed to be unlikely.

96 The planned actions were to pack and put the powder on hold, and check the radiator again at the next end of run (EOR). Accordingly, the product was given 'Product Hold' status and the issue was reported through the daily incident report.

97 It is noted that at the time the contamination incident occurred only about 1 tonne of WPC had been manufactured. Instead of isolating that product, cleaning the plant and recommencing manufacture, for reasons unknown manufacture of the remaining 41 tonnes occurred so making a 1 tonne contamination into a 42 tonne contamination.

98 The incident was categorised as a Foreign Matter Category B issue.

99 Full details of the incident were recorded in the Fonterra Product Safety Risk Management Programme (PSRMP) Exception Detail Report 562 raised by Fonterra on the 3rd of February 2012.

100 Exception Reports are created electronically following an incident such as a foreign matter issue and are sent to the Fonterra Product Safety Manager for review. The process uses a template form and follows the Fonterra Non Conforming Product Procedure – EXNC11. The process is described in the Fonterra Quality Manual that is applicable to all processes at Fonterra.

101 Process:

- Foreign matter found
- Report on the form called non-conforming product procedure on Intranet
- Product Safety Manager reviews report and decides on which category:

- Category A – low risk issue dealt with internally at Fonterra
- Category B – referred to the Recognised Agency (RA - AsureQuality) for review and for the RA to authorise Fonterra's disposition options for the product

102 Exception Report ID 562 was generated in two versions with the latter version including additional information that was not available at the time version 1 was created. Version 1 was raised by Fonterra on the 3rd February 2012 and identified a foreign matter contamination incident that occurred relating to ciphers GW02, and GW03 at Hautapu Whey factory 1239.

103 The exception report contained the following detail:

- Exception type: Foreign Matter
- Category: B
- Exception date: 3/2/2012
- Submitted: 3/2/2012 09:32
- Reviewed: 3/2/2012 13:26 by Kerry Bovey
- Recognised Agency notified: 8/2/2012 11:50
- Detail of the incident
- implications for product including the planned actions
- identified an intention to pack and put on hold implicated powder

104 The total amount of affected powder, 42,050 tonnes, was identified in the exception report by Factory ID, Product Specification and Type, Cipher, Volume, Storage Location and Hold type and number:

Unique factory ID	Spec. Material	Cipher	Volume (tonnes)	Physical location	Hold nos.
1239	104578	GW02	15.600	In Store	56116
1239	104578	GW03	8.300	In Store	56116
1239	108638	GW03	18.150	In Store	56116

105 The Fonterra Compliance System Approver allocated the incident an identification number (78267) which enabled corrective/preventative actions taken to be linked to Exception Report 562 and approving corrective action taken to prevent any recurrence.

106 A corrective action was approved in April 2012 that included coaching for supervisors on product safety in this foreign matter incident. It was considered by the Fonterra internal investigation that the supervisor made a poor call on product safety issues which resulted in more product being put on hold than should have been as production continued with a further 41 tonnes of WPC manufactured. If production had been halted at the time of the contamination, the amount of implicated product would have been limited to only 1 tonne.

107 Ceasing production would have required a full clean in place of the plant and delayed manufacture.

MPI Critical Exception Report

108 Fonterra submitted the Exception Report ID562 to the RA on the 8th of February 2012 and the RA subsequently submitted it to MPI on the 9th of February 2012 for review, noting that the RA had requested unit numbers to be added to the exception report.

109 MPI logged the Exception Report 562 as a Critical Exception Report (CER) and allocated it the identification number CER6266, advising the RA of this on the 12th of February 2012

Product Disposition Request

110 The first version of the Fonterra Product Disposition request (PD2550v1) for Ciphers GW02 and GW03 was created on the 10th of February and submitted by Fonterra to the RA on the 20th of February 2012 seeking approval to release the product to markets identified as 'restricted' i.e. not Japan, suggesting re-classing the product to a looser specification for general market release, including use in rework, reclassification, stock food, and restricted release to the domestic market.

111 On the 13th of March 2012, the RA advised MPI that having reviewed the product disposition request PD2550v1, the RA was of the opinion that Fonterra could not stipulate restricted markets under the disposal notice. The RA expressed further concern that the use of 'Restricted Market' implied that Fonterra were not confident that there was no foreign matter in the product.

112 Therefore the RA did not support the proposed option, but rather, considered release to further processing and filtration as more appropriate. This is referred to by MPI as a re-process and by Fonterra as a rework process.

113 On the 16th of March 2012 MPI advised the RA that the Fonterra Product Disposition request (PD2550v1) was declined.

114 On the 12th of April 2012 the RA provided MPI with a revised version of the Fonterra Product Disposition request (PD2550v2), advising MPI that they had reviewed the revised disposal application and were now satisfied that conditions of the Animal Products (Disposal of non conforming dairy material or dairy product) Notice 2010 had been fulfilled, confirmed the affected product was recommended for approval for release for reprocessing/rework in the Fonterra Whey plant (1239). The reprocessing/rework was to include a filtration step.

115 The product was also recommended as approved for release to local market stock food. The approval was conditional upon Fonterra assuming the commercial risk in the event of a foreign matter complaint

116 On the 13th of April MPI closed CER6266 in the expectation that the reprocessing/rework would take place in accordance with the production disposition approval granted.

117 No regulatory oversight of the reprocessing was undertaken nor was it required

The Rework of WPC Ciphers GW02 and GW03

118 Prior to reworking the GW02 and GW03 ciphers, the Hautapu Plant Manager designed a unique process by which the two ciphers could be reprocessed using both the SCUF (1282) and Whey (1239) plants to ensure that any residual foreign object contamination could be removed by filtration.

119 A rework of this nature had not been undertaken previously and was unique.

120 The rework instruction for WPC ciphers GW02 and GW03, titled 'WPC Recon through SCUF Wet', was both developed and authorised by the same person, the WPC Plant Supervisor.

121 The instruction identified the process of reconstitution and drying of the powder and identified three phases to the rework:

- WPC reconstitution through SCUF Wet,
- WPC Reconstitution to Silo,
- Drying as per setpoint sheet.

122 Specific instructions were documented on the rework instruction for each phase of the rework.

123 The rework instruction documented the fitting of flexi hoses to bypass unnecessary steps in the process and identified that reconstitution of powder via the SCUF reconstitution room would be required. Reconstitution basically meant that the powder was turned into a liquid form in the SCUF plant (1282) so that it could then be run through the Whey plant (1239), filtered and then dried into powder form again.

124 The approved rework PD2550v2 request identified that the wet rework would be undertaken in the Whey plant (1239) and did not refer to the use of the SCUF plant (1282).

125 The RA (AsureQuality) auditor responsible for the Hautapu site at the time of this incident has been spoken to. The auditor confirms the processes in regards to the exception report and the PD requests, both versions 1 and 2. He did not review or supervise the re-work.

126 He was aware that plant 1239 was stated on the approved PD2550v2 and because the plan had the required filtration step no concerns were raised. He went on to state that he was unaware the re-work was going to occur across two plants and further stated that even if he had known this it would not have made any difference to him.

127 He also indicates that he was unaware that this was going to be a wet re-work, but again said even if he had known it would not have altered his decision making. Interestingly he further states that if he had been in the plant and had seen the temporary pipes he may have asked for their HACCP or Risk management Plan. It is obvious from his statement that he has little knowledge of the Fonterra RMP in detail, instead conducting various audits against RMP documents obtained solely for that audit.

128 Both the SCUF (1282) and Whey (1239) plants are in the same building and there is considerable interchange of dairy materials between the two plants during normal processing. Historically the two plants have been regarded as a single plant by Fonterra albeit they are distinctly separate plants and they have separate HACCP Plans but have the same RMP.

129 There was nothing untoward in Fonterra's view in the use of the SCUF plant (1282) for the re-reconstitution of the WPC rework before evaporation and drying in the WPC plant (1239). Further, with no previous reworks of WPC having taken place there was no facility for the reconstitution of powder other than in the SCUF plant (1282).

130 When the product was re-worked it wasn't necessary for the product to go through the standard WPC manufacturing process. There were three parts of the process that were bypassed and temporary flexi-hoses were used to bypass these processes. There was also one 25m long fixed stainless steel pipe that was incorporated in the process. This piece of pipe is a permanent part of the WPC plant (1239) but is seldom used and in fact had not been used in manufacture for approximately two years.

131 The temporary flexi hoses and the 25m fixed stainless steel pipe were subject to Cleaning In Place (CIP) cycles. This is an automated cycle where a chemical wash is flushed through the pipes before and after each product run (*refer CIP section on page 56*).

132 Fonterra conducted a hydrolysate manufacturing process immediately before the first rework process of WPC was undertaken. No flexi-hoses were used and the standard processes were followed.

133 The first two batches of WPC re-work were run through with the flexi-hoses in place.

134 Following that, four standard hydrolysate batches were manufactured, then a further WPC re-work batch and finally a standard batch of hydrolysate.

135 A CIP cycle was run after every standard hydrolysate and rework run. Both plants were then shut down for the season.

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

136 The process used to reconstitute the WPC powder is a process that is used on a daily basis by Fonterra when manufacturing hydrolysate. The plant and equipment used is comprised of a powder tipping hopper, three reconstitution tanks (tanks 1, 2 and 3) and a process pathway to evaporation and drying.

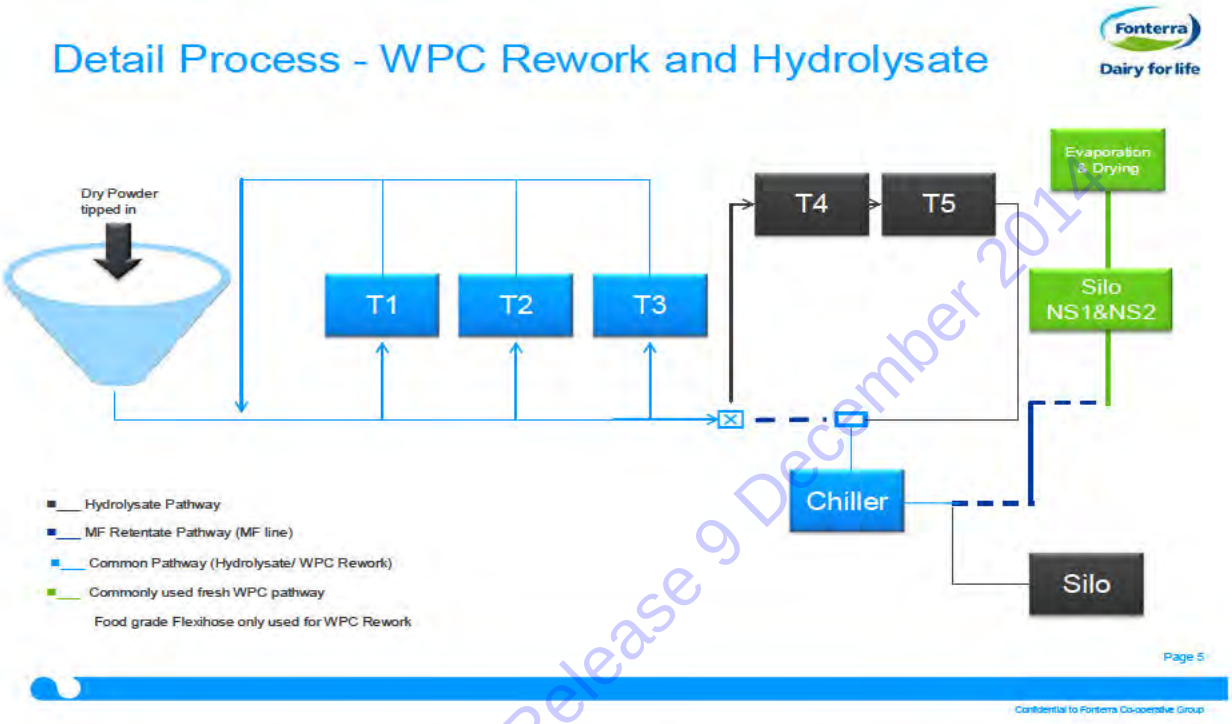
137 The three tanks are filled with a volume of water and then a predetermined volume of WPC powder is tipped through the hopper into each of the tanks in sequence. At the bottom of the hopper the water and the powder meet and go on the process pathway. The pathway from the tanks leads to a flow-plate. The standard WPC route then has the option of going up to tanks 4 and 5 which have a particular functionality that was not required for the WPC rework process.

138 At the flow plate, the standard line was disconnected and a food grade flexible hose was attached to an adjoining flow plate. From the second flow plate Fonterra then linked into a standard line for the liquefied WPC to pass through a chiller plate heat exchanger which is used to chill the WPC down to less than 10°C.

139 Fonterra attached a second flexible hose to the standard hard piping pathway out of the chiller and connected this flexible hose to the 25m stainless steel pipe that had not previously been used for approximately two years. This pipe is referred to as the MF

line. The MF line has in it a plate heat exchanger which was bypassed with a third flexible pipe as its functionality was not required for the rework.

140 The WPC then passed over a flow plate then passed into a standard pipeline which took the product through to one of two storage silos. From those storage silos, the WPC was taken through to evaporation and drying and subsequent transfer to a powder storage bin.



141 The entire process is recorded in log books which also record the Clean in Place (CIP) cycle. For the pathway detailed, there were thirteen separate CIP cycles.

142 The food grade flexible hoses were attached to the flow plates to incorporate them into the CIP cycle. A CIP cycle was undertaken seven times, twice prior to starting the initial processing run, once in between and once at the end.

143 The Hautapu dairy RMP RA, AsureQuality, was not involved on-site in the rework and did not inspect or verify the rework process.

144 The rework operation, with its change of pipe work, addition of hoses, by-passing of tanks and chillers, was not deemed to be a significant change to the premises by either Fonterra or AsureQuality.

145 After completing the rework of Ciphers GW02 and GW03, the reworked product was packed out as JW17, JW18, and JW22.

146	No testing for SRCs was required by regulatory specifications at the time of the rework and there were no customer specifications for the JW17, JW18 and JW22 ciphers requiring SRC testing

Clean in Place (CIP)

147 Clean in Place is a dairy industry term used to describe the process of automated cleaning of plant and equipment.

148 The CIP process is in effect a wash through of the internal plant using a chemical solution greater than pH7, usually a Sodium Hydroxide solution. This process requires a minor reconfiguration in order to connect standard processing lines to CIP equipment to create a CIP circuit.

149 Hautapu maintain log books which document all CIP procedures. The whole cycle is automated and controlled by plant workers from a control room rather than on the factory floor.

150 As part of the investigation, the CIP logbooks have been examined and these confirm that for product processed as part of normal manufacture, CIP was undertaken in accordance with the requirements of the RMP for the plant. For the reworked product, it appears that effective CIP was not undertaken.

151 CIP cycles used in the rework process are believed to have included standard WPC pipework flowpath, flexi hoses and the 25m stainless steel pipe. An examination of documentation provided by Fonterra identified six CIP circuits used in the 'pre-run' and 'in-run' cleaning cycles.

Further, the documentation identifies two 'pre-run' CIPs consisting of a caustic wash and sanitiser rinse took place over five of the six circuits. The sixth circuit, the feedline to SCUF, received only one 'pre-run' caustic wash and no subsequent sanitiser wash is documented.

No acid wash of any of the six circuits is identified at the 'pre-run' CIP stage. An acid wash took place in the activated hydrolysate line as an 'in-run' CIP process.

The CIP procedure adopted for the rework demonstrates a lack of consistency in its application.

152 The Animal Products (Dairy) Regulations 2005 provide for specifications whereby the DG may, either require or provide that in certain areas or for certain uses or equipment, only maintenance compounds that are listed in the specification or approved by the DG, may be used for cleaning relevant plant and equipment.

No such specification requiring the listing of dairy maintenance compounds covering their use in dairy factories has been created by MPI, although one exists for farm dairies (milking sheds).

153 No specific CIP procedures were put in place for the rework despite the fact that a non-standard process, equipment and pathway were used. A subsequent review by Fonterra of the CIP process found that it was unlikely to be 100% effective.

154 A Fonterra engineering report dated 13 September 2013 by [redacted], Group Engineering Quality Manager stated that *'based on the design review it is considered 'likely' (75% as per Fonterra risk matrix) that the pipe work in question (stainless steel pipe & flexible hoses) could be effectively cleaned'*.

The Flexi Hoses

155 Fonterra are unable to identify which of the flexi pipes currently stored at the Hautapu WPC and SCUF plants were used in the rework process in May 2012 as they did not record this information. The flexi pipes have not been used since May 2012 when the product was reworked.

156 Fonterra have stated that it was very rare to rework a product (not WPC), hence why the flexi pipes were used infrequently.

157 No testing was carried out by Fonterra to identify the flexi piping as the source of the SRC contamination but rather the flexi pipes have been identified as the likely source by Fonterra through a process of elimination. This conclusion was reached due to the fact that normal hydrolysate processing undertaken before, during and after the rework, not utilising the flexi pipes, did not test positive for elevated SRCs.

158 After Fonterra shut down the WPC plant for the season in May 2012, they had a clear out and threw out some of their flexi-pipes so it is possible that the pipes that were used for the rework may have been thrown away.

159 The Hautapu Plant Manager said that flexi hoses are available for use in other procedures, e.g. they are used for mineralised water when required.

Photo: Flexi Hoses located on site at Hautapu

The Hautapu Packing Process

160 WPC is transferred from the WPC plant to the bin room by way of a vacuum pressure transport system and then into a vacuum can. The product is forced into a packing hopper which can hold approximately 4-500kgs of WPC and then into a fully automated packing line.

161 There are retention samples taken from all products manufactured at Hautapu. Composite and unit samples are automatically preloaded and are drawn from the product lot on the way to the packing line. These retention samples are held on site for the duration of the shelf life of the product and may be sub sampled during the life of the sample.

162 Unit samples are defined as per the product specification and or laboratory requirement and the default frequency is one per two units.

163 The product is bagged in multi walled bags with plastic inners, heat sealed, weighed, and passed through a metal detector.

164 Post metal detector individual bags are identified with:

- Factory
- Unit
- Cipher
- Manufacturing date; and
- Shelf life data.

165 The whole process is within the packing hygiene envelope.

166 After coding, each bag moves to a robotic palletising process where WPC is packed as 25kg bags, 48 bags per pallet of 1200kg. Each pallet is shrink-wrapped, bar-coded and fork lifted to storage lane in the day store prior to moving to dry store. Once bar-coded all information is loaded into SAP software system of inventory control. Every further movement of product is scanned and logged through SAP

The Hautapu Warehousing Process

167 All product received at the warehouse has its barcode scanned and is directed to storage under SAP warehouse inventory control. A visual display unit on the forklift indicates where to stack the pallet in the store.

168 The warehouse is divided into sections depending on season with fast moving product placed to the front of the warehouse. Product can be consolidated for ease of access but remains under inventory control.

169 Product is picked and despatch to order with instructions electronically transferred to the forklift and marshalled into bins. The product is then loaded onto trucks or trains for distribution with despatch information showing any product loss through damage.

170 Product can be tracked through unit numbers and sales orders.

171 Distribution lists and sales orders identify movement of JW17 and from Hautapu Whey to Hautapu Dry Store (1287) to Fonterra Australia, JW 18 from Hautapu Whey to Hautapu Dry Store and onto Fonterra Australia, Fonterra Research Center and NZ Ag Business, and JW 22 to NZ Ag Biz., Wahaha Group, and Vitaco HEALTH:

- Consignment advice 10692746 – identifies JW17 and JW18 to Melbourne Australia powder weight of 11,950kg
- Consignment advice 10692747 – identifies JW17 18 19 to Melbourne Australia – total powder weight of 11775kg
- Consignment advice 10672977 identifies 1 x 25kg powder to Fonterra L5 9 Princess Street Auckland – destination Fonterra Research Centre
- Consignment advice 10701623 – 2 pages identifies 18807.36 powder weight – JW 17 is 2726.840 of this total
- Consignment advice 10656275 powder weight 1329kg (354 kg JW18) to NZ Ag Biz 2A King Street Temuka
- JW22 into store GRMO report (goods receipt) identifies JW22 into Hautapu store

Pipe Dismantling and Testing

172 On the 20th of August 2013 MPI issued a notice pursuant to section 88 and 89 of the APA directing Fonterra to identify and hold in secure storage equipment described as transfer pipe work in the Fonterra briefing pack dated 5th August 2013.

173 On the 27th August 2013 MPI revoked the 20th August direction and replaced it with a further direction permitting dismantling and examination of the transfer pipe work as part of a review of the contamination issue.

174 On the 27th of August 2013, Fonterra initiated dismantling, swabbing and collection of drainage samples of the implicated pipes and flexible hoses in both factories. This was being undertaken as part of the Fonterra trace back to determine the exact source of the SRC contamination. To ensure oversight and control of this process, MPI Dairy Auditor [redacted] was embedded in the team conducting the work.

175 A pre-prepared 3D schematic was used to track and trace each piece of pipe and equipment as it was cut out and removed from and between the factories.

176 All pipe pieces and flexible hoses were observed to be mal-odour free and visually clean and clear of residues except for two samples.

177 Drainage holes were drilled into the pipes and the pipes were cut into sections with electric hacksaws using drill bits and saw blades that had been sanitised.

178 The drainage holes were at pre-determined low points in the pipes and the first liquid that drained out of each hole was collected for microbiological testing. These samples were immediately visually inspected by Fonterra. It was found that all but two were clear of colour, debris and product solids.

179 The other two liquid drainage samples were slightly discoloured brown, with an unknown fine particle suspended residue.

180 None of the pipe unions, fittings or suspect welds etc were opened during removal although it was subsequently found during swabbing that some joints had been loosened and were only "finger-tight".

181 Many extra flexible hoses within both factories were also collected, marked and removed from the plants (approximately 60). This was because the plants did not have absolute traceability of their flexible hoses, and were not absolutely sure which hoses had been used. The SCUF plant was also being decommissioned and the hoses were removed as part of the decommissioning.

182 The site Process Microbiologist opened, inspected, smelt and removed if necessary all the fittings, unions, joints, etc.

183 Only one item, a pipe union O-ring (C37-C38) was identified as suspect (perished) and this was collected into a sample bag for swabbing.

184 GW02/03 testing completed and confirms SRC contamination occurred during re-work.

185 Microbiological testing for SRC was carried out at the Fonterra Whareroa microbiology laboratory (L4701) and high SRC counts were found in some water samples, stainless steel pipe swab samples and swab samples from flexible hoses.

186 This would suggest that the finding by Fonterra that the SRC contamination arose through the use of the flexi pipes and the infrequently used hard pipe (MF line) has validity although this does not explain why the flexi pipes or the MF line were contaminated with SRCs in the first instance.

187 Fonterra confirmed that no unions or fittings were cracked open or cleaned through the seals during CIP, because this would have created OSH hazards from the leaking cleaning chemicals.

188 A Fonterra report entitled "Hautapu Sampling of both fixed and flexible lines during the decommissioning and extraction of the MF Pipe – Hautapu WPC/SCUF, August 27 2013" states that "*during the investigation into the root cause of the SRC contamination it was discovered that non standard equipment had been used in the manufacturing process. The equipment, consisting of a fixed stainless steel pipe, various flexible hoses and a no return valve was later removed from the manufacturing plant, During this extraction process both water samples and swab samples were collected from the equipment. These samples were then tested for SRC spores. There were high SRC counts found in some water samples, stainless steel pipe swab samples and swab samples from flexible hoses. These high counts support the hypothesis that this equipment was the likely root cause of the SRC contamination.*"

189 The MPI Investigation found no evidence to dispute that statement and further did not identify any other likely causes

AsureQuality and AQ RMP Performance Based Verification Report June to September 2012

190 AsureQuality provide verification services to Fonterra Hautapu.

191 A selection of audit reports has been analysed by MPI so as to give an insight into the effectiveness of the verification regime and any obvious issues. A broad analysis identified the following:

192 AQ Performance Based Verifications (PBV's) for the Hautapu site are robust in scope, non conformances and corrective actions are identified and actioned appropriately. Despite this the site appears to be underperforming relative to other AQ Infant Formula sites.

193 The AQ RMP PBV report for the period 7th of June to 8th of September 2012 noted that 'the WPC plant was the best performing Fonterra WPC plant in the country with 99% grading while hydrolysates graded at 90% due mainly to SRC issues'.

194 Fonterra's explanation to the RA was that they had "*considered the potential for Hydrolysate to be impacted by this event and the extensive investigations and problem solving that have been completed have confirmed hydrolysates are not impacted. The reason for the 10% failure rate is that unlike WPC there are clearly defined specification limits for hydrolysate which are 10cfu/g or 50cfu/g depending on the specification.*"

195 Neither the RA nor Fonterra took action in respect of the RA observation of 90% compliance in hydrolysates, reasoning that it was not unexpected that some product would be outside of a customer specification. It is not considered by Fonterra to be a food safety issue.

196 Fonterra routinely test for SRCs in hydrolysates in accordance with the HACCP Plan or as required by customer specifications. Figures provided by Fonterra indicate some high levels of SRC at times in hydrolysates and therefore it may fail the specification.

197 A selection of spikes in hydrolysate SRCs identified in data supplied by Fonterra as '*in process*' recordings were described as SRC levels that are expected to be bought down or eliminated by further processing in the manufacturing sequence, such as heat treatment.

198 Out of specification hydrolysate is considered to have simply failed a grade but the business rule does not require that failure to be reported.

199 A grade failure does not represent to Fonterra any particular food safety risk or need to investigate the failure further.

200 Fonterra options for out of specification product are to:

- downgrade
- rework
- find a new customer
- persuade the customer to accept the out of specification product.

201 In summary, if the specification required SRC testing, then the product was tested. If it failed then options for the product would be explored, however this does not include investigating and determining the cause.

202 High SRC levels are an indicator of poor hygiene in the manufacturing process but are not considered to be a food safety risk in their own right.

203	Until the current issue emerged, it did not appear that the RA has asked why there are failures or what the follow up to those failures are.

204	High or out of specification SRC levels appear not to have attracted any investigation into cause or effect.

FONTERRA DARNUM

Work Stream Aim

205 The Fonterra Darnum plant in Australia received quantities of the contaminated WPC80 (ciphers JW17 and JW18) and used it as macro ingredients in manufacturing nutritional powders for the Danone Group. Testing subsequent to manufacture identified the high SRC counts that ultimately led to the microbiological testing undertaken in New Zealand.

206 The aim of the investigation at Darnum was to;

- confirm the link between Altona and Darnum
- confirm JW17 and JW18 was used and was the same product reprocessed at Hautapu
- understand their BAU manufacturing process
- confirm the manufacturing process used was in accordance with BAU
- identify the events leading to the high SRCs being discovered
- understand what actions they took
- understand what actions/communications they had with Fonterra NZ leading to the testing regime undertaken

Background

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

208 The vast majority (99%) of the Darnum nutritional powder is supplied to the Danone Group, a multinational infant formula company, who use the nutritional powders in a variety of consumer products.

Manufacturing Process

209 Fonterra Australia has a large warehouse store situated in the suburb of Altona in Melbourne, Australia. This warehouse receives and holds the relevant macro and micro ingredients until they are requested by Darnum or other Fonterra Australia sites.

210 Darnum only has day warehousing facilities on site. This means that macro and micro ingredients used in the manufacture of their nutritional powders are shipped into the day warehouse on a "just in time" basis. This means that those ingredients are timed to arrive the day before they are used in production.

211 The manufacturing process commences with the macro and micro ingredients arriving in the Darnum day warehouse.

212 These ingredients are numerous and are generally packaged in pallet form. The pallets contain barcode stickers that identify the source of manufacture and the batch number.

213 The warehouse is essentially a large pantry. A conveyor leads from the warehouse to the batching plant. Workers in the warehouse receive a macro tipping log sheet which is in effect a recipe created by the formulations team within the plant. This recipe details ingredient types and quantities. The store men retrieve and collate the various bags of ingredients as per the macro tipping log sheet (recipe) and forward them via conveyor to the batching plant.

214 The batching plant is essentially the kitchen area where the macro and micro ingredients are mixed as per the recipe. Macro ingredients are the bulk quantities such as WPC80. The micro ingredients can be vitamins, minerals, proteins, oils etc.

215 Darnum can process [redacted] mixes a day. If the mixes consist of the same recipe across the day a batch is the product derived from the complete days mixes. If the recipe changes a batch is collated to the mix. If the recipe changed 4 times in a day it would equal 4 different batches.

216 Approximate individual mix weight is [redacted] tonnes. Thus 39 mixes x [redacted] tonnes = [redacted] tonnes approximate. WPC 80 content in Nutritional products ranges from 1-3 %. Infant formula is generally approximately 3%.

217 They use their Macro Tipping Log Sheet to double check the ingredients and quantities of ingredients that have been sent through from the warehouse. They remove the bar codes from the product and enter the codes into SAP to record the consumption of the inward ingredients. This theoretically tracks a product/ingredient from manufacture to end consumption.

218 The products are tipped into large hoppers, mixed with water/milk and mixed together. Micro ingredients are also added into the hopper but some such as oils can also be added to the mix later in the processing of the product.

219 After batching, the product flows through evaporators, concentrate tanks and filters, pre heaters, homogenisers and ends up in the dryers.

Packing Line

220 When it leaves the dryers it makes it way to the packing line. Prior to being packed into bags the dried product passes through concentration points containing magnets

designed to extract metal. At this point two samples are automatically extracted (via a computer programme). The samples are heat sealed within tinfoil bags. They are marked with product identifiers. One sample is retained for internal product analysis and the other is sent to an external testing laboratory (Dairy Technical Services Ltd) based in Melbourne.

221 The samples are batch specific unless many batches of the same product is being produced on a continuous basis whereby the sample is made up of sub samples collected across a 24 hour period.

222 After the stage where the loose dry product passes through the magnets and has samples removed, it is bagged into 25 kilogram bags. The bags also pass under a powerful magnet.

223 They are then ink printed with product identification markings. From there the bags are taken by conveyor back to the day warehouse where they are palletised and shipped on a daily basis back to the Altona Warehouse.

224 Post production the product is entered into the SAP system as inventory but has a hold placed on it until testing is conducted to ensure the product meets regulatory and customer specifications. The product is not released until the technical team collate all testing.

Cleaning

225 Darnum use similar plant cleaning processes to Hautapu and other dairy plants. They purge all equipment post each batch and perform a clean in place cycle every 24 hours.

Testing

226 For macro and micro ingredients used at Darnum, they, as do all dairy plants, rely upon certificates of analysis (COA) provided by the source manufacturing plant as proof that those ingredients meet specifications. For example, the WPC80 supplied by Hautapu will have COA's produced and sent with the product. The COA's are not checked prior to being used in product manufacture. Instead what occurs is that they rely upon providers only sending product that meets regulatory specifications. The ingredients are used in the manufacturing process and, post production of the nutritional powder, retention samples are taken.

227 The retention samples are then sent to Dairy Technical Services (DTS) in Melbourne. DTS is an independent and accredited dairy laboratory under Australian Dairy criteria. The retention samples are then tested to check that they meet regulatory specifications and, if there is a customer specification, whether the product meets those requirements.

228 DTS then send their testing results back to the Darnum technical team who review the results.

229 If the tests show that the product meets all required specifications they then review the COA's to ensure that the ingredients met the required specifications. It is to be noted that dependent on the manufacturing tempo, the technical team may review the COA's prior, during or after manufacture.

230 In any event no product is released to customers until the technical team has reviewed and approved the COA's and the test results from DTS.

231 Once the technical team have reviewed and approved the ingredient COA's and the test results from the manufactured product, they then release the product to the customer via the SAP system.

232 Darnum nutritional products are all tested for SRCs. It is a customer specification – not a regulatory specification.

Quality Control

233 For product not meeting specifications the options Darnum have are:

- Down grade (eg stock food)
- Dump
- Re-work

234 The decisions are made by the Quality and Technical section. Testing results can vary from laboratory to laboratory and country to country. Darnum samples are tested by a NATA accredited laboratory. (National Association of Testing Authority) Darnum uses Dairy Technical Services (DTS) based in Melbourne.

WPC 80 Incident

235 Darnum received 190 25kg bags of WPC80 originating from JW17 and 349 25kg bags originating from JW 18.

236 The product arrived at the Altona Warehouse on the 22nd of October 2012. The product was moved to Darnum in varying quantities between 27th of February and 14th of March 2013 to meet manufacturing schedules.

237 The WPC 80 was used as a macro ingredient in 39 mixes of nutritional formula, all destined for Danone and was manufactured between the 1st and 21st of March 2013.

238 The finished product was sent back to Altona for storage and awaiting testing results prior to release to Danone.

239 The COA's for the WPC80 from Hautapu (JW17 and JW18) were in this instance checked before the DTS test results were received and no concerns were raised.

240 On the 21st of March 2013, DTS advised Darnum of positive test results for SRCs exceeding Danone specifications in some of the batches submitted for testing.

Directly Implicated Product

				SRC Initial Grading Results (cfu/g) using NZTM2, 59.03					
Batch Number	Production Date	Material Number	Product Code	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Initial Results Date
153060	1/03/2013	110831	FO121	<10	<10	<10	70	<10	7/03/2013
163060	1/03/2013	112463	IF166	160	160	20	<10	<10	16/03/2013
153061	2/03/2013	110831	FO121	<10	<10	<10	70	<10	7/03/2013
153062	3/03/2013	110868	FO124	60	120	<10	40	<10	9/03/2013
153070	11/03/2013	110833	FO120	360	340	210	140	290	24/03/2013
163070	11/03/2013	110832	IF122	10	30	<10	<10	<10	17/03/2013
153071	12/03/2013	110833	FO120	230	300	110	10	140	24/03/2013
153072	13/03/2013	111691	GUM008	<10	<10	<10	<10	<10	29/03/2013
163072	13/03/2013	110832	IF122	<10	<10	<10	30	<10	20/03/2013
163073	14/03/2013	110832	IF122	<10	<10	<10	<10	<10	20/03/2013
163074	15/03/2013	110832	IF122	<10	<10	<10	<10	<10	20/03/2013
163075	16/03/2013	110832	IF122	30	10	<10	<10	<10	22/03/2013
153075	16/03/2013	110833	FO120	30	<10	<10	20	10	22/03/2013
163076	17/03/2013	110832	IF122	<10	<10	<10	<10	<10	24/03/2013
153076	17/03/2013	110833	FO120	<10	10	50	10	<10	24/03/2013
163077	18/03/2013	110832	IF122	10	<10	<10	<10	<10	24/03/2013
153077	18/03/2013	110833	FO120	<10	<10	<10	<10	<10	24/03/2013
153078	19/03/2013	110833	FO120	<10	<10	<10	<10	<10	26/03/2013
163080	21/03/2013	110831	FO121	<10	<10	<10	<10	<10	26/03/2013

Internal Investigation

241 Upon receipt of the positive test results, Darnum commenced an investigation to determine the source of the SRC contamination. They firstly considered the local raw milk as this was the greatest quantity of macro ingredient used in the mixes.

242 This was quickly ruled out as a possibility. They then considered the other macro and micro ingredients such as WPC80, lactose, sucrose, oil etc.

243 After ruling out raw milk Darnum conducted an analysis of the macro and micro ingredient records and concluded that the common denominator across all batches that had tested positive for SRCs was the WPC 80 from JW 17 and JW18.

244 It is to be noted that other batches of WPC80 were used but none of the nutritional powders Darnum produced using these other batches tested positive for SRCs. This then showed a clear causal link to JW17 and JW18

245 On the 21st March 2013, [redacted] the Technical Manager of Powders and Nutritionals at Darnum, contacted [redacted] Senior Research Technologist at the Fonterra Research and Development Centre (FRDC) NZ and [redacted] Process Technologist-Microbiology at Clandeboye NZ. [redacted] advised that Darnum was undertaking an investigation into high SRC levels identified in their infant base powder to determine whether the source of the SRCs was raw milk.

246 The events, actions and reactions that then occurred are outlined in the Fonterra section of this report.

Withheld under 9(2)(a)

DANONE GROUP

Work Stream Aim

248 The Danone Group is a multinational food company who purchase significant quantities of nutritional powders from Fonterra. Danone use these nutritional powders as macro ingredients in the manufacture of a range of infant formulas.

249 The aim of investigating Danone was to;

- Identify all events that occurred between Fonterra, Fonterra Darnum and Danone in relation to the WPC80 incident
- Identify if any of those events or communications were material to the investigation and liability of Fonterra
- Establish if Danone (Nutricia) had any liability in this case

Background

250 The Danone Group is a French food-products multinational corporation based in Paris, France. It produces fresh dairy products, bottled water, cereals and baby foods, and yoghurts.

251 The baby foods that it produces include infant milk formula products. In New Zealand these are manufactured and marketed under the Nutricia brand. As established, 99% of the production at Darnum is used in Danone products which include a variety of infant and early childhood nutritional products.

252 The supply agreement between Danone and Fonterra include customer specifications detailing the microbiological testing requirements for nutritional powders supplied to Danone. This includes SRC testing of each batch of nutritional powder used for infant formula; follow on formula and growing up milk powder (GUMP) Darnum are also required to maintain samples of each batch for a minimum of four years post manufacture.

253 The basis for Danone's SRC standards were established in 1996 when Nutricia Research issued a document entitled "Microbiological Criteria for Dried Pathogen-Free Products, Scientific and Statistical Background of the Elaboration and Use in Practice of Reference Ranges and their Corresponding Sampling Plans".

254 Standards are issued by Danone on an annual basis and form the basis for "Finished Product Standards for Danone-Nutricia Products". The finished product standards are then converted to appropriate customer specifications for raw materials.

255 The 1996 standards are based on those that had been achieved for a number of years before 1996 in the Nutricia factories. SRC tests have been used by Danone since 1996 as a relevant indicator for hygiene and are applied throughout their organisation.

WPC80 Incident

256 On the 18th of April 2013, Danone personnel in Singapore received a teleconference invitation from Fonterra account management personnel based in New Zealand to discuss some product that had failed Danone's SRC product specification requirements at Darnum.

257 This meeting was scheduled for the 23rd of April 2013.

258 On the morning of the 23rd of April 2013, Fonterra sent an updated meeting invitation and attached a summary of the issue prior to the call. This was entitled "Investigation Report – SRCs in Danone Nutritional Products" and was dated the 22nd of April 2013.

259 The summary stated, among other things, that Fonterra had traced the source of the elevated SRC levels in the base powder to two batches of WPC80 ingredient manufactured by Hautapu that were used in batches at Darnum. The summary stated that the WPC80 lot codes of concern were tested for SRCs and found to have very high loadings of SRCs, up to 8000 cfu/g.

260 It stated that all lot codes of WPC80 were put on hold and that in future WPC80 required SRC tests before Fonterra would clear it for use.

261 Fonterra advised Danone that it had tested the base powder exhibiting elevated SRC levels in its Palmerston North research facility, and determined that the clostridia present were a relatively pure strain of clostridium sporogenes and that no clostridium perfringens (commonly associated with food poisoning) were detected.

262 Fonterra stated that it had cleared the other sub lots of product as being compliant with Danone's SRC specification but requested that Danone accept the batches that had failed Danone's SRC requirements.

263 Fonterra stated that the testing that it had done, including the use of MALDI-TOF, had confirmed no clostridium perfringens and that the contamination was from a "non-pathogenic" strain of clostridium sporogenes and therefore not a food safety risk.

264 Fonterra recommended that Danone accept the implicated product despite it being outside of Danone's specification criteria based on Fonterra's assessment that there was no food safety risk.

265 On the 23rd of April 2013, Danone and Fonterra held a teleconference where Fonterra reiterated these points and encouraged Danone to accept delivery of the base powder.

266 On the 25th of April, Danone informed Fonterra that they would not accept any batches of nutritional powder that have failed their SRC customer specification for its Infant Formula (babies 0-6 months) or Follow On formula (6 months – 1 year) products.

267 After having received advice from their microbiologist, Danone advised Fonterra that the main concern in relation to their SRC specification is the possibility of infant botulism caused by toxicogenic strains like *C. botulinum* (and others). This is a risk for infants under one year of age, so SRC levels above 100cfu/g are not acceptable for Infant Formula and Follow on Formula, although it might be acceptable for Growing up Milk (GUMP) but requires further investigation.

268 On the 29th of April 2013, there was a further teleconference between Danone and Fonterra in which Fonterra submitted to Danone a preliminary report that outlined four options to recover the nutritional powders that were outside of specification in terms of SRC levels.

269 The options were:

- Bactofugation,
- Heat,
- Germination and elimination of vegetative cells,
- Rework

270 On the 1st of May 2013, a paper entitled "SRC Recovery Proposal" was provided to Danone by Fonterra which indicated that the recommended recovery option was for SRC reduction by heat and Danone's agreement to this option was sought. Fonterra proposed that a small scale recovery trial would be undertaken involving 25 tonnes of base powder. This was to confirm that the spore reduction results achieved at laboratory scale could be replicated at full commercial scale.

271 On the 8th of May 2013, Danone agreed to the trial with some conditions and asked that Fonterra share the results with them before they release and ship any product.

272 After this interaction Danone heard nothing further from Fonterra on this matter until a teleconference was convened by Fonterra on the 2nd of August 2013 at which they made a presentation to Danone regarding the Clostridium Botulinum findings.

273 Danone agreed to accept base powder from Darnum that exceeded their SRC specification of 50cfu/g but was less than 100cfu/g on the basis that this would only be used for GUMP. As a consequence Danone accepted 1758.6 tonnes of base powder which then went into the supply chain.

274	Based on the investigation to date, no evidence has been found that Danone knew that the product it accepted may have been processed by Fonterra outside of Fonterra's RMP or the regulatory standards.

Work Stream Aim

275 Following the discovery of the high SRCs in the Darnum nutritional powders, Darnum analysis indicated that the cause was the WPC80 used as a macro ingredient by them. Upon determining this, Darnum communicated with the Technical Services Team at Fonterra NZ requesting testing as confirmation. This then set in motion a wide and varied testing regime that ultimately ended with a false positive test result for Clostridium Botulinum as advised to MPI on the 2nd of August 2013.

276 This is the fourth work stream in the logical flow of product, events, actions and reactions in this case. It was decided early that there would be two sub work streams;

- Technical – to identify the communications, events and actions in regards to the technical testing. What was done, who by, how, why and the outcomes including what communications and information was passed to managers for decision making

- Strategic – the communications, events, actions and decisions (or lack of them) by Fonterra management in dealing with this incident. What were they told, who by, why and what decisions were made when

277 The events that transpired from when advised by Darnum through to when Fonterra advised MPI on 2 August are now outlined;

Date	Theme
18 March – 25 May 2013	Darnum investigation of high SRC levels in infant base powder
8 May – 7 June 2013	Darnum compensation complaint to Hautapu regarding affected WPC80
29 May – 1 July 2013	Escalation to "serious event" of the Darnum compensation claim and re-investigation of the Hautapu WPC80 contamination
6 June – 24 July 2013	Investigation of Waitoa Nutritionals using affected WPC80
20 July – 2 August 2013	Escalation to "critical event" of the WPC80 contamination
31 July – 2 August 2013	*C. botulinum* confirmation and notification to MPI

Darnum Investigation of High SRC Levels

18 MARCH – 25 MAY 2013

278 Between 1 – 17 March 2013, 190 25kg bags of JW17 and 349 25kg bags of JW18 WPC80 were used as a macro ingredient in the manufacture of 19 batches of infant base powder at Darnum.

279 Routine retention samples from the infant base powder were tested for SRCs. The testing was a requirement of the Danone customer specification. Test results indicated that 7 of the 19 batches contained out of specification levels of SRCs.

280 21 March: [redacted] the Technical Manager of Powders and Nutritionals at Darnum, contacted [redacted] Senior Research Technologist at the Fonterra Research and Development Centre (FRDC) NZ and [redacted] Process Technologist-Microbiology at Clandeboye NZ. [redacted] advised that Darnum was undertaking an investigation into high SRC levels identified in their infant base powder to determine whether the source of the SRCs was raw milk.

281 22 March: [redacted] advised [redacted] that he and [redacted] considered that the high SRC counts were unlikely to be a raw milk issue and more likely to be related to an ingredient such as demineralised whey. [redacted] requested a sample of the infant base powder with the elevated SRC levels be forwarded to FRDC so that they could do some ID work.

[redacted] advised [redacted] that Darnum was currently undertaking a detailed traceback to determine what linkages there were between the elevated SRC counts and all key ingredients.

[redacted] specifically asked whether it could be expected that WPC80 could be a risk factor. He raised this because WPC80 was not currently tested for SRCs when manufactured.

[redacted] contacted the NZ Products Technical Team (NZPTT) and requested the testing of retention samples from Hautapu for WPC80 ciphers JW17 and JW18 for the presence of SRCs.

The NZPTT arranged for the JW17 and JW18 retention samples to be retrieved from Hautapu and forwarded to the Te Rapa laboratory for testing.

282 28 March: The samples of the Darnum infant base powder requested by [redacted] were received at the FRDC.

Withheld under 9(2)(a)

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283 3 April: [redacted] from the NZPTT forwarded to [redacted] the SRC test results for JW17 and JW18 with SRC levels ranging between 400cfu/g and 8,200cfu/g reported.

284 4 April: Samples of the affected Darnum infant base powder were forwarded to [redacted] at Clandeboye to investigate rework and recovery options for discussion with Danone so that the powder may be accepted by them.

285 9 April: [redacted] requested that [redacted] test the Darnum infant base powder for *Clostridium perfringens* and to use the MALDI-TOF for positive confirmation.

The presence of *C. perfringens* would be key information for determining whether Danone would accept the out of specification product.

286 10 April: [redacted] requested the NZPTT consider the inclusion of SRC testing in the WPC80 product specification at a limit of 100cfu/g when manufactured.

287 11 April: [redacted] advised [redacted] the preliminary results of the tests on the infant base powder indicated the presence of *Clostridium sporogenes*, confirmed by the MALDI-TOF test.

288 15 April: [redacted] supplied [redacted] with the final testing report and he responded that the fact the SRCs are largely *C. sporogenes* was valuable for discussions with Danone.

289 17 April: [redacted] arranged for additional samples of JW17 and JW18 to be forwarded to FRDC and Clandeboye for further testing and strain identification. He advised [redacted] and [redacted] that by way of preparation of the Darnum case with Danone they have recognised that it would be beneficial to have more information on the WPC80.

[redacted] specifically wanted to confirm that:

- There was no appreciable presence of *C. perfringens* in the WPC80
- SRCs in the WPC80 were predominantly *C. sporogenes* as found in the Darnum infant base powder
- The dendrogram generated by the MALDI-TOF pertaining to the *C. sporogenes* from the WPC80 was equivalent to that found in the Darnum infant base powder

It was [redacted] s view that if the two dendrograms matched it would provide further evidence to support the already compelling case that the WPC80 was the source of Darnum's issues.

290 18 April: Fonterra scheduled a teleconference with Danone on 23 April regarding product that had failed their specifications at Darnum.

Withheld under 9(2)(a)

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NZPTT arranged for WPC80 samples to be forwarded to FRDC and Clandeboye as requested by [redacted]

291 19 April: [redacted] provided [redacted] with his final report in relation to the recovery options.

Two options were recommended:

- Reconstitute affected product, subject it to a heat treatment high enough to significantly reduce the level of SRC spores, and then re-dry product for incorporation as rework via the standard process at Darnum.
- Reconstitute affected product, provide conditions in which the SRC spores will germinate, eliminate the vegetative cells via a standard pasteurisation process, and then re-dry product for incorporation as rework via the standard process at Darnum.

292 29 April: The JW17 and JW18 samples requested by [redacted] arrived at FRDC.

293 7 May: The FRDC confirmed the dendrogram from the WPC80 samples indicated several variants of *C. sporogenes* with similar typing patterns to the Darnum product.

> They noted the MALDI-TOF was reporting unidentified strains that clustered close to *C. perfringens*.

In anticipation of further testing at AgResearch, FRDC requested a quote for *C. sporogenes* confirmation testing.

294 8 May [redacted] Senior Technologist, Process and Projects, Edgecumbe, recommended to [redacted] the addition of SRC testing into WPC80 specifications.

(a) [redacted] emailed [redacted] with results and recommendations pertaining to the testing of the JW17 and JW18 WPC80 samples received from Hautapu on 29 April.

> "Hi all. We received two whey powders to test for SRCs. This is what the results are looking like at this stage:
> **JW17 Comp**
> ~14000/g
> ~8000/g (after 80C/10min heat treatment)
> **JW18 Comp**
> ~900/g
> ~250/g (after 80C/10min heat treatment)
> As far as the typing is concerned:

Withheld under 9(2)(a)

Withheld under 9(2)(a)

- we are picking up several variants of *C. sporogenes* with similar typing patterns as in the Darnum product i.e. there is little doubt that there is a strong link between source (the ingredient) and the contaminant in the final product
- we are also picking up strains that Maldi is not giving a 'strong' ID for. However, at this stage they 'cluster' close to C. perfingens

To clarify their identity and thus their specific pathogenicity, we have no choice but to do 16S sequencing on these to confirm whether they are significant - This will take some time to get done. Unfortunately, nothing in microbiology is simple. So, you should also know that a *C. botulinum* is a simply a *C. sporogenes* without the toxin gene.
This being the case we are checking out whether AgResearch (at Massey University) can assay for the presence of the toxin gene.
It is EXTREMELY UNLIKELY that these organisms, which Maldi identifies as *C. sporogenes*, as carriers of the toxin gene.
We certainly don't want to be alarmist. However, we would be derelict in our duty if we did not consider the possibility. The bottom line is that the ingredient powder contained very high levels of clostridia which certainly indicated a lost process control / failure to maintain good hygienic practice. Please feel free to discuss. [redacted]

Withheld under 9(2)(a)

Darnum Compensation Complaint Regarding WPC80

9 MAY – 7 JUNE 2013

295 9 May: [redacted] advised [redacted], Site Manager, Hautapu, and [redacted] Hautapu Plant Manager, that their WPC80 product was unfit for purpose because it contained grossly high SRC levels. [redacted] requested a phone conference for the following day.

296 10 May: Prior to the conference call [redacted] provided [redacted] and [redacted] with a document referred to as the "SRC Complaint Background Document V01 2013 05 10".

Key messages from the document were:

- Infant base powder manufactured at Darnum for Danone is routinely tested for SRCs pursuant to the Danone customer specification for those products.
- Darnum detected out of specification SRC levels for Danone infant base powder manufactured during March.
- A total of 468 tonnes of product was affected across six ciphers with SRC levels up to 360cfu/g.
- WPC80 from ciphers JW17 and JW18 ex Hautapu were identified as the cause of the high SRCs.
- Testing of the Hautapu WPC80 indicated SRC levels >8,000cfu/g.
- The estimated liability cost to Darnum of the Danone affected product is [redacted]

Withheld under 9(2)(b)(ii)

- The SRC levels in JW17 and JW18 (up to 8,800cfu/g) demonstrate a significant GMP failure and render the product unfit for the purpose for which it was supplied.

During the conference call Darnum raised concerns to Hautapu that a traceback had identified elevated SRC levels in WPC80 from Hautapu.

After the conference call, [redacted] Central Waikato Operations Manager, was alerted to the SRC issue by [redacted] and advised that Hautapu would conduct an investigation into the cause of the SRCs.

Withheld under 9(2)(a)

297 20 May: [redacted] forwarded his final report regarding the investigation of the SRC contamination of Darnum infant base powder to [redacted]

"Summary

- The dominant *Clostridium* species isolated from the Darnum nutritional powder blend and the Haputapu WPC80 was *C. sporogenes* (identified using the MALDI-TOF method).
- The presence of large numbers of *C. sporogenes* stimulates the question about whether they might pose a health risk to infant consumers i.e. has *C. sporogenes* the potential to be pathogenic. Clostridium experts have stated that strains of the pathogen *C. botulinum* Group1, which are unable to produce toxin, are referred to as *C. sporogenes*.

- Although the risk appears to be low, the Food Assurance team recommends that representative isolates of the *C. sporogenes* from the nutritional powder blend should be screened for the ability to produce the *C. botulinum toxin* at AgResearch in Palmerston North (~$2000/sample).
- The alternative is to withdraw the product in question from the infant food chain.

298 24 May: [redacted] contacted [redacted] seeking a response to the FRDC recommendation that AgResearch test the infant base powder for the ability to produce the *C. botulinum* toxin.

Withheld under 9(2)(a)

299 25 May: [redacted] replied to [redacted] and stated:

"All product affected by this incident has been rejected by Danone and has been withdrawn for sale as either stock food or edible disposal for general populations. That is, all product has been withdrawn from the infant food chain.

Based on this, I cannot justify proceeding with the screening work to confirm that the *C. sporogenes* are non toxin-producing.

Thanks again for all your detailed work relating to this incident.

Regards, [redacted]

300 27 May: [redacted] Senior Research Scientist, FRDC, specialising in microbiology, advised AgResearch that the suggested testing to screen for *C. botulinum* is no longer required.

Withheld under 9(2)(a)

Comment: This effectively closed the investigation phase into the cause of the Darnum infant base powder SRC contamination that was the subject of the complaint.

Escalation to Serious Event of the Darnum Claim and Re-investigation
29 MAY – 1 JULY 2013

301 29 May: [redacted] Director Operations and Supply Chain, Fonterra-Australia, followed up on the status of the initial compensation complaint made by Darnum to Hautapu on 10 May.

Withheld under 9(2)(a)

[redacted] brought the complaint to the attention of [redacted] Director New Zealand Milk Product Operations and [redacted] General Manager Operations, Central North Island and highlighted the following:

- Hautapu WPC80 contained grossly high SRC levels and was unfit for purpose
- 440 tonnes of NUT's (Nutritionals) had to be downgraded to stock food
- Hautapu site team is apparently reviewing the claim but delay in response is caused by illness among team members
- If the claim is not accepted the Australian business will need to absorb an [redacted] loss
- The issue is likely to be escalated by [redacted] Managing Director, Fonterra-Australia to Theo Spierings, CEO, Fonterra
- The claim should be accepted or rejected by Monday, 3 June.

Withheld under 9(2)(b)(ii)

[redacted] advised [redacted] and [redacted] of the follow-up complaint from [redacted]

[redacted] indicated that he had first been made aware of the complaint by [redacted] on 10 May and was awaiting the outcome of an investigation by the Hautapu team before advising [redacted]

Withheld under 9(2)(a)

[redacted] indicated his position was that the claim should be rejected because the WPC80 had been manufactured within the required specification which did not include testing for SRCs.

[redacted] suggested the matter be escalated to [redacted] General Manager Quality and Technical.

302 30 May: [redacted] provided [redacted] with a copy of the email he had sent to [redacted] In the email he sought [redacted] endorsement for refusing the [redacted] claim, on the following grounds:

- Product was manufactured to specification
- Product passed all grading requirements
- SRCs are not in the final product specification for 104579 – and there are no testing requirements for SRC on the WPC80
- The manufacturing process (rework in this case) was conducted according to Good Manufacturing Practice– and Product Disposition instructions
- Hydrolysate that was manufactured pre and post this WPC80, which **is** tested for SRCs, was well within the specification thus there would have been no indications of any issues.

Comment:
WPC80 is manufactured to two different product specifications, 104578 and 104579. These specifications identify the 'recipe' under which the WPC80 is manufactured.

303 31 May: [redacted] contacted [redacted] and [redacted] about his concern that the ciphers were manufactured from 100% rework.

Fleming indicated the 100% rework could be significant because it is a non-standard manufacturing process and there is the possibility that SRCs may have come from flexi hoses or demineralised water used to reconstitute the WPC80.

[redacted] forwarded this information to [redacted]

[redacted] asked [redacted] Process and Projects Manager, to answer the following:
- Who authorised 100% rework?
- Is level limited in WPC (powders has 10% max)?
- Are rules enforced?
- Did it follow change control?
- Who approved from technical and did they do adequate risk assessment?

[redacted] contacted [redacted] Technical Team Lead, Process Technical, CNI region and [redacted] Regional Technical Manager, NZ Operations requesting that they have one of their team at Hautapu look at the issues that [redacted] raised.

[redacted] was concerned that he had been given conflicting information about the rework.

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Withheld under 9(2)(b)(ii)
Withheld under 9(2)(a)
Withheld under 9(2)(a)

304 2 June: [redacted] advised [redacted] he considered NZ Milk Products (NZMP) were not liable for the cost of the compensation claim because the WPC80 was manufactured according to a specification which did not include a requirement to test for SRCs.

[redacted] acknowledged that the cause of the downgrade of the Darnum infant base powder was the WPC80 from Hautapu.

Withheld under 9(2)(a)

305 4 June: [redacted] responded to [redacted] and highlighted the following:

- The WPC80 specification did not contain testing for SRCs because the WPC80 is used at low addition rates in the final product (traditionally around 2%)
- The WPC80 contamination can only have occurred if there was growth of SRCs in the plant because typical SRC results in WPC80 are less than 1cfu/g.
- The recorded levels from JW17 and JW18 are 1,000 to 10,000 times higher than typical levels, indicating that a significant deviation from normal hygiene conditions or process had occurred.
- The affected batches of WPC80 were manufactured by 100% wet reconstitution of previously downgraded product.
- A 100% reconstitution is not considered to be standard practice and increases the risk of quality issues arising.
- NZMP should not hide behind the "not in specification" excuse and accept liability for this downgrade caused by a significant deviation from normal hygiene conditions or process and pay the claim.

Comment:
[redacted] comments to [redacted] triggered the formation of a serious event team.

Work streams relating to the compensation claim and the investigation into the cause of the WPC80 contamination were identified and allocated. The serious event was de-escalated on 1 July.

Withheld under 9(2)(a)

[redacted] contacted:

- [redacted] - Process Technologist, CNI region
- [redacted] Technical Team Lead, Process Technical, CNI region
- [redacted]

[redacted] advised them that [redacted] was putting pressure on [redacted] about the issue, that it was a very high priority and whatever resources were needed should be thrown at it. He reiterated [redacted] comment that the 100% rework was a non-standard manufacturing process as confirmed by a member of the serious event team.

[redacted] expressed concern that there appeared to be no process in place to look at the risk around the rework and queried whether the product disposition (PD) should have stated a percent of rework. He also questioned whether there should have been a level of DA (decision analysis) applied to the decision.

[redacted] appointed [redacted] to lead the serious event team. Key participants were:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

Foote headed a sub-group focussed on determining why the initial compensation claim had not been escalated.

They determined the complaint was not escalated because the provisional costs template only claimed [redacted] product costs, with a net impact of [redacted] involving no more than 13.5 tonnes.

The actual costs should have included the customer's (Darnum) manufacturing costs and impact to a total of [redacted]

306 6 June: A scoping call was held in relation to the serious event in which key participants, among others, were – [redacted] and [redacted]. The meeting identified work stream leads, tasks, escalation end points and key stakeholders as:

Work stream	Proposed Lead	Success Factors
JW17 and JW18 information and records	[redacted]	Full trace-back details available outlining all inputs into the production process for ciphers. Product Disposition available on re-worked product.
Complaint process to date	[redacted]	Clear summary available of all comms, both internal and with 'customer'.
100% rework option	[redacted]	Clarity on process followed for 100% rework and associated procedures. Summary of past instances of 100% rework being produced. Final product data for previously produced 100% rework ciphers.
Purchase and sale of product	TBC	Clarity on what was ordered by Fonterra Darnum, against what spec and how JW17 and JW18 matched up to this spec.
SRC elevation root cause	[redacted]	Identification of likely cause of elevated SRCs in these ciphers.
Communication breakdown	[redacted]	Problem solve outcomes regarding failure to escalate this complaint within NZQT and NZ Ops.
Event Comms	[redacted]	Communicate out progress regularly.

Withheld under 9(2)(a)

Withheld under 9(2)(b)(ii)

Withheld under 9(2)(a)

Escalation end-points

- Clear understanding of escalation of event and corrective actions underway to ensure future events are clearly escalated.
- Definitive customer response regarding complaint, including all related evidence
- Robust approval process in place (if not already) for 100% rework, or other high re-work level processing.

Key Stakeholders

[redacted]
[redacted]
[redacted] (Sponsor)
[redacted]
[redacted]

Withheld under 9(2)(a)

Investigation of Waitoa Nutritionals using Affected WPC80

6 JUNE – 24 JULY 2013

307 6 June: [redacted] advised [redacted] that, "NZMP's Waitoa site also doesn't have SRC in the specification for their WPC80."

308 7 June: [redacted] requested [redacted] to review the Waitoa ingredient specifications before the new season started.

Gary Romano, Managing Director, NZ Milk Products, agreed with [redacted] to split the cost of the Darnum compensation claim.

Comment:
This closed the Darnum compensation claim.

[redacted] facilitated a meeting to allocate work streams for the serious event investigation into the Hautapu WPC80 SRCs. The attendees were:

[redacted]
[redacted]
[redacted]
[redacted] – Process Manager, WPC/SCUF/Lactoferrin, Hautapu
[redacted] - Quality and Compliance Support Coordinator
[redacted] - Process Technologist, Process Technical, CNI region

Withheld under 9(2)(a)

The following actions, responsible persons and completion dates were identified:

Action	By who	By when
Investigate historical rework & associated micro in Hautapu WPC80.	[redacted]	14/05
Test retention samples: Cheese WPC GW02 & GW03 and Rennet WPC GW03 & new cipher JW22.	[redacted]	Initiate by 14/05
Discuss Customer Spec with OTS.	[redacted]	14/05
Visit Hautapu Whey Plant to walk through process.	[redacted]	14/05
Assist Will to gain deeper understanding of the process.	[redacted]	14/05
Initiate problem solve with clear problem definition (How do we ensure this doesn't happen again?)	[redacted]	14/05
Provide direction on sample point placement for Hautapu Whey to include SRC testing in IPT.	[redacted]	14/05
Discuss IPT testing with Protein.	[redacted]	14/05
Send out meeting appointment to discuss follow up actions.	[redacted]	12/05

Withheld under 9(2)(a)

309 10 June: [redacted] requested [redacted] Nutritional Technical Manager, check whether the WPC80 used for nutritionals was tested before use or if there was a dedicated infant powder specification with SRCs included.

[redacted] delegated this to [redacted] Programme Manager, Multi-National Nutritional Projects.

Withheld under 9(2)(a)

310 12 June: The specification change to WPC80 (material 104579) concerning the addition of SRC testing at a limit of 100cfu/g maximum was approved and implemented. Howard at Darnum was advised.

311 14 June: [redacted] forwarded to [redacted] and [redacted], Project Lead – Formulation Performance, Nutritionals Technical, an itemised list of action points for the investigation of contaminated Waitoa Nutritionals.

- Further review of NZ based Nutritional products which use WPC80 as a raw material (from both NZ and global source), checking what WPC80 specifications are used, if they have limits already in place and clearly identify the risks and mitigation plan.
- Determine if the affected batch of WPC80 from Hautapu has been used in any Nutritionals products in NZ.
- Determine if a specific Nutritionals WPC80 specification is required with tighter SRC limit (or keep current limit on general specification), and agree a definite maximum limit with technical team that is suitable for all nutritional products.

- Determine if a risk review of other dry dairy ingredients should also be undertaken for potential contamination of SRC and of other heat stable bacteria.
- Agree if an internal SRC safety limit should be applied to nutritionals products which do not currently have SRC limit, or if current measures in place are effective enough.

312 18 June: [redacted] engaged with [redacted] from FRDC seeking [redacted] observations as to why or how SRCs may end up in WPC80. [redacted] responded with the following:

- Under normal manufacturing conditions, ie, compliance with HACCP, GMP, PSRMP's, elevated levels of SRC should not be a concern.
- Given the manufacturing process of concentrated whey products, if product does become contaminated, spore-forming bacteria will survive and be present in the final nutritional product.

313 20 June: [redacted] became aware that affected WPC80 from cipher JW17 was used in the production of infant powder nutritionals at Waitoa.

[redacted] informed [redacted] of the presence of SRCs in Waitoa products and sought input regarding testing. [redacted] advised the following:

- The elevated levels of SRCs in the WPCs that we tested earlier (for the Darnum situation) indicate a serious breakdown in process hygiene.
- From what you have said, other ciphers of WPC also contained elevated levels of clostridia.
- Developments in the microbiology of the clostridia suggest that Fonterra should be very careful when it sees such levels of clostridia and *C. sporogenes* specifically.
- It is important to be confident that the organisms are actually *C. sporogenes* and not *C. botulinum* which would pose a serious risk to infants (infant botulism).
- One option is to demonstrate whether the organisms in WPC's related to the nutritional product of other customers are in fact *C. sporogenes* and not *C. botulinum*.
- Please let us know if you wish to proceed with this and wish us to arrange: The cost would be approximately $2500, (as quoted by AgResearch) per isolate (a minimum of 3 isolates would need to be tested). It would take approximately one week to isolate the clostridia from the WPC then a further two weeks for a contract lab to perform the confirmatory testing.
- Such testing would rule out a food safety issue relating to *C. botulinum* leaving only the process hygiene / product quality issue.

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[redacted] advised [redacted] that affected WPC80 had been used at Waitoa and requested a decision from [redacted] to approve the further testing of the affected product to determine if there was a food safety risk. He highlighted the testing would isolate the clostridia and determine if it was toxin producing or not.

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314 21 June: [redacted] approved [redacted] s request for further testing including toxin testing by AgResearch. [redacted] provided [redacted] with a draft report containing recommended actions for the ongoing Waitoa investigation. Key recommendations were:

- Immediately initiate SRC, *C. perfringens*, and toxin risk analysis on Yashili FO (Follow On) powder and Abbott Saudi/Vietnam GUMP (Growing Up Milk Powder), and
- Due to the time delay in identifying affected product all three tests to be conducted simultaneously to minimise further delays.

315 25 June: [redacted] advised [redacted] that she had covered off the decision to test with [redacted] and that she would re-engage with him at a later date.

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Comment:
When interviewed, [redacted] denied that [redacted] had contacted him or that he had approved further testing. [redacted] said the first time he was aware that testing was being undertaken was 20 July.

[redacted] advised [redacted] that she had initiated testing of the Waitoa product to confirm the presence of SRCs / *C. perfringens*. [redacted] also confirmed to [redacted] that [redacted] had requested the toxin testing to be conducted in parallel to this.

316 26 June: [redacted] alerted AgResearch to prepare for testing to identify the strain of *C. sporogenes*.

[redacted] sought a formal requisition and the financial authority for clostridium toxin testing of the Waitoa product from [redacted]

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317 27 June: [redacted] provided the requisition and financial authority to [redacted]

318 28 June: Three samples of the Waitoa product were sent to [redacted] [redacted] sought approval from [redacted] to de-escalate (close off) the serious event. He reported on the key work stream outcomes:

- SRCs are not included in the WPC specification 104579.
- Ciphers JW17 and JW18 were made from 100% rework, as was JW22 (Rennet WPC).
- Product passed FTG and LTG with no issues so complaint unsubstantiated.

- Problem defined – 3 ciphers of WPC80 manufactured with atypically high SRC profile.

[redacted] identified outstanding action points which would be dealt with as business as usual.

Four of those action points were:

- Review of plant set-up for 100% rework
- Add 100% rework procedures to SOPs
- Identify potential hot-spots for SRCs in the process
- Develop testing protocol for next time 100% rework process is required

Comment:
The investigation has revealed that where a unique event such as the 100% rework of the WPC80 ciphers GW02 and GW03 occurs, the RMP requires the use of the specified change control process. In this case, the change control process was not followed.

AgResearch provided a draft contract relating to PCR and mouse bioassay testing to [redacted]

319 1 July: [redacted] approved the de-escalation of the serious event investigation.

Comment:
This closed the serious event escalation into the compensation claim and the problem-solve investigation into the rework.

320 2 July: Retention samples from Waitoa were received at FRDC.

321 3 July: [redacted] provided [redacted] with the following test results for the Waitoa affected product tested for SRCs and *C. perfringens* at the Te Rapa laboratory:

FX22C	1037	M1110-10	SRC80	340 cfu/g
FX22C	1037	M1100-01	Cperf	< 100 cfu/g
FX23A	1037	M1110-10	SRC80	42 cfu/g
FX23A	1037	M1100-01	Cperf	< 100 cfu/g

[redacted] advised [redacted] that the test results for the Yashili specification 1113 were not ready but expected them to be of a similar outcome.

322 5 July: [redacted] selected the isolates that would go to AgResearch for analysis. These were prepared over the weekend of 6-7 July.

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323 8 July: [redacted] updated [redacted] about the isolates, the anticipated toxin testing and potential outcomes, as follows:

- Did get good growth and counts in the end.
- Key types isolated and these were very similar to those isolated from the Darnum product, ie, pointing to the whey being the most likely source.
- Key isolates have been taken across to AgResearch at Massey today
- This week they will do PCR (polymerase chain reaction) based technique to look for toxin genes. If these are found then we have an answer.
- If no toxin genes then do we send the representative material to AgResearch in Hamilton next week for mouse bioassays?
- If dead mice then we have an answer – if ***no*** dead mice then we have an answer.

[redacted] delivered the isolates to AgResearch, Palmerston North.

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324 12 July: [redacted] updated [redacted] and [redacted] specifically recommending that the clostridium toxin investigation be completed to determine any food safety risk regarding the three affected batches of nutritionals products made at Waitoa.

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325 17 July: [redacted] requested an update from [redacted], asking if the PCR test for the toxin gene had been completed and when the mouse bioassay would be completed.

326 18 July: [redacted] updated [redacted] as follows:

- The PCR work at Massey (AgResearch) has been completed.
- There have been major contract issues between AgResearch and Fonterra and AgResearch will not release any results until the contract is signed – all to do with liability etc.
- We are very hopeful that this signing will happen tomorrow.
- We may have a verbal indication about the PCR work late tomorrow or Monday next week.
- Based on those results I am assuming the call will then be made on the next stage, ie, mouse bioassay.

327 19 July: [redacted] updated [redacted] as follows:

1. The contract document has now been signed so information can be shared.
2. [redacted] visited with their senior scientist last night and obtained the following preliminary information:
   a. The colony morphology of the product isolates is more comparable with *C. botulinum* than with *C. Sporogenes.*
   b. AgResearch had a difficulty extracting DNA from the product isolates which is a phenomenon more often experienced with *C. botulinum* than *C. sporogenes* isolates.
3. AgResearch's recommendation is that we should not read too much into point 2 at this stage.
4. The toxin gene work will proceed over the weekend – they have a team working until it is finished and they hope the results will be available towards the end of the weekend.
5. Unfortunately this process is slow as the AgResearch team has to work in extreme containment facilities (not surprising when the control organisms are *C. botulinum*) and only selected staff are allowed to work with these samples (OSH rules).
6. Gene expression will be confirmed through the mouse bioassay in Hamilton (according to FDA this test is required to confirm absence/presence of *C. botulinum*). This will start towards the end of next week (governed by the condition of the mice) and the results will be available 5 days post injection.
7. One important question we have is whether Fonterra has tracked <u>all</u> the whey powder, ie, irrespective of whether it has been used as an ingredient in IF/GUMP product or whether it is still in the form of WPC. Are you the one who has tabs on that?

[redacted] alerted [redacted] to [redacted] point 7 above and asked, "do you know if anyone in [redacted] team has done this traceback?"

[redacted] sought clarification from [redacted] or [redacted] on the following issues to which [redacted] replied (answers shown in bold):

- If the test over the weekend comes back indicating the likely presence of *C. botulinum* toxin what does this mean?
  - Do we get enough information at this stage to assume there is a food safety risk? **If this test is positive it implies that our contaminant is not *C. sporogenes* but a *C. botulinum* and pose a potential food safety risk for infants.**
  - Or is this just a test that indicates further testing is required? **If the test is negative we have to progress towards the FDA method (bioassay) to validate the organisms as *C. sporogenes*.**
- I understood initially that if this comes back positive, then the mouse bioassay is not required?

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This is correct, however the bioassay is the only regulatory approved method to confirm *C. botulinum* and expression of the toxin gene.

- If the mouse model begins end of next week we should have results back by 5th August latest?
  - Is there anything we can do to speed this up if the gene expression is positive? **Not really, they can only start once the mice are at an adequate weight.**
  - If this comes back negative (and the gene test was positive) what does this mean? No food safety risk?
    If the toxin gene is present but not expressed it implies that the organism has the ability to cause harm and should be deemed a food safety risk. However, this will depend on who the target consumer is.

Escalation to Critical Event of the WPC80 Contamination

20 JULY – 2 AUGUST 2013

328 20 July: [redacted] escalated the preliminary results of the clostridia testing to [redacted] and [redacted] and provided a background of what had occurred to date, along with the following key points:

- **Impact**
  - Fundamental and critical if results are pathogenic
- **What still needs to be done:**
  - Track all the whey powder ie, irrespective of whether it has been used as an ingredient in IF/GUMP product or whether it is still in the form of WPC.
  - Confirm how all communications should be managed until a clear testing outcome is available
  - Undertake preliminary business continuity planning??
- **What I need you to do:**
  - Make a call whether to escalate the issue any further at this stage or wait until more information available
  - Identify any other next steps that should be undertaken

[redacted] emailed [redacted] Quality and Compliance Manager, and [redacted] Exception Stock Lead, NZ Operations. [redacted] advised [redacted] that [redacted] would discuss the issue with [redacted] on Monday (22 July). [redacted] also advised [redacted] to discuss with [redacted] whether the issue needed escalating to a critical event when the species and counts were known from the testing.

329 21 July: [redacted] first became aware of the WPC80 contamination issue by reading [redacted] email of 20 July.

330 22 July: [redacted] emailed [redacted] and [redacted] Project Coordinator, Nutritionals Technical and requested answers to the following questions:

- That the WPC is ONLY in these ciphers and no others
- If there is any nutritionals base powders product still in stock
- Current whereabouts of the ciphers in the supply chain

[redacted] Team Lead, Product Release, confirmed the presence of SRCs as listed in the following table, by way of email to [redacted]

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Cipher	Date	Metric Tonnes Manufactured	Product	SRC (cfu/g)	C.perf (cfu/g)
FX22C	23.1.13	57.24	Abbott Gain GUMP (1-3 years)	340	<100
FX23 A/B/C	24.1.13	59.94	Abbott Gain GUMP (1-3 years)	42/8/1	<100
HX09 HX10B	9.3.13	140.92	Yashili Gold FO (6-12 months)	5/??	<100

[redacted] forwarded these results to [redacted] and [redacted] and provided additional information, as follows:

- The product isolates tested negative for botulinus neurotoxin genes A, B, E and F.
- Preparation of the extracts for the bioassay should be completed within the next 24 hours.
- The extracts will be transported to the Hamilton AgResearch facilities in time for the mouse bioassay which will be started on 28th July and will take approx 5 days.
- Approve additional costs associated with transporting the toxin extracts or delay testing a further 2-3 days and no additional costs are needed (AgResearch person will deliver the extracts)
- Initiate trace back of affected WPC80 batches (JW17, JW18, JW22) – Action Owner TBC
- [redacted] is looking at trace back options for affected GUMP/FO product that has gone to Canpac.

[redacted] confirmed with [redacted] and [redacted] that regardless of the preliminary PCR results, the mouse bioassay method was the only way to confirm the presence of *C. botulinum*.

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[redacted] initiated the formation of a critical event team.

331 23 July: [redacted] emailed [redacted] and copied [redacted] and [redacted] North Island Operations General Manager. He advised the following:

Issue

- FRDC testing of the WPC80 indicated it was suspicious for pathogenic strain.
- It would be August 5th before they would get confirmation of toxin production.
- Until then the view/advice was that it was a non-pathogenic strain.

- There were impacted ciphers from the January/February Waitoa production.

What will be done

- We will review this issue for escalating to critical event today.

- We need to get ourselves ready (where is product, recall process, what are the decision criteria, comms heads up, what is risk, when will decision be needed). On that basis it is highly likely we will go to a Critical event today.

- If positive for toxins, we will go to NZ Milk Products or Fonterra Crisis (on basis of reputation, media and possible financial impact)

- If negative for Toxins, it will de-escalate

Action required from you

Please give Gary (Romano) a heads up that the critical event is to ready ourselves, including understanding risk of waiting until August 5th for toxin result.

[redacted] advanced the formation of the Critical Event Team by providing the following information in an email to [redacted] and [redacted]

- Escalated critical event status is necessary due to the potential recall of all product and severe media exposure
- Suspicious pathogenic strain of clostridia in WPC80 product (possibly *C. botulinum*) used as ingredient for infant powder manufactured at Waitoa
- Testing conducted at FRDC has now indicated colonies of a pathogenic clostridia with the potential for toxin production
- Further testing is underway for toxin production
- The escalated critical event process will now be invoked
- An estimate of the financial impact for Fonterra

[redacted] invited [redacted], [redacted], [redacted], [redacted] Site Operations Manager and [redacted] Business Manager, to a 4:30pm conference call to review the status of the emerging issue. During the meeting the event was escalated to "Critical". [redacted] was designated the role of Critical Event Leader. The Critical Event Sponsor was [redacted]

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332 24 July: The Critical Event Team held a second meeting at 1:00pm and identified four key work streams:

- **Investigation**: [redacted], Product Safety Co-ordinator, to investigate the manufacturing of the WPC80 at Hautapu and to review the previous investigation into the affected infant base powder.

- **Product Identification/Recall**: [redacted] Quality Lead, Canpac and Waitoa, to identify the location of the affected Hautapu WPC80 and the subsequently affected Waitoa infant base powder.
- **Testing**: [redacted] to work with [redacted] and [redacted] to collate all test results and to contact the Event Leader as soon as the high priority test result is confirmed.
- **Communications**: [redacted] to communicate to stakeholders and to de-escalate or escalate as required.

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Comment:
Stakeholders did not include MPI at this point.

[redacted] completed her review of the re-work at Hautapu. In her report she made the following comment;

"The re-work was not standard work for the Whey Plant (1239). The process is not documented in the plant Rennet Whey or Cheese WPC HACCP plans and is not within the scope of the Hautapu site PSRMP. The re-work should not have proceeded"

The prepared toxin extracts were transferred from AgResearch, Palmerston North to AgResearch, Hamilton by [redacted]

That evening [redacted] verbally briefed Romano and followed this up with an email the next day.

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333 26 July: The first senior stakeholders' critical event meeting was held. Romano, [redacted], [redacted] and [redacted] General Manager Policy and Risk, were among the attendees. Although [redacted] was not supportive of continued testing, there were concerns about the impact of the issue if it was to be aired on "Campbell Live". Romano gave the go-ahead for the further testing with the mice.

334 28 July: AgResearch began mouse bioassay testing.

335 30 July: Preliminary results from the mouse bioassay testing were communicated by [redacted] Technical Manager, Food Assurance, to [redacted] and others within Fonterra.

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The results indicated some type of toxin, that may or may not be *C. botulinum*, was present. Further testing was necessary to confirm the presence of *C. botulinum*.

[redacted] ensured [redacted] and [redacted] were aware of these preliminary findings.

C. botulinum Confirmation and Notification to MPI

336 31 July: Fonterra received confirmation from AgResearch that a mouse mortality confirmed the presence of *C. botulinum* in WPC80 ciphers from Hautapu.

[redacted] immediately informed [redacted] and an appointment was made for a crisis call at 5:15pm. The call was held and led by Romano in the presence of [redacted], [redacted], [redacted] [redacted] [redacted] MPI Relationship Manager and [redacted] Director of Global Sales for NZMP.

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[redacted] suggested during the meeting the MPI should be advised and this became one of the actions which he delegated to [redacted] [redacted] further advised [redacted] that because of the seriousness of the issue he wanted it to be directly reported to MPI, as opposed to the RA, AsureQuality.

337 1 August: Fonterra began preparation of the ENC document.

At 2:08pm, [redacted] emailed [redacted], Manager Systems Assurance, MPI and [redacted], Manager Food Assurance, MPI, requesting an online meeting at 4:30pm that day.

At 3:29pm, [redacted] replied to [redacted] and advised they could not make the meeting and asked if they could talk the following day at 1:00-1:30pm.

At 4:05pm, [redacted] sent a text message to [redacted], "Hi [redacted] Just wondering if you could give me a heads up as to what you wanted to discuss?"
[redacted] replied, "Hi Paul, am still in a meeting saw your email re meeting time, currently myself and [redacted] won't make it either, will be in touch shortly."

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At 3:00pm and again at 8:30pm, a meeting of senior stakeholders was held. Attendees included Romano, [redacted] and [redacted] A key agenda item of the meeting was the current location of affected product. It was determined that most of the affected product was already in the possession of the intended customers or on hold. There was also a lot of discussion about notifying customers and finding out how the affected ingredient had been used by them.

[redacted] again raised the reporting of the issue to MPI. Romano asked what would happen once it was reported to MPI. He was advised it would go to Ministers, and would go public.
There was further discussion around notifying customers prior to notifying MPI. Romano directed that Abbott and Danone were to be advised overnight.

At 10:02pm [redacted] emailed [redacted] and suggested a time of 11:00am the following day for a meeting with MPI.

At 10:30pm, Romano called Spierings and informed him of the issue and the need for a recall.

Fonterra began contacting major customers.

Comment:
At no stage did Fonterra identify to MPI the issue or how serious it was.

338 2 August: Fonterra requested a meeting with MPI for an 11:00am teleconference call to discuss "SRC".

At 9:39am [redacted] tried to call Carol Barnao, Deputy Director General – Standards, MPI.

At 9:45am [redacted] sent a text message to [redacted] - "Hi [redacted] Heard that you want teleconference at 11:00am. We can listen but no idea what SRC is?" [redacted] replied, "Hi Paul, sulphite reducing clostridia, cheers."

At 9:46am [redacted] sent a text message to Barnao, "Hi Carol, Sorry to interrupt your leave but we have an issue you need to be aware of. We are in the process of organising a call later this morning with Tim (Knox, Director Market Approval, MPI), Mary, Paul. [redacted]

At 10:00am a conference call headed by Romano was held. There was discussion about the feedback received overnight as a result of the affected customers being advised. **Romano gave clear instructions not to report to MPI until he gave the approval.** [redacted] believed Romano issued this directive because he wanted to inform Spierings before MPI was advised.

After the conference call [redacted] received a phone call from Knox. Knox asked why the call had been delayed. [redacted] replied, "I can't talk to you until Gary has briefed Theo."

At 10:59am [redacted] Executive Advisor, sent a meeting request to [redacted] Trade Strategy Manager, [redacted] Director of Policy and Advocacy, [redacted] Manager, Global Market Access, and Knox, Barnao, [redacted] and [redacted] with the subject heading, "URGENT PLEASE NOTE CHANGE OF MEETING TIME : WPC SRC Investigation/Issue – Highly Important TO NOON TODAY".

At 11:12am Romano phoned Spierings and told him that Fonterra had not talked with MPI yet but they would be shortly.

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At 11:30am, [redacted] Fonterra Chairman, and three members of the Board – [redacted] and [redacted] – were briefed by Spierings and Romano about the issue. They also discussed potential withdrawal or recall of product.

At 11:49am, [redacted], sent an email to [redacted], [redacted] and [redacted], copying in Romano. [redacted] advised that she still not have the approval from Romano to go ahead with informing MPI.

At 11:54am, Romano replied to [redacted]'s email and stated, "Go ahead."

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

FONTERRA RMP

Work Stream Aim

340 Fonterra Hautapu like all Dairy Manufacturers must operate within an approved Risk Management Plan (RMP) registered with MPI. The RMP sets out a wide range of regulatory requirements designed to ensure food safety and market requirements are met. The RMP sets out multiple processes and actions that the manufacturer must comply with at all times.

341 The aim for this work stream was to;

- Review, identify and confirm what Fonterra's RMP requirements are for the manufacture of WPC
- Using the investigatory timeline from the WPC80 incident, overlay those events, actions and reactions to the RMP to establish whether Fonterra have complied with their requirements under their registered RMP
- If it was identified that Fonterra may have not complied with their RMP on reasonable grounds, then identify what those breaches are that would require further investigation

342 It is to be noted that this has been a complex and difficult task. Like most, there was an expectation that the Fonterra RMP was a singular document able to be pulled off a bookshelf and read. That assumption was totally wrong.

343 The Fonterra RMP is in fact made up of multiple documents numbering in the hundreds which contain many thousands of pages. Fonterra were asked to provide copies of their RMP documents to the investigation team under the examination powers contained in the APA.

344 The Hautapu RMP was requested and where that RMP referred to manuals, process documents and other referenced documents those documents were in turn requested. To give perspective to the complexity and volume involved Fonterra themselves struggled to identify the documents required and it took them a number of months to finally provide all of the relevant documents.

345 It in fact took numerous prompts from the investigation team to identify and provide the relevant documents and it was apparent that Fonterra themselves struggled to identify what documents were relevant.

346 The review of the RMP took approximately 12 weeks to complete. Initially two MPI Solicitors were deployed for four weeks to this task reducing to one MPI Solicitor for the final 8 weeks.

Introduction

347 Fonterra Limited ('Fonterra'), Fonterra Brands (New Zealand) Limited, Fonterra Excipients (NZ) Limited, Fonterra Brands (Tip Top) Limited and Fonterra Co-operative Group Limited collectively have 42 Registered Risk Management Programmes ('RMPs') listed on the Ministry for Primary Industries ('MPI') Register.

348 Of these, 29 have Fonterra Limited listed as the operator, including Product Safety RMP numbered R007 which is referred to as the Product Safety Risk Management Programme ('PSRMP') for Hautapu.

349 Pursuant to section 20(2) (a) (ii) of the Animal Products Act 1999 (APA) only an 111 page outline of the contents of the PSRMP was supplied to MPI in the application for registration of R007. The outline currently held on file is version number 22 and is stamped, 'Authorised copy of RMP under the Animal Products Act 1999' and dated 25 February 2008.

350 There is a notice of registration dated 13 June 2007, effective from 20 April 2007. When it became apparent that MPI only held an outline of the RMP our investigators had to direct that Fonterra supply us with the full RMP which we then had to wait to receive from Fonterra electronically in several disks over several weeks.

351 As a result it has become clear that Fonterra's individual PSRMP outlines are part of a Fonterra 'RMP System' containing multiple sets of documents, manuals and reference material rather than just a single RMP document or manual.

352 Annexed to this report is a 200 page synopsis of just a collection of these RMP documents and some selected non-RMP documents that were determined may be of some relevance to the investigation and/or surrounding circumstances of the WPC80 incident.

353 There are several manuals and sets of RMP documents that broadly apply across all sites, such as Systems Procedures ('SYSs'), the Fonterra New Zealand PSRMP Manual, Exceptions and Non-Conformances Manuals ('EXNCs'), Product Performance and Manufacturing Control Manuals ('PPMCs') and Quality Reference Documents ('QRDs'), formally known as Fonterra Standards of Excellence ('FSOE').

354 There are then the specific PSRMP outline, site specific manuals, HACCP Plans and Standard Operating Procedure Manuals ('SOPs') that apply specifically to each site, including Hautapu.

355 Apart from the abundance and complexity of documentation making up Fonterra's RMP system, there are also multiple versions of each document over the applicable time period that we are concerned with. For example, the RMP outline kept on file at

MPI has had 6 new versions since its registration, with the latest version, numbered version 28 and dated 9 April 2013.

356 The relevant version for the applicable timeframe that we are interested in is version 27, dated 8 December 2010. Most of the version updates were clearly not deemed significant by Fonterra as they have not attracted a significant change notification. Although it may be accepted that many of the version updates do not by definition contain significant changes it is nonetheless crucial that where an investigation or prosecution is anticipated that MPI are able to quickly and efficiently obtain the version or versions which are applicable to the relevant timeframe because that will be the document which was being referenced and followed by Fonterra at that time.

357 Perhaps more concerning is that PSRMP outline R007, and versions 27 and 26 before it are almost half of the size of the copy kept by MPI at just 55 pages.

358 An analysis of Fonterra's entire RMP system for Hautapu has concluded that the missing content was moved from the R007 outline and appears to now be contained in an RMP Manual entitled 'Fonterra New Zealand PSRMP Manual – Hautapu Manufacturing Site Specific Data'. Technically therefore the information is still within Fonterra's RMP but as we only hold an outline MPI would have no idea that it existed or where to find it.

359 A further issue that had to be worked through is that the registered outline R007 that MPI held named the RMP Operator as 'Fonterra Co-operative Group Limited' whilst versions 26 up until the latest version had 'Fonterra Limited' named as the operator as did the formal register of RMPs created and held by MPI.

360 A companies search has determined that these are different listed companies.

361 In order to determine who the correct operator is we have had to search within MPI archived folders to source the original documentation. In short, under the old system RMPs were in fact called Product Safety Programmes ('PSP') and New Zealand Milk Products had a PSP for Hautapu numbered P007 and there is a certificate of approval, as they were then, confirming the registration of this programme.

362 In June 2004 P007 received a new certificate of approval under the operator 'Fonterra Limited, formally known as New Zealand Milk Products', and when the new RMP system came into place this PSP was deemed to be an RMP until its full conversion to RMP R007 in May 2006 with Fonterra Limited as the operator.

363 It appears that a typographical error on the physical RMP outline itself (rather than in any official registration) led to the confusion as to who was the operator and that in 2009 Fonterra amended this typographical error on the outline to match the

registration. Although this has been unable to be confirmed by MPI and Fonterra have not been approached on this point.

364 For the purpose of overlaying the RMP obligations with the factual information as we know it two key topics are addressed, the first is the re-work process itself and secondly is Fonterra's RMP reporting obligations, which also covers risk assessment and elevation issues.

365 This high-level overlay should also be read in conjunction with the synopsis of Fonterra's RMP referred to above and the analysis of the Animal Products Regulations, Guidance and CODEX Synopsis which are each annexed to this report.

The RMP and the Rework

366 The rework of the 2 ciphers of WPC80, GW02 and GW03, which had originally been manufactured on the 2nd and 3rd of February 2012 occurred on the 17th, 18th and 22nd of May 2012 resulting in JW17, JW18 and JW22.

367 The rework was the result of the incident with the torch which was categorised as a foreign matter 'Category B' event.

368 What this means in relation to the RMP is that 'EXNC11: Fonterra RMP Procedure: Managing Product Safety Events' was followed by Fonterra and the exception was reported to the RA, Assure Quality ('AQ') as required. EXNC11 states that this must be, *"as soon as practicable, but no later than 24 hours after the occurrence of the exception or after the result is known by the testing laboratory."*

369 The first product disposition for the affected product was for its intended use in restricted markets but this was declined. The second product disposition for release for reprocessing including a filtration step was approved.

370 This Product Disposition recommendation from AQ to MPI identified that the rework would take place in factory 1239, which is the WPC Plant.

371 The 'Summary of Fonterra's WPC80 Operational Review' – dated 6 September 2013 and 'CEO Paper' dated 9 September 2013 ('Fonterra Operational Review') articulates why this was not possible at page 2 stating,

> *"The Product Disposition instructions for the reprocessing required wet reconstitution. The Hautapu whey plant does not have wet reconstitution facilities so a non standard process was developed. This process involved items of non-standard and little used equipment including flexi-hoses and a transfer pipe between plants. The process was unique and outside normal operation procedures for Hautapu."*

372 The 'non-standard', 'unique' and as is known now never before undertaken rework process, used on this occasion explains why there is no reference in the RMP to rework of this type and little other inclusion of any type of rework procedure for WPC80 in the RMP system itself.

373 This is other than to state in the PSRMP outline and in the HACCP plans for both Cheese WPC and Rennet Whey WPC that *"rework is reprocessed in dry form by tipping back via a hopper direct to the temporary powder storage bins."* Following this process would keep the rework within the relevant HACCP Plan for the product.

374 Whether AQ and MPI expected, on the information provided by Fonterra that the rework of GW02 and GW03 would take place in the manner as stated in the PSRMP outline and whether this was a reasonable assumption were asked of [redacted] Auditor from AQ, who was the Auditor who dealt with this incident at the time. He indicates that he only checks the PD for compliance with the Animal Products (Disposal of Non-Conforming Dairy Material or Dairy Products) Notice 2010 (No.2) that was in force at the time.

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375 [redacted] states that, "there was no need to consider the RMP when I considered the PD because they requested that it occur in a plant operated by them and I know they have RMPs". He further states he was not aware it was to be a wet rework or that the rework was to occur in two plants but even if he had it would have made no difference and he would not have altered his decision at all.

376 Following this, whether there was or should have been knowledge on behalf of AQ and MPI when the product disposition for the rework was approved that it could not have taken place in the WPC plant due to the requirement of reconstitution, is a separate consideration.

377 It is understood from conversation by our investigators with [redacted] (Hautapu Plant Manager) that the rework operation, with its change of pipe work, addition of hoses, by-passing of tanks and chillers, was not deemed to be a significant change to premises by either Fonterra or AQ. This was mainly because the SCUF plant is a development plant where the equipment and processes were routinely changed. Such a statement implies some degree of knowledge or at least discussion between AQ and Hautapu on the process that was to be used for the rework.

Withheld under 9(2)(a)

378 It is indicated in the 'Report of WPC80 Independent Inquiry for Fonterra Board' – 23 October 2013 ('Fonterra Board Inquiry Report') that there was discussion of section 3.5 of FSOE08 Good manufacturing Practice and ensuring that the plant had considered each point under that section and have documentation recording what they did. Section 3.5 is entitled rework controls and states that;

"all rework (including tipping, blending, re-processing and re-packaging) shall be included in the manufacturing operations HACCP Plans. Consideration shall be given to:

- *Limitations on amount of rework to be used;*
- *Acceptance criteria;*
- *Conditions of storage;*
- *Reprocessing steps;*
- *Identification of allergens;*
- *Use in like-labelled products;*
- *Age limitations;*
- *Special handling requirements;*
- *Lot number identification for traceability."*

379 As is stated above, rework must be included within the applicable Hazard Analysis Critical Control Point Plans ('HACCP Plan'). This is in light of the Fonterra New Zealand PSRMP Manual and PPMC06 'HACCP Management Document' which specify that the processes in the site-specific PSRMPs are operated under HACCP.

380 The requirement in PPMC06 is for all HACCP plans to comply with the requirements of CODEX and FSOE 03 which describe how Fonterra applies CODEX.

381 There is a HACCP plan in place for Hautapu Cheese WPC and another for Hautapu Rennet Whey WPC and for completeness the SCUF HACCP was also obtained. HACCP is referred to in each plan as *"a systematic and science based method for identifying and controlling specific hazards to ensure the safety of food."* HACCP is considered crucial to the operation of a successful RMP.

382 FSOE08 is part of Fonterra's RMP and if it is accepted that consideration was given to it by the Fonterra staff undertaking the rework of the WPC80 in this case, then it should have raised concerns.

383 First, because of the unique and never before attempted nature of this rework which took the process across two different plants it should have been clear that there was no single HACCP Plan in place to cover this.

384 Secondly, the rework capability of the WPC Plant 1239 appears to be limited to smaller quantities of dry powder and there is further suggestion in email traffic obtained from Fonterra staff that a 100% rework was not usual and that 10% would normally be the amount for 'powders'.

385 Third, a consideration of the fourth bullet point in paragraph 377 would have raised the unusual nature of the reprocessing steps that were to be undertaken with the inclusion of the temporary flexible hosing and not often used fixed pipe, a process not covered by Fonterra's Standard Operating Procedures.

386 A full and proper assessment of the rework process to be employed should have highlighted the unusual practice and degree of change required in creating this new process, which follows into discussion over a further procedure also included in Fonterra's RMP.

387 There is a systems procedure called SYS19 'Fonterra RMP Procedure: FTO Change Control' and the applicable version is numbered 4, dated 22 July 2011.

388 The purpose of this document is to describe the formal procedure for the management and control of changes and applies to all of Fonterra New Zealand Operations. A full outline of this document is set out on pages 117 – 119 of the annexed RMP synopsis.

389 It requires that any changes that have *"the potential to introduce a new, or increase an existing, health and safety hazard or could affect product quality"* to be approved using the change control system prior to the change being made.

390 Attachment 1 to SYS19 is a Change Control Checklist which gives guidance on when a Change Control is required and includes the following examples:

- Any activity outside Standard Operating Procedures
- Non Standard equipment replacement
- New Equipment Installation
- Changes to any utilities which may influence the product and/or process
- Changes to processing, e.g. new or modified process step
- CCP changes or PCP (Process Control Points) changes
- Changes to cleaning procedures
- Changes to product/plant alignment

391 The document is also clear that *"if there is any doubt as to whether or not Change Control is required, a change request should be raised"*.

392 Following detailing of the change request this procedure then requires a risk analysis action plan to be created which in turn requires a risk assessment to be undertaken with the assistance of any appropriate subject matter experts.

393 It is mandatory that at least one risk is identified and a corresponding mitigation action proposed. Section C requires a stakeholder analysis which involves identifying the departments that need to be part of the approval process and in this respect there is a 'Change Control for Review and Approval Matrix' which is found at attachment 2 to SYS19.

394 The level of authority for approval required corresponds to the potential risk level. It is difficult to determine what approval would have been required in this case because as it is understood no change control process was followed and therefore no risk assessment was made.

395 However, at the lowest level of risk of a Product/Safety or quality issue the approver is the Site Product Safety Quality Assurance Coordinator. A significant risk involves the Regional Product Safety/Quality Assurance Manager and a high risk would need approval from the Product Safety/Quality Assurance Manager.

396 There is nothing in [redacted] description of the rework process or on the rework instruction showing that this change control process was followed when the product was reworked.

397 The rework instruction document is a single page which states how the WPC would be processed but does not show any consideration of change control, risk assessment nor mitigation actions. It is possible that [redacted] considered that a change control process was not required because the rework followed a reconstitution process that she describes as *"that we use on a daily basis when we manufacture a product called Hydrolysate."*

398 This understanding could be why operational recommendation 3 at page 10 of the Fonterra Board Inquiry Report calls to *"[i]mprove understanding of, and criteria for, change control procedures when any non-routine use is made of equipment used in relation to nutritional products and their ingredients."*

399 The General Manager for Operations in the Central North Island, [redacted] was asked about the rework and whether any change control process was used in this case. He responds that;

> *"We had a system where we go through and describe what the change is and we require individuals to comment on it and either approve or decline the change. Today this change control process would have happened at the start but back then it was a new process and hadn't been implemented fully. It wasn't mandatory in May 2012 as it had only been introduced 6 months before that. Back then not every rework was considered a change control – now it is. It doesn't matter how big or small the rework is now."*

400 When asked how the change control process relates to the RMP he answers that *"it's all part of the HACCP Plan. The change control would have a line asking 'is it covered in the HACCP Plan'."*

401 In relation to his comments that the change control process had not been implemented, this is not supported by the documentation we have which for the

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relevant period is version 4, dated 22 July 2011. His additional comments about the change control process being tied into the RMP through HACCP shows a misunderstanding of the interrelation of HACCP and the change control documentation and tends to suggest that he was not aware of the actual RMP documentation entitled SYS19 Change Control.

402 As the Fonterra Operational Report finds at page 5, *"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."*

403 This is reinforced in the Fonterra Board Inquiry Report's main findings in relation to the rework process where they make the following comments,

- *"...There were process errors in relation to the May 2012 rework of the relevant WPC80 batches."* (paragraph A3)
- *"The "wetting" part of the rework, necessary to achieve the very fine filtration sought, was not a normal operation for WPC production and required some improvisation inside the scale-up facility (SCUF) and whey plants."* (paragraph B9)
- *"one stainless steel pipe that had not been used for over two years, and two flexible hoses not used in the usual production processes."* (paragraph B9)
- *"did involve a departure from appropriate risk management processes for the improvisations developed for the wet reworking process."* (paragraph B10)

404 The Fonterra Board Inquiry Report summarises these points at page 59 when it states;

> *"Nevertheless, the failure to identify in PD#2 both plants and, in particular, the process that was employed to link them undermined the regulatory safeguard. It was also indicative of the Hautapu plant not sufficiently engaging with the novel nature of the process that was being proposed."*

405 As the rework procedure involved a process not undertaken before, then the RMP documentation does not contain a standard operating procedure that would have outlined the cleaning and hygiene aspects and procedures applicable in this case.

406 Therefore it is understood that the procedures followed were those applicable to each plant, 1239 and 1282. The question of whether this was sufficient in relation to the process adopted is not one that the RMP can answer but what is clear is that had a change control process with a risk assessment taken place then it is possible that one of the risks identified could have related to whether the processes used, including the Clean in Place that were done, would be adequate for what was occurring.

407 As the Independent Review states in its operational recommendation number 4 that Fonterra revise operational cleaning in place programmes to address the desirability

of acid washes for pipes and equipment that have been unused for 24 hours or more." (pg10)

408 In conclusion, the change control process contained within the RMP was required to be followed by Fonterra in the circumstances of the reworking of GW2 and GW3 because it involved a unique procedure not previously undertaken, with a change of normal re-working process for WPC80, and the use of non standard equipment and a fixed pipe that had not been used for approximately 2 years.

409 Had a change control process been adopted then a risk assessment would have been mandatory and in relation to this rework could likely have included identified risks surrounding the unusual and new process, quantity and percentage of product to be reworked, the awareness that the SCUF plant had high SRCs already, the use of temporary flexible hosing and the use of a fixed pipe that hadn't been used for approximately two years.

410 It is not clear however whether identification of these risks would have changed the ultimate outcome and to what level approval would have required to be sought.

The RMP and Reporting/Notification Requirements

411 Fonterra's RMP was analysed in relation to any obligations to report to either AQ or MPI on any food/product safety issue, or otherwise.

412 It was also examined for any guidance on when the reporting obligation under section 51 of the APA to notify the Director-General of an exporter non-conformance ('ENC') would arise and in relation to the escalation process that Fonterra did, or should have, followed in a sequence of events such as those they faced here.

Reporting Generally

413 According to PSRMP R007, as the processes covered within, involve the management of primarily edible grade product then the expected outcomes are those covered in 'PPMC12 Product Safety Testing Requirements for NZ Origin Products' and any importing country testing requirements.

414 PPMC12 describes the product safety limits and minimum product safety testing requirements that apply to all Fonterra Limited NZ origin dairy products in accordance with Dairy Processing Criteria 1 ('DPC1').

415 It further states that the Plant Manager is responsible for the raising of exception reports under EXNC11 and that it is Fonterra Customer Service Personnel who are responsible for the raising of ENC's.

416 This document also sets out that dairy material for further processing in a Fonterra Premises shall not contain *"microbiological contaminants at a level that may result in the dairy product not being safe or otherwise fit for its intended purpose following manufacture..."* and that the New Zealand microbiological limits is the tighter of either, *"the pathogenic micro-organism criteria from DPC1 or the microbiological criteria from Food Standards Australia and New Zealand Standard 1.6.1."*

417 Attachment 1 to PPMC12 includes a spreadsheet that combines these for the limits that apply to each type of product. SRCs are not included anywhere on the spreadsheet. This is the overall theme of Fonterra's RMP, that unless the microbiological organism is one that is referenced by DPC1, food standards or an importing country requirement then they do not have to test for it and will only do so if it is a customer requirement.

418 The Fonterra New Zealand PSRMP Manual contains a section on product safety reporting to the verified agency and states that *"the following exceptions are notified: significant concerns about the fitness for intended purpose of dairy material or dairy products..."* It further states that all reporting must be in accordance with the MAF requirements and reference is then made to EXNC11 'Managing Product Safety Events'.

419 The set of documents entitled EXNCs provide the majority of content surrounding the reporting obligations. EXNC06 'Fonterra Dispositions' and EXNC07 'FTO Product Dispositions' cover the processes surrounding disposal of product both within Fonterra control that fails to meet sample identity, has been incorrectly graded, requires tight control to ensure it meets product identity and importing country market access requirements or needs to be micro managed to a specific market or customer (EXNC06) or disposal of product *"suspected to be unsafe, not truthfully labelled or defined as non-conforming for any other reason by MAF"* (EXNC07).

420 All product that is unsafe, deemed to be non-conforming as defined in DPC1, not correctly labelled or does not meet identity requirements must have a formal disposition approved by MPI or the RA before disposal occurs.

421 Attachment 17 to EXNC07 outlines preferred disposition responses and includes breaches of critical control points, foreign matter contamination events and dairy product not meeting regulatory limits. Again, this reflects why a product disposition was obtained for the torch foreign matter event but the list does not include SRCs or *C. botulinum*.

422 EXNC11 'Managing Product Safety Events' states its purpose as to *"ensure product safety events are managed in accordance with the approved PSRMP with appropriate reporting to relevant Fonterra personnel and that any reports submitted to the RA are in a consistent format with all relevant data included"*.

423 It places the responsibility for determination of the category of an event, the preparation of any product disposition and communication with the RA with the

Fonterra Quality Team with the initial exceptions having been reported to the Quality Team by the Department Manager operating a PSRMP.

424 There are 2 categories of event categorisation, Category A exceptions are dealt with internally by Fonterra and Category B exceptions must be reported to the RA as soon as practicable, but no later than 24 hours after the occurrence of the exception or after the result is known by the testing laboratory.

425 Attachment 1 to EXNC11 details by way of spreadsheet several types of event along with their categorisation and the actions required. The foreign matter event with the torch fell within a category B exception and that is why it was reported to AQ as it was. It is noted that for some exceptions an ENC is generated and those examples state ENC on the spreadsheet and will only generate an exception report if affected product is still within New Zealand.

426 If product has left New Zealand then the procedure is that under EXNC12 'Managing Exporter Non-conformances for New Zealand Origin Dairy Products'. Fonterra do not consider this document as forming part of their RMP. There are two possible explanations for this non-inclusion, one is that this type of reporting is directly covered by the APA and therefore does not need to be part of the RMP directly. The other is that it involves product that has left New Zealand and therefore considered not covered by the RMP.

427 [redacted]

Withheld under 9(2)(h)

Reporting in Relation to the High SRCs/*C. botulinum*:

428 It was on 2nd August 2013 that Fonterra briefed MPI by telephone of the positive result for *C. botulinum* in three batches of WPC80. There are two possible ways in which this could have been reported to AQ or MPI, either as an exception report as a result of being categorised as a category B event under EXNC11 or as an ENC under section 51 of the APA.

429 [redacted]

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430 In relation to microbiological results, according to Fonterra's RMP procedure under EXNC11 an Exception Report will only be generated where the microbiological contamination is in excess of product safety limits, which by Fonterra definition appear to only include limits outside of those in DPC1 or standard 1.6.1 of the Australian New Zealand Food Standards. Therefore, this part of the RMP does not require an exception

report for high SRCs or arguably even for *C. botulinum*, given that neither have a product safety limit.

431 However, a breach of a microbiological limit is not the only cause for an exception report. A failure to identify when dairy material or dairy product is non-conforming or a failure to stop a non-conformance or allowing product to be released when it is not fit, or may not be fit, for human or animal consumption are all category B procedural failures according to EXNC11.

432 The definition of Non-conforming under the Animal Products (Dairy Processing Specifications) Notice 2011 is "*any dairy material or dairy product that is suspected or known not to meet regulatory requirements or not to have been processed in accordance with regulatory requirements.*"

433 There is further discussion on this point in relation to the rework below but for the purposes of the SRCs and *C. botulinum* it may be possible to show that the WPC80 did not meet regulatory requirements because of this contamination (albeit a false positive for the *C. botulinum*). [redacted]

434 The notification to Fonterra of the high SRCs was as a result effectively of a customer complaint from Fonterra Darnum Australia to Fonterra New Zealand (if they could be considered a customer of Fonterra New Zealand). Fonterra New Zealand have an RMP procedure for customer complaints EXNC 'Managing Customer Complaints' which uses a risk matrix for escalation based on the consequence of the complaint in terms of health and safety, media/reputation, food safety/product quality, customer/market impact against the financial impact.

435 This assessment determines a colour green, orange or red and internal processes surrounding managing the complaint. However this document does not provide any guidance on when notification should be made to either the RA or MPI on the basis of a customer complaint and therefore again the RMP does not support an exception report on this basis.

436 In conclusion, Fonterra's RMP reporting requirements meant that only microbiological contamination which was in excess of product safety limits had to be reported to AQ and as SRCs were a customer requirement and not covered in either the RMP, DPC1 or the Food Standards then there was no obligation under this aspect of Fonterra's RMP to report the high SRCs.

437 Whether Fonterra had to report once the *C. botulinum* testing and results were known and at what stage in that process depends on the legal analysis of whether the WPC80 could be considered non-conforming or not fit for intended purpose, generating either a category B exception report or an ENC.

Reporting in Relation to the Breach of RMP Process – Not following 'change control' for the rework:

438 The conclusion above is that the rework procedure did not follow the RMP change control process and was not covered by a HACCP Plan and therefore that Fonterra have breached the obligations under their RMP.

439 A further question to ask is whether there was also a reporting obligation in relation to this breach and if so when this should have arisen.

440 Fonterra RMP document PPMC06 'HACCP Management' requires in its rules that *"if a process is not being operated in accordance with the approved HACCP plan, or if records are not available for verifying compliance, then an exception report must be sent within 20 hours."*

441 There is then a reference to EXNC11 'Managing Product Safety Events', which has been outlined above. Effectively, not operating in accordance with a HACCP Plan is the same as acting outside of an RMP, as is not following the change control procedure which was outlined above.

442 According to EXNC11 it is a procedural failure when "*product intended for export has been processed (including transport and storage) outside an RMP or outside the boundaries of the Animal Products Act..."* A procedural failure of this sort requires either an exception report to the RA or if the product is outside of New Zealand an ENC to MPI directly under section 51 of the APA.

443 On the face of it, accepting the above that the rework failed to follow a change control process and was not in accordance with a HACCP Plan and therefore in breach of the RMP, then a further breach of the RMP has occurred in a failure to raise either an exception report to AQ or an ENC to MPI once it was realised that the product had failed to be processed in accordance with the RMP.

444 The difficulty with this conclusion is determining at what point this notification should have occurred and whose obligation it was.

445 EXNC11 places the obligation to determine the category of an event and to notify the RA on The National Quality Team. The National Quality Manager, who at the relevant time was [redacted], is responsible for verifying that exceptions are category B and ensuring escalation to critical event when appropriate.

446 According to the Serious Event Manager, [redacted] who is a Technical Team Lead for Fonterra, the high SRC event was categorised as a serious event and he took over this role from [redacted] on 4 June 2013. [redacted] and [redacted] were

sponsors of the event and three escalation end-points, or objectives, were defined. The third of these was to look at the process involved in the rework at their plants.

447 He confirms that there was no Standard Operating Procedure or HACCP Plan for rework and so these were subsequently implemented. Each of the 3 objectives was looked at and concluded and the event was de-escalated with [redacted] approval. However, on 31 July 2013 he was contacted and instructed that the matter had been reopened as a critical event but with a different focus.

448 During the serious event timeframe there are a series of emails indicating an awareness that the rework procedure was not done properly or in accordance with the proper procedures. [redacted], Director Operations & Supply Chain, emails [redacted] and [redacted] on May 31 and comments on key points arising from a discussion that was had with [redacted] and [redacted]

449 These comments include, *"the fact that these ciphers were manufactured from 100% rework may be significant. This is a non-standard manufacturing process and there is the possibility that SRCs may have come from flexi hoses (or even the demineralised water used to reconstitute the WPC80."*

450 A further email from [redacted] to [redacted] states, *"Who authorised 100% rework? Is level limited in WPC (powders has 10% max)? Are rules enforced? Did it follow change control? Who approved from technical and did they do an adequate risk assessment?"*

451 There is reference to [redacted] questions being answered in an email attachment and confirming that the 100% rework was not a standard manufacturing process but we do not have a copy of this to confirm.

452 However, on the face of it the indication is that there was an awareness within these individuals that the rework was not done in accordance with correct procedures and given [redacted] is a Manager within the team responsible for determining event categorisation and notifying the RA under EXNC11 this supports a conclusion that there was knowledge available with sufficient scepticism of the process having not followed the RMP that should have involved notification.

453 Had this occurred then the affected product in New Zealand would have been placed on hold pending a product disposition and for the product overseas an ENC should have been generated which would have allowed MPI to have worked with Fonterra to establish the appropriate response and to commence trace back following the procedures outlined in EXNC12 Managing Exporter Non-conformances for NZ Origin Dairy Products.

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454 It is of note that had it been followed then the change control process in itself did not require notification to the RA but there is another RMP document entitled PPMC03 'Fonterra Operations: Project/Plant/Process change approvals' which does require approval of the RA for new and/or significantly changed equipment and/or premises. Although the definition of significant change is *"any change made to environment, premises, equipment, facilities, process, or product that may affect food safety"* read as a whole the document appears directed to permanent structural type changes rather than temporary changes to equipment or process that are covered by the change control process.

455 The conclusion on this aspect is that Fonterra had an obligation under their RMP to raise an exception report for the product within New Zealand and an ENC for the WPC80 product which had left New Zealand at the point that it realised that the product had not been processed in accordance with the RMP.

456 There is however much work to do in establishing the point in time of this knowledge and once again the question of whether AQ were aware that the rework had occurred outside of the RMP change control process becomes very relevant should prosecution be anticipated.

Event Categorisation and Escalation

457 Categorisation in regards to category A, B and ENC's has been dealt with above and relate to the external reporting obligations of Fonterra. This section looks to the parts of the RMP that deal with the categorisation of serious events, critical events and crisis.

458 According to the Fonterra Operational Review a Critical Event Team was formed on 26th July and on 31st July a Crisis Team was put in place. Although the Independent Review agrees that the elevation to a 'Crisis' occurred on 31 July, they say, as a result of the advice from AgResearch around midday of the positive Mouse Bioassay result for *C. botulinum*, they put the date of formation of the critical event at 22 July 2013. Prior to this escalation there is indications that the high SRCs had been categorised as a serious event' in around late May or early June.

459 According to EXNC11 'Managing Product Safety Events' the National Quality Manager is responsible for ensuring escalation to critical event when appropriate and EXNC26 'Critical Event Procedure' is then referenced. Fonterra's RMP procedure EXNC14 'Event Escalation' process shows a flowchart for escalation which is also based on the colour coded risk assessment referred to in EXNC13 'Managing Customer Complaints'.

460 There are several factors that impact the assessment for evaluation including financial impact, reputation, management effort, customer/market impact, recall and product quality/safety.

461 The Critical Event Procedure is covered by EXNC26 'FTO Critical Event Procedure' but determines that EXNC14 must first be used to determine that the event is deemed 'critical'.

462 The Critical Event procedure outlines the internal escalation process and no reference is made to external escalation or reporting. It is also of note that version 1 of this document is only dated 13 April 2012 and therefore it is not certain that this procedure was adopted at the relevant time and it is to be read in conjunction with a non-RMP manual 'Fonterra Critical Event Manual' which was created around the same time.

463 There is also EXNC32 'Non Critical Event Procedure'; version 1 dated 17 January 2013, which again outlines the internal procedure and escalation for events that are classed in this category.

464 The purpose of EXNC22 'Fonterra Operations Food Safety Business Continuity Plan' is to provide guidelines for ensuring that product events which may threaten the integrity of Fonterra are classified as crises and handled accordingly. It states in its rules that;

> *"Where a non-conforming product has caused, or has the potential to cause, sickness, injury or death the following people shall be immediately notified, the Managing Director Fonterra Global Ingredients & Foodstuffs, the Managing Director Trade and Operations and the Chief Executive Officer."*

465 It further states that the Manager Product Safety/Quality Assurance will notify NZFSA (MPI) of the situation "*as appropriate*" and latter in discussion over the role of the Crisis Team it reiterates this point by stating, "*as required*" notify NZFSA (MPI)

466 An interesting aspect of this process is that Fonterra have defined non-conforming product as "*product that is suspected or known not to meet NZFSA regulatory requirements including food safety and truth of labelling*" and reference is made to DPC1. This is a similar definition to that contained within the Animal Products (Dairy Processing Specifications) Notice 2011 and already outlined above, which states that it means, "*any dairy material or dairy product that is suspected or known not to meet regulatory requirements or not to have been processed in accordance with regulatory requirements.*"

467 It is on this basis that Fonterra would have defined the positive *C. botulinum* result as falling within the definition on non-conforming product which met the further definition for a crisis situation to ensue. The further question is whether this should have occurred at an earlier point in time but the RMP does not provide any further assistance in this respect.

468 In summary, the event categorisation RMP documents provide Fonterra with guidance on assessing for the purposes of an internal escalation process where an event falls in regards to the factors listed. Other than possible notification when a crisis has occurred they do not provide direct guidance or instruction on external escalation or reporting to either the RA or MPI, this being covered by other documentation within the RMP.

469 On that basis, whether and when Fonterra classified the event as serious, critical or crisis, does not appear to have a direct bearing on when it should then report to AQ or MPI as that assessment is being made independently on a different basis, namely, whether the event generated either an Exception Report or an ENC.

Conclusion

470 In conclusion the assessment of the RMP has resulted in establishing reasonable grounds to believe that 3 breaches of the RMP have been committed by Fonterra Limited, the operator of the RMP in that;

471 They failed to comply with the RMP, namely, in not having an appropriate HACCP Plan in place and failing to follow SYS19 'Change Control' process when it reworked ciphers GW02 and GW03 in the manner they did on 17, 18 and 22 May 2012.

472 That Fonterra failed to comply with the RMP, namely, EXNC11 'Managing Product Safety Events', by failing to notify AQ or MPI once they became aware that the WPC80 product had not been processed in accordance with the RMP.

473 It is further possible, depending on the legal analysis of non-conforming product and not fit for intended purpose, that there may be reasonable grounds to suspect a third breach of the RMP by Fonterra Limited the operator in that;

474 They failed to comply with the RMP, namely EXNC11 'Managing Product Safety Events', by failing to notify AQ or MPI once they were aware that they had failed to identify non-conforming product or failed to prevent that non-conformance or release product that was not, or may not be, fit for intended purpose.

475 This third breach is technically more difficult than the first two as it relies on the WPC80 being deemed non-conforming and based on the report of Dr. Roger Cook in relation to the SRCs and the false positive for the *C. botulinum* this could prove quite difficult. [redacted]

USE OF ACCREDITED LABORATORIES

Work Stream Aim

476 To establish that the laboratories used by Fonterra for tests conducted as part of the WPC80 incident were accredited to conduct that work.

Laboratories, Monitoring Programmes and Testing for Dairy Products

477 The Animal Products Act (APA) provides that dairy products must be safe and suitable for their intended purpose. Food safety risks are managed through a range of measures including Risk Management Programmes, and export controls. Dairy product exported from New Zealand must meet all NZ domestic regulatory requirements, as well as any specific requirements stipulated by the overseas country.

478 Risk Management measures include the monitoring and testing of dairy products under the following programmes;

- National Chemical Contaminants Programme (NCCP) which tests for a wide range of agricultural compounds and veterinary medicines in dairy products and milk.
- Independent Verification Programme (IVP) which verifies the accuracy of commercial testing

479 Testing is carried out by laboratories specifically recognised by MPI for this work. Dairy products are tested to prove they conform with;

- New Zealand minimum food safety requirements
- Overseas Market Access Requirements

480 Dairy laboratories are divided into two categories:

481 Category 1 laboratories test dairy product and material intended for domestic and export markets and are recognised by MPI for testing to demonstrate that the product:

- Is fit for purpose including food safety, wholesomeness, and standard of identity or truth of labelling
- Meets specific requirements for overseas markets

482 Category 2 laboratories are laboratories that belong to an animal product business and are recognised by MPI for testing the business's dairy material including raw milk that is intended for the domestic market to demonstrate that the product:

- Is fit for purpose for sale in New Zealand, including food safety, wholesomeness, and standard of identify or truth of labelling
- Meets requirements set out in the company's Risk Management Programme for internal quality control and Good Operating Practice.

483 All category 1 laboratories are required to meet the requirements of ISO17025 as they apply to the testing of dairy products and these requirements are published by International Accreditation New Zealand (IANZ)

484 Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body. The standard is about competence, and accreditation is formal recognition of a demonstration of that competence. A prerequisite for a laboratory to become accredited is to have a documented quality management system.

485 All Fonterra labs are recognised by MPI and are accredited Category 1 laboratories operating to NZS ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

486 Individual Fonterra laboratories are accredited to carry out a range of testing with some laboratories accredited to carry out chemical testing of dairy products, some for microbiological testing, some for micronutrient testing, and with most accredited to carry out a combination of testing.

487 MPI maintains a searchable list of all dairy laboratories.

488 In regards to the Clostridia testing and in particular the mouse bioassay testing, requirements are uncertain. ISO/IEC 17025 set general requirements for the competence of testing and calibration laboratories.

489 FRDC have this accreditation but not for *C. sporogenes* testing or *C. botulinum* testing. AgResearch also have this accreditation also, but not for *C. sporogenes* testing or C. *botulinum* testing.

490 The MPI microbiologist Dr. Roger Cook was queried regarding requirements and he suggested that this is a red herring. AgResearch and FRDC are well resourced research laboratories with highly competent staff. So the fact that they are doing a test that they are not accredited for does not immediately invalidate the results. MPI uses ISO 17025 accredited laboratories for mainly regulatory assurances i.e. has a product that is going to export market been tested by an accredited laboratory.

491 It would be more important to ensure the method used meets the criteria for the gold standard in CB testing, the 'US FDA Bacteriological Analytical Manual for CB'. In the case of the WPC, AgResearch were found to be wanting in some aspects when the comparison was made.

492 So the fact that they are doing a test that they are not accredited for is not so important, more the fact that they did not follow the method properly.

493 In conclusion it does not appear that Fonterra Laboratories or AgResearch have breached any requirements but the work of AgResearch when compared to 'US FDA Bacteriological Analytical Manual for CB' was found wanting.

MICROBIOLOGICAL ADVICE

Work Stream Aim

495 The microbiological knowledge of the investigation team was limited and it was considered critical that suitable advice and support was available to guide the thinking of the investigation team in understanding the microbiological aspects and international best practice regarding food safety.

496 The aim for this work stream was to;

- Understand relevant microbiology in the dairy food sector
- In terms of SRCs, does Fonterra manufacture using best practice
- Understand the risks SRCs pose
- Understand why SRCs are not tested for
- If SRCs can ultimately lead to Clostridium Botulinum, why is there no concern with SRC detection
- Did Fonterra act in a responsible manner once SRCs were detected

What Are SRCs

497 SRC is an acronym for sulphite reducing clostridia and is a subset of bacteria known as sulphite-reducing anaerobes.

498 Clostridium is a genus of Gram-positive rod shaped bacteria (i.e. cells that stain purple by Gram's stain) and are obligate anaerobes (i.e. they grow in the absence of oxygen).

499 They are capable of producing spores which not only allow survival of the bacteria in harsh environments (e.g. dry powders, the acid gut of humans and animals, soil etc) but also during commercial and domestic cooking. The spores are, however, sensitive to the higher temperatures achieved in retort processes (e.g. canning) and ultra-high temperature (UHT) processing.

500 SRC are ubiquitous environmental organisms that are found all around us including in soil, decaying vegetation, marine sediment, and the intestinal tract of humans and other vertebrates.

501 Generally most SRC are innocuous or cause food spoilage under certain conditions.

502 SRC testing is quantitative using traditional bacterial plate counting techniques; the results reported as colony forming units (cfu) of viable bacterial cells and/or spores per gram for solids or per ml for liquids. Dead cells are not included.

503 In general, bacteria and spores in the sample will suspend individually and each resulting colony on an agar plate is representative of one bacterium in the sample. Samples are usually shaken vigorously to break up clumps. However, on occasion some bacteria in some matrices will remain clumped and one colony on a plate may have originated from several bacteria. To cover this possibility, microbiological results are reported as cfu rather than an actual count and replicates are usually performed.

504 Sulphite reductase activity is a common property among clostridia that is found in only a few other bacteria capable of growth under anaerobic conditions and on the selective agar media used for clostridia. Ferric ammonium citrate is added to the bacterial growth medium and when bacterial growth occurs, iron sulphide is produced and the colonies acquire black pigmentation. Sometimes the growth media turns black.

505 Black colonies on these agars are generally called SRCs, but could be any or all of the 21 different species of Clostridium, including:

- *C. perfringens*
- *C. botulinum*
- *C. septicum*
- *C. sporogenes*
- *C. beijerinckia*
- *C. butyricum*
- *C. bifermentans*
- *C. haemolyticum*
- *C. novyi*

506 Speciation of clostridia requires the performance of a range of diagnostic tests from simple biochemical assays through to complex molecular biology procedures. The mouse bioassay may be required for confirmation of the identity of *C. botulinum*.

507 Some species are known pathogens such as *C. perfringens*, *C. botulinum*, *C. septicum* and *C. tetanus* but only *C. perfringens* and *C. botulinum* are recognised food borne pathogens, albeit usually only when there is serious processing failure (e.g. poorly cooked and cooled meat products or poorly fermented home preserves) or when consumed by susceptible populations (e.g. infant botulism).

508 SRC testing is not intended for food safety, rather it is an indicator for food hygiene and to help determine where any identified contamination originates. The observation of elevated SRC results should cause a plant operator to respond through trace back and review of plant cleaning.

509 The detection of SRC has been used extensively in food microbiology as either an indicator of human faecal contamination, quality of raw materials especially milk when animals are exposed to poor quality silage or bedding, and/or a process control indicator related to potential growth and survival of anaerobic spore-forming bacteria.

510 *C. sporogenes* is generally considered an environmental bacterium that is not pathogenic for humans, although on rare occasions it has been associated with illness in susceptible persons and septicaemia in immuno-suppressed patients. Such cases are considered opportunistic and unusual, and should not be considered normal when assessing food safety.

SRC Standards

511 The only limits for SRC currently used in trade range from a regulatory limit of the Russian Federation of 25-100 cfu/g for import of dairy derivatives, including milk proteins and advisory maximum levels of 10-25 cfu/g in the United States of America, Algeria AMF(n=5, c=2, m=9, M=not stated) Powders (M=10).

512 Countries have generally used quantitative 3-class microbiological criteria for *C. perfringens* which is a minor subset of SRC. SRCs are present in many uncooked foods and, because SRC spores survive cooking, they are also in cooked foods.

513 The New Zealand Ministry of Health (MOH) describe guidelines, but not standards, for *C. perfringens* in;

- Cooked meat/poultry products and other cooked foods that are ready to eat or require minimal reheating, gelatine, herbs and spices (/g) n = 5, c = 2, m = 10^2, M = 10^3
- Dried and instant baby foods (/g) n = 5, c = 1, m = 10, M = 10^2
- Vac-packed meat, pudding powders, dried soups (/g) n = 5, c = 2, m = 10, M = 10^2
- Powder for infants (/g) n = 5, c = 2, m = < 1, M = 10

n = number of samples to be chosen randomly and independently and randomly from the lot.
c = maximum allowable number of sample units yielding results between m and M
m = a microbiological limit that separates good quality from marginal quality
M = a microbiological limit about which results are unacceptable or defective

514 MPI administers these guidelines.

515 While there are no microbiological criteria for *C. perfringens* in dairy products in the Food Standards Australia New Zealand (FSANZ) Food Standards Code, Standard 1.6.1 *Microbiological Limits for Foods*, associated guidance criteria are described for both sterilised milk powder and powdered infant formula of n=5, c=2, m=< 1, and M=10.

516 In comparison, the microbiological criterion (cfu/g) for powdered infant formula in Canada is $m=10^2$, $M=10^3$. This is currently under review to determine whether it should be excluded in accordance with the recent Codex Alimentarius Commission (CAC) revision.

517 The International Commission on Microbiological Specifications for Foods recently indicated that under certain circumstances monitoring for SRCs could be used as a hygienic processing indicator, and if so, proposed a SRC threshold of 100cfu/g for powdered infant formula.

518 Determining what can be considered a high SRC level is difficult as it depends upon:

- the establishment of robust baseline levels in a product over an appropriate period of time so trends can be monitored
- the potential for multiple sources of SRCs e.g. raw product and/or manufacturing process
- the end use of the product being tested
- whether or not the SRC are pathogenic species or not
- whether or not the product will support the growth of pathogenic species to dangerous levels during the shelf-life of the product, or allow the production of toxins into the product.

519 In most cases, test results for SRCs might be considered higher than expected rather than definitively high. The detection of *C. perfringens* at levels $>10^6$cfu/g (1,000,000cfu/g) would be considered high as it is a known pathogen.

520 Detection of any *C. botulinum* would be considered high.

521 All parameters must be established and their context understood before any decision can be made about a specific level of SRC for a specific product or commodity.

522 [redacted] describes in his report of 10 May 2013 entitled 'Darnum Sulphite Reducing Clostridia Incident', that counts up to 100cfu/g in WPC80 would not be unexpected.

523 New Zealand dairy companies regularly monitor thermoduric bacteria in the raw milk supply which are the bacteria that will survive pasteurisation (but excluding strict anaerobes like clostridia). Farmers are penalised at 100cfu/ml which translates to 1,000cfu/g in powder or 10,000cfu/g in WPC.

SRC Testing

524 If a manufacturer has established a robust testing system for SRCs and is able to determine that they have a higher than expected level in their product, it would be expected that an investigation would be carried out to:

- identify the cause
- assess the risk
- notify the regulator if there is a risk identified, or if unsure; and
- implement corrective actions to prevent recurrence of the cause

525 SRC testing is normally only one element of a suite of tests undertaken by manufacturers. Which microbiological parameters an operator elects to routinely measure, and at what frequency, will be determined through the HACCP-based analysis performed during development of their risk management programme (RMP) and how they elect to monitor for, and control, hazards identified as likely to occur, hence significant for, their process.

526 MPI sets the food safety criteria for dairy products manufactured in NZ, and the Food Standards Code sets out the limits applying for food at retail sale. While compliance with a standard doesn't mean that every parameter needs to be tested for, the operator would need to be able to show through validation studies that their process, and the control measures employed, will ensure that the microbiological standards will be met. For example, cans of finished product are often incubated and observed for gas blowing to demonstrate that gas-producing SRCs have been killed by retorting.

527 High SRCs, if used as part of the suite of tests, are a trigger for an operator to then look at the control of their process with reference to their HACCP-based RMP.

528 With the exception of Ultra High Temperature (UHT) processing it would be unusual for a dairy RMP to use the SRC test for food safety assurance purposes. When it's used as a process hygiene test, then a result showing elevated SRC levels is not evidence that product is unsafe. The obligation under the RMP would be to assess the result against any trigger limit in the RMP and take whatever actions the RMP requires.

529 If an SRC test is being done purely to satisfy a customer specification then a failure means that the product doesn't comply with the customer specification and isn't suitable for sale to that customer. It does not automatically mean that it is unsafe or unsuitable for other customers or uses.

530 There are a number of reasons for SRCs to be high or higher than expected. The context of the levels detected is important in determining meaning. A breakdown in manufacturing hygiene may result in higher than expected counts. This may indicate a failure to control environmental contamination. In contrast, they may purely indicate a

change in the quality of the raw materials through seasonal use of alternative animal feeding practices (e.g. a greater use of silage).

531 Importantly, high SRCs can only be evaluated in the context of a well validated testing system and with appropriate consideration of the product being tested. For example, an SRC count in WPC could be ten times higher than the count in raw whey or infant formula (IF) because of the concentration step in the former and because of the low concentration of WPC in the IF.

532 MPI understands that Danone implemented their SRC requirement following an outbreak of infant botulism attributed to the consumption of honey by infants. Whilst IF was not implicated, Danone was concerned that the infants were also consuming IF and implemented the SRC testing requirement to provide some level of assurance.

533 There have not been any documented cases of botulism associated with appropriately processed general foods. Similarly, infant botulism is associated with children <6 months of age, less so with children between 6 and 12 months, and rarely with children >1 year of age. It is therefore appropriate to consider the risk of foods prepared for children up to 1 year of age.

534 There has never been a documented case of infant botulism confirmed as caused by consumption of powdered IF.

535 When testing is performed to detect a group of bacteria representing both pathogenic and non-pathogenic species, on detection but before further speciation, there needs to be an assessment of the likelihood of pathogenic species being present.

536 In the case of *C. botulinum*, it would be important to consider that prevalence of the hazard, in this case human pathogenic types of *C. botulinum*, in the country of manufacture, any associated human disease in the country of manufacture, the manufacturing process and the associated food safety and quality assurance programmes implemented.

537 Most competent authorities regard *C. botulinum* as being reasonably unlikely to occur in powdered infant formula.

538 In New Zealand, *C. botulinum* type A, the most likely to contaminate powdered IF, has never been isolated but has caused illness in two sisters eating an inadequately prepared home fermented shellfish/watercress mix.

539 *C. botulinum* type A is not thought to be present in the NZ environment at levels of concern.

540 In the opinion of MPI scientists, the presence of SRCs cannot be considered an indicator of the presence of *C. botulinum*, although the absence of SRC does preclude the presence of *C. botulinum*.

Lichfield Plant Testing

541 Results for testing of whey products at the Fonterra Lichfield plant were low at no more than 8cfu/g. These results are interpreted against a 100cfu/g limit set by Fonterra Darnum, although the Fonterra Product Specification for WPC80 (104579), at the time of testing, did not describe a microbiological criterion for SRCs.

542 It is noted that the testing data identified cfu counts of 6700 etc in whey product from Hautapu were referenced as cfu/0.01g whereas all other reports reference the unit as cfu/1g. Interviews with Fonterra staff have indicated that this is likely to be a simple typographical error.

Hautapu SCUF Testing

543 Several sets of Hautapu SCUF plant test results that were reviewed by MPI recorded SRC results for both in-process tests (W) and final product (M).

544 For one set of data, labelled 'Final Product', the results were recorded and compared against a microbiological limit to determine whether or not they pass (P) or fail (F). For M samples, generally dried powders, it was apparent that 20cfu/g was the cut-off between pass and fail, although product type appears to determine whether 20cfu/g was a pass.

545 It was noted that the counts greater than 20cfu/g were in a tight date/batch cluster indicating an event, although the nature of that event is not clear. It could be attributable to the raw material itself, e.g. from a high silage use farm, or a hygiene issue. Given the very low counts in the rest of the database, it would be expected that Hautapu should have questioned these results.

546 In another set of results, labelled 'In Process', there were both W (collected at the evaporator feed) and M (collected ex drier) results, recorded as /10ml and /g respectively, for each day of production. In addition, there are results for each at the start of the run (SOR) and end of the run (EOR).

547 While comparison of the results may be indicative as to whether there were major changes occurring through the process, the results were not directly comparable as the materials tested and units differed. Pass fail determinations were not recorded.

548 Generally, the results were 20cfu/g or below (usually <10cfu/g or <1cfu/ml) with an occasional single sample at 100cfu/g although there were clusters which may reflect the raw material used.

549 Notably, there were two clusters where the counts were substantially higher. On 24th March 2013, the milk coming into the drier had counts of 100cfu/g at the start and 300cfu/g at the end; and counts after drying (concentrating) of 5000cfu/g at the start and 4000cfu/g at the end.

550 This suggests that the milk was evenly contaminated prior to drying, although the reasons for this are not clear. Alternatively, there was contamination associated with the sampling point. It would be expected that Hautapu should have carried out an investigation to find out if there was a hygiene issue that led to these higher than usual results.

551 The second cluster on 29th May 2013 was similar and should have elicited a similar response from the company.

552 MPI has not found any evidence to suggest that an investigation was undertaken.

553 In the opinion of MPI scientists, neither of these clusters suggested a problem with the drying process and rather, that they demonstrate uniformity of the incoming product for drying and uniformity of the concentrated dried product.

Why Are SRCs Not Tested For

554 Typically food manufacturing does not aim to produce a product that is sterile, rather a product that is free from food borne pathogens (e.g. foods that are cooked) or the pathogens are very low in number (e.g. raw foods), or in which food spoilage organisms are as low as possible such that spoilage does not occur during the expected shelf-life of the product. Only foods that have been retorted or subjected to an UHT process will be commercially sterile.

555 SRC produce spores that are resistant to the heat of cooking and pasteurisation and are ubiquitous in the environment. Therefore their presence in product, especially that which is concentrated by drying says little about a cooking or pasteurisation process that is generally not indicated by other microbial indicators such as aerobic plate count (a.k.a. standard plate count or total plate count), coliforms or faecal coliforms.

556 Monitoring for SRCs is useful for judging the efficiency of retort or UHT treatments although simple incubation of cans/packs and looking for gas production due to microbial growth is a more efficient and less costly alternative.

557 A manufacturer would need to decide what value SRC testing would add to a monitoring programme for their manufactured product to determine whether useful or not.

558 In the opinion of MPI scientists, historically, there was little to be gained by testing for SRCs.

How do you Confirm the Presence of *C. botulinum* or the Type of Clostridia

559 The process for confirming the presence of *C. botulinum* is complex and few laboratories in the world have the capability and are accredited for the tests.

560 Initially, colonies on the primary isolation agar that have the appropriate morphology are isolated into pure culture. There are many different agars used for this purpose, media containing sulphite will be useful but not definitive.

561 The presence of spores in the culture is verified by staining and microscopic examination. *C. botulinum* spores are positioned at the end of the cells (i.e. the rod-shaped bacteria look like drum-sticks or tennis racquets).

562 Biochemical tests are used to characterise the isolated bacteria but these tests do not separate the closely related *C. botulinum* from *C. sporogenes.* Other tests such as sequence analysis of the 16S rRNA gene and MALDI-TOF tests will provide further information but are unlikely to provide a definitive answer. Fonterra's response in relation to the WPC contamination issue was initially precipitated by confusion in the latter test.

563 Currently there are two recognised types of tests that will separate *C. botulinum* from *C. sporogenes* based on the presence of toxin genes in the former and absence in the latter. Firstly, the molecular biology based PCR test or next generation sequencing (NGS) test that look specifically for the botulinum toxin genes and an associated gene called the non-toxic non-hemagglutinin (NTNH) gene. Absence of these genes confirms the isolate is not *C. botulinum*.

564 Secondly, presence of these genes requires the isolate to be confirmed as *C. botulinum* by demonstration of toxin production using the internationally accepted mouse bioassay performed correctly with replicate mice and anti-toxin neutralisation controls.

565 In the absence of the molecular tests, the mouse bioassay when performed correctly can be used on its own, and historically has been.

566 These tests are difficult and require a high level of experience and competence. Diagnostic laboratories carrying out these tests for regulatory assurances should be accredited to ISO 17025 and specifically accredited for the mouse bioassay test.

Is the Presence of Clostridia Unexpected in Processed Dairy Product such as WPC

567 In the opinion of MPI scientists, the presence of SRCs is not unexpected in WPC as they are ubiquitous in the environment, are detected in raw milk, are resistant to pasteurisation, and are concentrated during manufacture.

568 The presence of higher than expected levels of SRCs in a product can be an indicator of a process failure. Equally, however, it can be an indicator of seasonal variations in farming practices.

569 In the opinion of MPI scientists, the simple presence of SRCs in WPC would not require an exception report to be produced nor is it indicative of a potential food safety risk.

What is the Purpose of a MALDI-TOF Test

570 MALDI-TOF is an acronym for Matrix-assisted laser desorption/ionization (MALDI) time-of-flight (TOF). It is a recently developed scientific analytical procedure used to differentiate the genus and species of different bacteria by comparing the patterns of proteins detected directly from viable bacteria against substantial databases of profiles of cultures of known identity.

571 The profile databases are specific to the brand of MALDI-TOF equipment used.

572 The databases for the Bruker MALDI-TOF system used by Fonterra are insufficient to enable the differentiation of *C. sporogenes* from *C. botulinum*.

573 When a protein profile is produced from an unknown bacterial isolate, it is compared with protein profiles of known bacterial species in a database that is supplied with the MALDI-TOF machine. There are several manufacturers of MALDI-TOF and each manufacturer uses a different database.

574 Bruker require strict confirmatory testing of a bacterial species before its profile is entered into their database. Bacterial species that cannot be definitively identified to species level can be entered into the database to genus level e.g. Clostridium species.

575 In addition to the database supplied with the Bruker machine, owners of machines can create their own database which can be shared with other Bruker users around the world. The accuracy of the user generated database is dependent on the accuracy of

the identification associated with the bacterial isolate. The databases are not sharable between different manufacturers of MALDI-TOF machines.

576 Bruker also supports a closed database for bacteria that may pose a biosecurity risk such as *C. botulinum*. If a biosecurity-risk organism is suspected, the Bruker software will generate an alert to investigate further.

577 Further investigation could involve sending the suspect protein profile to Bruker for comparison with their closed database and/or further diagnostic testing.

578 In the case of *C. sporogenes/C. botulinum*, the database supplied with the Bruker instrument is not able to identify the species and comparison with the closed database may also not be able to identify the species.

579 Potential reasons for this include a limited number of representatives of *C. sporogenes/C. botulinum* in the database and the method in which the sample was prepared for analysis.

580 Identification of toxin producing bacteria (e.g. *C. botulinum*) can be challenging as the toxins are typically associated with small proteins and these will be present at lower concentrations in the sample. This could impact upon the sensitivity of detection of the MALDI-TOF.

581 Following 'identification' of the unknown bacterial isolate, it is possible to establish the level of similarity with other known and unknown bacterial species. This is done by producing a dendrogram which is generated initially using default settings available with the Bruker software. However, it is recommended that this is optimised to establish the cut point at which similarity between bacterial species being analysed is established. It is critical for any dendrogram analysis that an appropriate known reference is used to enable meaningful conclusions to be drawn about relationships between bacterial species being analysed.

582 A dendrogram is a tree diagram frequently used to illustrate the arrangement of the clusters produced by hierarchical clustering. Dendrograms are often used in computational biology to illustrate the clustering of genes or samples.

Why Progress from MALDI-TOF to Mouse Bioassay

583 MALDI-TOF should be considered a rapid screening tool for presumptive identification rather than a confirmatory test for Clostridium species. There is still substantial uncertainty associated with identifications produced by MALDI-TOF for clostridia. The level of certainty with identifications will be reliant on the in-house validation done by the user to demonstrate specificity, sensitivity, repeatability and reproducibility of the test.

584 It is the opinion of MPI scientists that MALDI-TOF results should not alert the user to move directly to a mouse bioassay.

585 Given the uncertainty of identification of *C. sporogenes* and *C. botulinum* using the MALDI-TOF, several steps can occur before initiating mouse bioassay testing. These include (but are not limited to):

- Risk assessment on the likelihood of *C. botulinum* being present
- Appropriate validated molecular testing. For example:
  - PCR detection of toxin and NTNH genes
  - 16S rRNA gene sequencing
  - Next generation sequencing

586 It is the opinion of MPI scientists that only if there was a strong likelihood of presence and that the molecular tests were not available or that the molecular test results were positive, would the mouse bioassay be appropriate.

587 Mouse bioassay tests are used when necessary to identify toxicity in food, algae, shellfish and microbial isolates. However, while the use of the mouse bioassay for confirmation of *C. botulinum* is still considered the gold standard, there are few ISO 17025 accredited laboratories around the world that perform the bioassay for *C. botulinum* as per internationally accepted guidelines (e.g. USA - Food and Drug Administration).

588 There are no laboratories in New Zealand accredited or even fully capable, of carrying out an internationally accepted mouse bioassay for *C. botulinum*.

589 Prior to initiating a mouse bioassay for *C. botulinum*, a body of scientific evidence would be expected that supports the presumptive identification of *C. botulinum*. This would include high likelihood of presence in the product, and by definition either in the New Zealand environment or an ingredient, and confirmed molecular test results for genes specific to *C. botulinum*.

What is the Likelihood that a Clostridia Spore Presence could be the *C. botulinum* Spore

590 The likelihood of a clostridial spore detected being *C. botulinum* can only be determined following appropriate risk assessment for the specific product or commodity in question. In New Zealand, while it is possible that a spore could be *C. botulinum*, it is highly unlikely. Instead it is more likely to be *C. perfringens*, *C. sporogenes* or one of the multitudes of non-pathogenic clostridia that cause food spoilage rather than human illness.

591 Should the isolate be shown to be *C. botulinum*, it is more likely to be a toxin type that does not cause illness in humans (e.g. C & D).

592 The presence of clostridial spores in liquid milk or finished product following pasteurisation of liquid milk is not unexpected and usually would not be of concern, provided hygienic manufacturing practices were intact.

593 Even in the absence of specific regulatory requirements or provisions in a company's RMP, detection of spores at levels higher than expected and at a greater frequency than expected would be expected to result in an investigation to determine the cause, and if necessary, to implement corrective actions which might include decisions on product disposition.

594 Fonterra and AgResearch, in collaboration, have previously applied to the Foundation for Science, Research and Technology (FRST) and Ministry for Business, Innovation and Economics (MBIE) for funding for investigating the science of clostridial spores in the dairy industry. Both applications were unsuccessful.

595 There are limited studies on microbial species present in IF. IF is not a sterile product and requires adherence to manufacturer's instructions for safe preparation and storage. A 2005 study in the United States reported the presence of Clostridium spores in 31% of IF purchased. Representatives of 12 species of Clostridium were identified although neurotoxigenic species were not detected. *C. sporogenes* were found to be the most common species identified.

596 Despite *C. sporogenes* being the most abundant Clostridium species identified in the US study, there have not been any reported cases of infant illness directly associated with IF or *C. sporogenes*. This is consistent with expectations.

597 It is the opinion of MPI scientists that the presence of clostridial spores in IF at the levels expected would not be of concern provided the IF is manufactured under a quality system and the product is handled by the consumer as per the label instructions.

CER & ENC REPORTING TRENDS

Work Stream Aim

598 For the period 1 January 2012 to 31 August 2013 review all Critical Exception Reports (CERs) and Export Non Conformances (ENCs) submitted to the RA (AQ) and MPI in accordance with APA and/or RMP requirements to;

- Establish whether Fonterra have been generally complying with their requirements
- Understand any trends regarding performance of any parties
- As background information that may inform any future decisions to hold Fonterra liable for non conformance, establish whether MPI have been proactive in managing the regulatory process and have promptly dealt with lateness issues

Critical Exception Report (CER)

599 These documents are referred to by MPI as Critical Exception Reports whereas Fonterra terms them as Exception Reports.

600 CERs contain information as required by Dairy Processing Criteria (DPC1) regarding:

- identification of non-conforming dairy material or dairy product; and
- occurrence of a critical non-compliance (ie failure to comply with regulatory requirements)

601 Non-conforming in relation to dairy material and dairy product is defined as any dairy material or dairy product that is suspected or known not to meet regulatory requirements or not to have been processed in accordance with regulatory requirements.

602 A critical non-compliance is an action, event or omission which may result in a;

- failure to follow the lawful direction of an Animal Products Officer;
- an alleged offence against the Animal Products Act 1999;
- a critical situation;
- failure of a critical control point within a risk management programme or approved plan;
- failure to identify when dairy material or dairy product is non-conforming;
- failure to stop a non-compliance;
- failure to keep accurate and complete records;
- failure to provide accurate, complete, and timely reports;
- failure to dispose of non-conforming dairy material or dairy product in compliance with regulatory requirements;

- failure to prevent recurrence of a non-compliance; or
- failure to rectify a non-compliance within the specified timeframe.

603 The procedure for managing CERs was identified in section EXNC11 of the Fonterra RMP version 5, dated 27 January 2011.

604 The purpose of the CER procedure is to ensure that all product safety events are managed in accordance with the RMP and so that internal Fonterra reports and those submitted to the Recognised Authority (RA), AsureQuality, are consistent in terms of format and data.

605 These reporting procedures are applicable to all New Zealand Fonterra sites operating under an RMP and all staff involved in the management of product from any of these sites.

606 The CERs contain information including the exception date, time, premise and details of what critical event happened at the site and what follow up action is planned. The reports also provide details of the RA contacted as well as the date and time contacted. The report does not however provide details of how the RA was contacted, e.g. by phone, text or email.

607 The MPI DPC1 and the Fonterra RMP require the RA to be notified of any CER within 24 hours of occurrence, with written notification being received by MPI within 72 hours.

608 Once an event has been detected the Fonterra on-site department manager is responsible for investigating why the event occurred and report the matter to the quality team. This team is then responsible for determining the category of the event and notifying the RA.

609 There are two categories of events scheduled in Fonterra's RMP. Category A events are able to be managed internally by Fonterra whereas category B events require disposition approval by the RA or MPI.

610 All Category A exceptions are reported to the Fonterra Quality Team as soon as practicable. Up until January 2013, Fonterra required this reporting no later than 20 hours after the occurrence of the exception or the result is known by the testing laboratory. After January 2013, the 20 hour reporting time was further reduced by Fonterra to 16 hours.

611 Category B exceptions are required by legislation to be reported to the RA as soon as practicable, but no later than 24 hours after the occurrence of the exception, or after the result is known by the testing laboratory.

612 Fonterra amended their RMP in January 2013, reducing the 24 hour reporting time to 20 hours and inserting the word *confirmed* to read "...or after the confirmed result is known by the testing laboratory".

613 This amendment was not notified to MPI as it was not deemed to be a significant change to the RMP as defined in legislation.

614 Fonterra RMP versions post January 2013 detail the responsibilities of the National Quality Managers who are required to verify exceptions that are category B, and ensure the escalation to a critical event when appropriate.

615 A critical event is defined by EXNC26, 'Critical Event Procedure', as "an internal issue indicating a performance failure of any product safety failure of defined magnitude found prior to shipment overseas which requires either immediate investigation and/or identifies an improvement opportunity".

616 If an incident is determined to be a critical event then the Critical Event Manager is responsible for leading the crisis team, defining and assigning responsibilities, recording and reporting decisions and actions.

CER Statistics

617 All Fonterra CERs were analysed for the period 1 January 2012 to 31 August 2013. A total of 389 CERs were submitted by Fonterra for the period of analysis. On average 19 CERs were submitted by Fonterra each month.

618 Of the CERs submitted, 149 (or 38%) were not received by the RA within the required 24 hours.

619 47% of CERs were received three to five days after the 24 hour notification period.

620 The table below provides a breakdown of all CERs received after the required 24 hour period.

Lateness period (hours)	# of reports	% of reports
Received between 24 - 26 hours	18	(12%)
Received between 27 - 48 hours	24	(16%)
Received between 49 - 72 hours	10	(7%)
Received between 3 to 5 days	70	(47%)
Received between 6 to 10 days	12	(8%)
Received after 10 days	15	(10%)

621 The majority of CERs (68 or 45%) were generated because foreign matter, such as metal, rubber or other (plastics etc) was found in the product either during manufacture or post manufacture.

622 The next largest contamination was from residues, such as chemicals (31 or 21%). Critical control point failures accounted for 17 or 11% of CERs whilst procedure failures accounted for 13 or 9% of CERs.

623 Of the 389 CERs analysed, 290 or 75% were received by MPI from the RA within the required 72 hour period.

624 25% of CERs referred to MPI by the RA were not submitted within the required timeframe.

625 The following table illustrates the timing of when MPI received the 389 CERs from the RA.

Received period (days)	# of reports	% of reports
Received within 3 days	290	(75%)
Received within 4 to 5 days	44	(11%)
Received within 6 to 10 days	39	(10%)
Received >10 days	16	(4%)

626 There is little correspondence on MPI files that refer to the late referral of CERs by the RA and the need for the RA to comply with the 72 hour requirement.

627 Of the 99 CERs submitted late by the RA there is only one instance where the lateness was queried by MPI.

628 There were three instances where MPI queried the RA about additional information required.

629 There were seven instances where the RA consulted with MPI regarding CERs submitted by Fonterra that were either late, had been overlooked or where Fonterra was confused about whether they in fact needed to complete a CER.

630 There were two identified instances, other than lateness, where Fonterra failed to follow their own CER procedures as defined within their RMP.

631 There were also two instances where MPI initiated written directives to Fonterra to hold product with one incident where a letter was written to Fonterra regarding the failure of Fonterra to control product effectively.

Export Non Conformance (ENC)

632 These documents are referred to by MPI as Export Non Conformance reports whereas Fonterra terms them Exporter Non Conformance reports.

633 The Fonterra procedure for managing ENC's is covered in EXNC12 entitled "Managing Exporter Non-Conformances – NZ Origin Dairy Products" version 12 dated 27 January 2011.

634 The Fonterra ENC procedure in accordance with the Animal Products Act (APA) 1999 sets out the requirements for notifying and managing instances where a delivery;

- is subject to dispute with Overseas Market Access Requirements (OMAR's) and/or regulatory authorities
- is in breach of NZ food safety and/or export or labelling standards
- has the potential to be subject to dispute or in breach of regulatory standards.

635 The Fonterra ENC reports contain an extensive amount of information including the non-conformance date, time, current location of product, details of the product, the result or implication of the ENC and what follow up action is planned. The reports also provide details of the date and time MPI are to be notified, what corrective actions have been put in place and any actions required by MPI to assist in resolving the ENC.

Analysis of ENC's

636 304 ENC's submitted by Fonterra for the period 1 January 2012 to 31 August 2013 were analysed with 117 or 38% received by MPI later than the required 24 hour notification period stipulated in section 51 of the APA 1999.

637 There is no correspondence on MPI files that refer to the late submission of ENC's by Fonterra, any follow up action and the need for them to comply with the 24 hour notification period.

638 All 117 late ENC's have been analysed and the following reasons for non-conformance were identified:

Reason	# of reports	% of reports
Certification issues	38	(33%)
Labelling issues	26	(22%)
Product Failure	27	(23%)
Foreign Matter	14	(12%)
Procedures issues	8	(7%)
Other issues	4	(3%)

639 The non-conforming certification and labelling issues mainly related to incorrect or incomplete information being included on the export documentation or labels by Fonterra.

640 The product failure ENC's mainly related to suspected or confirmed product contamination testing such as;

- salmonella
- chromium
- sodium thiocyanate
- nitrates
- sanitiser
- strep haemolyticus
- odour
- colour
- low fat content

641 The 117 ENC's submitted by Fonterra outside of the 24 hour notification period can be grouped as follows;

Lateness period (hours)	# of reports	% of reports
Received between 24 - 27 hours	35	(30%)
Received between 28 - 48 hours	37	(32%)
Received between 49 - 72 hours	12	(10%)
Received beyond >3 days	33	(28%)

642 45 or 38% of the ENC's were received more than one day outside of the required 24 hour notification period.

Fonterra ENC's Involving WPC/Infant Formula

643 The analysis of the 304 Fonterra ENC's revealed that three ENC's related to dairy product that went to Australia, albeit none of them related to WPC or infant formula.

644 There were however 7 ENC's that related specifically to the export of infant formula and 6 of them covered exports to China.

645 Four of these ENC's were not notified to MPI within the required 24 hour notification period.

646 There were 11 ENC's that related specifically to the export of WPC product. The 11 ENC's covered;

# of WPC Non conformances	Destination Market
4	China
2	Japan
2	USA
1	Germany
1	Peru
1	Singapore

647	Eight of these ENC's were not notified to MPI within the required 24 hour notification period

648 It is apparent that MPI did not appear to either monitor or hold Fonterra to task in regards to their tardy compliance with their requirements to notify as required by the APA and/or their RMP

[Pages 142 to 165 withheld in full under s.9(2)(h)]

CONCLUSIONS

649 The following general conclusions are drawn from the investigation;

650 The contamination of WPC80 ciphers GW02 and GW03 was caused when a dryer operator investigating a high static fluid bed pressure reading shone his torch up the air intake. The torch was sucked in breaking the plastic lens of the torch and not all broken pieces were recovered, so raising the possibility that the missing pieces had contaminated the WPC80 under manufacture.

651 At the time of the torch lens contamination incident, only 1 tonne of WPC80 had been manufactured. Instead of stopping the plant, dumping the contaminated product, cleaning the plant, and then recommencing manufacture, Fonterra continued the manufacture of a further 41 tonnes of WPC80. This decision resulted in contamination of a further 41 tonnes of product needlessly.

652 The incident was reported as an exception report and version two of a Product Disposition request to re-work the WPC80 was approved.

The re-work process was designed and approved by the Hautapu Plant Manager with no independent peer review. The re-work plan saw the product reconstituted in the SCUF plant and then transferred back to the Whey plant for filtration and drying.

This process only required some parts of both plants to be used so a number of flexi hoses and a disused 25 metre section of hard pipe were used to move the product between the plants in accordance with the plan

653 The Plant Manager's plan was unique as Fonterra had never before conducted a 100% re-work of any powders. The re-work plan did not follow the Change Process requirements as set out in the Fonterra RMP and did not involve any mandatory risk assessment, mitigating steps or approval. This was a significant departure from HACCP and RMP requirements

654 Whilst it is not possible to definitively identify the SRC source that contaminated JW17, JW18 and JW22, the investigation concurs with Fonterra's own review that the most likely cause was SRC contamination pre-existing in either the temporary flexi hoses and/or the 25 metre stainless steel pipe that had not been used for approximately two years prior to the rework.

It could never be confirmed as Hautapu removed and dumped a number of flexi pipes (for legitimate reasons) and also they did not record which pipes were used from an area containing a large number of such pipes.

What does support this conclusion is the fact that post event testing confirmed that GW02 and GW03 did not contain SRCs whereas post re-work testing confirmed the JW

ciphers as containing high levels of SRCs. Thus it is known that SRCs were not present pre re-work but were present post re-work.

655 For the reworked product, it appears that effective CIP was not undertaken. The CIP procedure adopted for the rework demonstrated a lack of consistency in its application.

No specifications, as provided for under the Animal Products (Dairy) Regulations 2005 in regards to listing of dairy maintenance compounds, has been created for dairy factories by MPI, although one exists for farm dairies (milking sheds).

656 The SRC contamination of JW17 and JW18 (and ultimately JW22) was discovered by the Fonterra Darnum Plant in Australia following their use of that WPC80 as a macro ingredient in the manufacture of nutritional powders for Danone. Darnum regulatory testing confirmed 7 of the 19 batches contained SRCs with the 7 contaminated batches all containing either JW17 or JW18.

Darnum reported the issue to Fonterra NZ Technical Services which commenced a course of events and testing that ultimately led to the false positive *C. botulinum* test being advised to MPI.

657 Based on the investigation to date, no evidence has been found that Danone knew that the product it accepted may have been processed by Fonterra outside of Fonterra's RMP or the regulatory standards.

658 As far back as May 2013 Fonterra internal communications raised concerns, albeit extremely unlikely, that it could not be ruled out that the Clostridia identified did not carry the toxin gene and this commenced the MALDI-TOF and eventual mouse bioassay testing.

659 Darnum raised a [redacted] compensation claim with Fonterra NZ. When that claim was eventually settled Darnum withdrew from further testing claiming that as their product had been downgraded to stock food, they had no further interest in the issue.

The continuation of the testing leading to the mouse bioassay, resulted from the realisation by Fonterra NZ that they had used JW17 and JW18 in the manufacture of infant formulas at their Waitoa plant and were concerned that if the Clostridia was toxic they may have a food safety issue.

660 It is evident that Fonterra discovered that the re-work of the JW ciphers was not completed in accordance with their RMP in that it did not follow the change control process and risk assessment. Questions began to circulate regarding who authorised 100% re-work, failure to follow change control and risk assessment processes.

661 Due to the level of concern regarding this incident Fonterra established a serious events team in relation to this issue who again raised concerns with the re-work process.

662 A realisation that Fonterra Waitoa did not have SRC specifications for product used in the manufacture of infant formulas caused a review to be conducted and the establishment of SRC specifications within Fonterra for nutritional products.

663 As the testing continued and whilst AgResearch began preparation for mouse bioassay testing there was a growing concern amongst Fonterra managers regarding the possibility of identifying *C. botulinum*. Such was the concern that this led to work commencing to trace back all product containing the JW ciphers

664 From 19 July, concerns grew regarding possible outcomes of testing, with FRDC preliminary testing indicating suspicion of a pathogenic strain. On 23 July, Fonterra upgraded from a Serious Event to a Critical Event. Such was the concern that further work was directed to identify all products that used the JW ciphers and the recall process. Escalation to crisis level was indicated if a positive test was returned

665 AgResearch commenced mouse bioassay testing and on 30 July advised Fonterra that they had preliminary results indicating some form of toxin was present that may or may not be *C. botulinum*. On 31 July they advised Fonterra that a mouse mortality had confirmed the presence of *C. botulinum*. A crisis team was then formed.

666 Fonterra began preparation of an ENC on 1 August and also emailed MPI requesting a meeting that afternoon. A number of communications occurred between MPI and Fonterra regarding availability and reason for meeting.

That same evening a member of the crisis team raised the issue of informing MPI but was directed not to do so until authorised by the Director NZMP. There was however discussion regarding advising customers before advising MPI and the Fonterra CEO and relevant Customers were advised overnight

667 Communication between MPI and Fonterra occurred throughout the morning of 2 August with Fonterra asking for a meeting with MPI. A number of postponements occurred, all at Fonterra's request with Fonterra refusing to reveal what the issue was and the serious nature of the issue. It is noted that Fonterra advised MPI, when asked, that the issue related to "SRC", whereas at the time Fonterra were fully aware they were dealing with positive *C. botulinum* results.

668 The Fonterra Board, their CEO and Customers were all briefed before the matter was raised with MPI.

669 The two Senior Fonterra Managers who were stood down immediately after the event was advised to MPI, have been identified and were spoken to as part of the enquiry. Both were stood down, on the face of it, for failing to manage events occurring within their areas of responsibility as opposed to any fraudulent or deliberate actions on their part.

670 A review of the accreditation of the laboratories used by Fonterra indicates that they have complied with requirements in regards to dairy product testing.

ISO/IEC 17025 set general requirements for the competence of testing and calibration laboratories but it does not appear that Fonterra Laboratories or AgResearch have breached any requirements but the work of AgResearch when compared to 'US FDA Bacteriological Analytical Manual for CB' was found wanting.

671 SRC testing is not intended for food safety; rather it is an indicator for food hygiene and elevated SRC results should instigate causal investigation. The only regulatory trade limits for SRCs are for Russian Federation dairy imports and there is an advisory maximum level for the United States and Algeria. If an SRC test is being done purely to satisfy a customer specification then a failure means that the product isn't suitable for sale to that customer only.

672 Most competent authorities regard *C. botulinum* as being reasonably unlikely to occur in powdered infant formula. In New Zealand, *C. botulinum* type A, the most likely to contaminate powdered IF, has never been isolated but has caused illness in two sisters eating an inadequately prepared home fermented shellfish/watercress mix. *C. botulinum* is not thought to be present in the NZ environment at levels of concern.

673 A review of CERs submitted by Fonterra to the RA over an 18 month period shows that 149 (38%) were submitted outside the required 24 hour notification period with 47% of those late being submitted between 3 and 5 days late.

674 It is established that of the 389 CERs analysed, 290 or 75% were received by MPI from the RA within the required 72 hour period but 25% were not submitted to MPI by the RA within that timeframe. The RA (AsureQuality) are not meeting their reporting requirements with MPI.

675 No evidence could be found on any MPI files that indicates MPI Standards Branch queried or held the RA to account over these issues of lateness in submitting CERs as is required.

676 A review of ENCs submitted by Fonterra over the last 18 months shows that they submitted 117 (38%) late, that is outside the required 24 hour notification period required. Of these 45 (38%) were received more than one day outside this period.

677 No evidence could be found on any MPI files that MPI Standards Branch queried or held Fonterra to account over these issues of lateness.

678 The RA (AsureQuality) audit Hautapu every 3 months with one in ten being unscheduled and one in ten being unannounced. For the unscheduled audits they simply bring a scheduled audit forward a week or so but still give notice of when the audit will occur.

For unannounced audits, Fonterra insists the RA gives 48 hours notice for OSH and logistical purposes and the RA complies with that demand. This nullifies the intent and impact of unannounced audits and is one that gives Fonterra sufficient time to prepare for the 'unannounced audit'. This must be perceived as circumventing the intent of the regulatory system.

679 Fonterra amended their RMP in January 2013, reducing the 24 hour reporting time to 20 hours and inserting the word *confirmed* to read "...or after the *confirmed* result is known by the testing laboratory". This amendment was not notified to MPI as Fonterra did not deem it to be a significant change to the RMP as defined in legislation and so not requiring notification of a significant change to MPI.

There may be an explanation to the changes made by Fonterra to their RMP [redacted] Unlike some other comparable legislative notification obligations, the knowledge element in section 51(c) is couched in relatively strict terms, namely the duty is triggered only when the exporter *knows* that the product *is not* fit for intended purpose. Many other legislative notification obligations are triggered when the relevant person *believes or suspects* that the event *may* have occurred. By way of example, a comparable notification Australian legislative provision imposes an obligation on an exporter to notify immediately on forming a *suspicion.*

Considering the intent of the Act is to protect or prevent risk, the legislation should be clear that the obligation to notify would arise in cases such as the present incident, where Fonterra knew that adverse health effects from *C. botulinum* could result in fatal infant botulism.

[redacted]

[redacted]

[redacted]

[redacted]

Withheld under 9(2)(h)

Withheld under 9(2)(h)

[redacted]

Withheld under 9(2)(h)

RECOMMENDATIONS

681 It is intended to make recommendations under two headings. First will be organisational recommendations and these are in regards to those organisational issues that have been identified incidental to the investigation but that are important issues that need strategic consideration by MPI.

682 Secondly recommendations will be made in regards to whether to escalate to a formal investigation.

Organisational

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[Withheld under 9(2)(g)(i)]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[Withheld under 9(2)(g)(i)]

Investigation

690 Based on the investigation to date, no evidence has been found that Danone knew that the product it accepted may have been processed by Fonterra outside of Fonterra's RMP or the regulatory standards and therefore, no further investigation into the actions of Danone is **recommended.**

691 As has been established and discussed in this paper, reasonable grounds have been established, and confirmed by the Wellington Crown Solicitors Office, for three breaches of the APA1999 and a fourth breach is also likely.

692 It is **recommended** that this case is escalated to a formal investigation with the focus of that investigation being to establish sufficiency of evidence for the matters outlined in the Crown Solicitors opinion under headings 28 (a) (b) (c) and (e) in the conclusion above.

Agree/Disagree/As Amended

Dean Baigent
Director Compliance
Ministry for Primary Industries
Date:

APPENDICIES & ATTACHMENTS

[redacted]

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