

**GOVERNMENT INQUIRY INTO THE WHEY PROTEIN CONCENTRATE CONTAMINATION INCIDENT**

**PROVISIONAL LIST OF ISSUES – STAGE TWO**

**TERMS OF REFERENCE PARAGRAPH (A) – HOW THE POTENTIALLY CONTAMINATED WHEY PROTEIN CONCENTRATE ENTERED THE NEW ZEALAND AND INTERNATIONAL MARKETS, AND HOW THIS WAS SUBSEQUENTLY ADDRESSED**

1. **Background**
   1. What are the relevant aspects of the company’s[[1]](#footnote-1) history as a significant manufacturer and exporter of safe dairy products?
   2. What were the company’s contingency plans for food safety events before the incident?
   3. In summary, what processes are used in the manufacture and distribution of Whey Protein Concentrate (WPC80), from sourcing raw materials to the product entering the market?
2. **The company’s management and governance oversight of food safety at Hautapu, other relevant sites and the company in general**
   1. What management and governance processes were in place to oversee food safety at Hautapu and any other relevant sites?
   2. What systems were in place to test and review those processes?
   3. What were the results of such testing and review?
   4. What processes were in place to create, foster, and monitor food safety culture at Hautapu, other relevant sites, and at the company in general?
   5. What lessons can be learned from the incident?
   6. What changes have been made as a result of the incident?
3. **The company’s risk management framework and programme for food safety in relation to the contaminated WPC80**
   1. Was the risk management programme (including any other relevant process) governing the WPC80 sufficiently accessible to, and understood by, the relevant people?
   2. To what extent did the company follow its risk management programme(s) in dealing with the WPC80 in 2012-2013?
   3. Were the food safety aspects of the risk management programme(s) relevant to this incident adequately tested, audited and reviewed?
   4. To what extent did the company’s food safety processes operate as planned in relation to this incident?
   5. What lessons can be learned?
   6. What changes have been made?
4. **Initial decision-making following foreign-matter contamination** 
   1. What process was followed, and what factors were taken into account, to decide how to deal with the WPC80 contaminated by plastic in February 2012, including the decision to continue manufacture? Who was involved? What consideration was given to the fact that the WPC80 could be used as an ingredient in infant formula?
   2. Was the decision-making appropriate, and consistent with an appropriate food safety culture?
   3. Was there sufficient oversight of the decision-making within the company in relation to the initial contamination by plastic?
   4. What lessons can be learned?
   5. What changes have been made?
5. **The rework and subsequent processes**
   1. What process was followed, and what factors were taken into account, in deciding to rework the WPC80? Who was involved? What consideration was given to the fact that the WPC80 could be used as an ingredient in infant formula?
   2. Was the decision-making in relation to rework appropriate?
   3. Was there sufficient oversight of the decision-making within the company in relation to the rework?
   4. Were the relevant decisions consistent with an appropriate food safety culture?
   5. What lessons can be learned?
   6. What changes have been made?
6. **The role of the regulators (including recognised agencies) in the rework and subsequent processes**
   1. To what extent were the regulators / recognised agencies (MPI and AsureQuality) aware of the potential issues with the WPC80 at Hautapu, including the timeline of their involvement prior to August 2013?
   2. What steps did the regulators take during this phase regarding the process of rework? Who was involved?
   3. Were those steps appropriate?
   4. Should the regulators have taken any further steps in relation to the rework of WPC80?
   5. What lessons can be learned?
   6. What changes have been made?
7. **The process of testing for *Clostridia* species**
   1. Why were each of the various decisions taken by the company to carry out further testing in 2013, and what was the timeline from the initial SRC test results of product at Darnum until further testing for *Clostridia* species took place at AgResearch?
   2. From the initial detection of high SRC levels at Darnum, what information was provided to customers, and what was the nature of their involvement in subsequent decision-making?
   3. Who was involved in each decision to carry out further testing?
   4. What process(es), including escalation processes, were used to determine whether to carry out further testing? What consideration was given to the possible outcomes, and the potential responses to those outcomes?
   5. What products were selected for further testing, and why?
   6. What steps were taken to trace, hold and release the WPC80 pending, and following, each test result, by whom and when? What consideration was given to the possible end use of the WPC80, including as an ingredient in infant formula?
   7. What process / criteria were used to select the laboratory or laboratories to test the potentially affected products in 2013?
   8. What information was sought by, and provided to, the laboratory/ies?
   9. What process(es) were used to determine the method(s) of testing?
   10. What relevant accreditation and expertise did the laboratory/ies have?
   11. Did the laboratory/ies have the relevant capability and capacity to carry out the testing?
   12. What processes were adopted by the laboratory/ies to carry out and manage the testing?
   13. How were the results reported?
   14. In relation to the above matters:
   * Were the relevant processes or matters noted above adequate?
   * Was best practice followed?
   * What lessons can be learned?
   * What changes have been made?
8. **The company’s response to the testing**
   1. What was the timeline of the company’s response to the various test results?
   2. What processes did the company have in place to manage the response to the incident?
   3. What escalation processes did the company have?
   4. Had those processes been tested and reviewed, and with what results?
   5. Were those processes followed, and if not why not?
   6. What lessons can be learned?
   7. What changes have been made?
9. **Notification to customers and the regulator**
   1. What was the timeline leading to the company’s notification of the incident to the regulator, and to customers?
   2. What information was given to the regulator and to customers?
   3. What information was provided to, or obtained by, AsureQuality regarding this incident in 2013, and when?
   4. Was the notification of the incident to the regulator and to customers adequate?
   5. What lessons can be learned?
   6. What changes have been made?
10. **The response of the regulator during the post-notification phase**
    1. What was the timeline of events from initial notification of the incident to the regulator?
    2. What systems and processes did the regulator have in place to deal with incidents of this sort?
    3. Had those systems and processes been tested and reviewed prior to the incident?
    4. Were the systems and processes effective in this case?
    5. What technical and scientific advice did the regulator obtain following notification of the incident, and when?
    6. What were the regulator’s decision-making processes in response to this incident? Were these processes appropriate?
    7. Were the regulator’s substantive decisions and responses to the incident appropriate?
    8. How well was the regulatory response coordinated among relevant agencies?
    9. How did regulators in other jurisdictions respond to this incident?
    10. Are there any international best practices for regulators relevant to the response to this incident? How well were they implemented in this incident?
    11. Did the regulator communicate effectively and appropriately with stakeholders including affected companies, consumers, public, media, and foreign markets?
    12. How effective were the regulator’s risk communication processes?
    13. Has the regulator conducted a review of its response to the incident? What were the results of that review?
    14. What lessons can be learned?
    15. What changes have been made?
11. **The response of the company during the post-notification phase**
    1. What was the timeline of the company’s response during the post-notification phase?
    2. Did the company provide the regulator with adequate information in a timely manner during this phase?
    3. Did the company communicate effectively and appropriately with stakeholders including affected companies, consumers, public, media, and foreign markets during this phase?
    4. How effective were the company’s risk communication processes and contingency plans?
    5. What lessons can be learned?
    6. What changes have been made?
12. **Identifying and tracing the potentially affected product**
    1. What was the timeline for the company’s identification and tracing of all potentially affected product from 2 August 2013?
    2. What were the specific challenges faced in identifying and tracing all of the potentially affected product, and why did these issues arise?
    3. What lessons can be learned?
    4. What changes have been made?
13. **Overall observations**
    1. Standing back and considering the incident overall:
    * What were the key immediate causes of the incident?
    * What were the underlying causes of the incident?
    * How well-managed was the response to the incident by the company, regulator and any other party?
    * What are the major lessons to be learned from, and changes made as a result of, this incident?

12 May 2014

1. “The company” refers to Fonterra Co-Operative Group Ltd and any relevant related company. [↑](#footnote-ref-1)