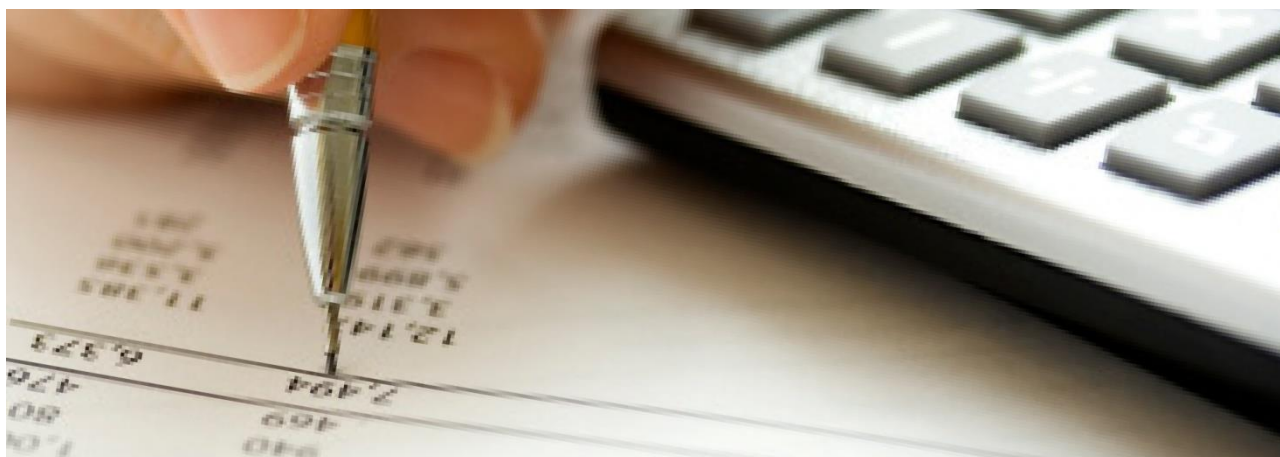

Primary Growth Partnership New Dairy Products and Value Chains
Programme

Progress Review of Primary Growth Partnership Whai Hua Programme - Summary Report

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About Sapere Research Group Limited

Sapere Research Group is one of the largest expert consulting firms in Australasia and a leader in provision of independent economic, forensic accounting and public policy services. Sapere provides independent expert testimony, strategic advisory services, data analytics and other advice to Australasia's private sector corporate clients, major law firms, government agencies, and regulatory bodies.

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Figure 1 Dairy products value staircase

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Executive summary

Overall the New Dairy Products and Value Chains programme (Whai Hua programme) has made good progress with four of the five projects that comprise the programme, tracking close to where planned at the outset. As can be expected in innovation programmes there will be challenges. The product B¹ project, which aims to develop a safe and effective vaccine for an immune-enhancing compound, is facing some difficulties which may mean it does not achieve its original goals. Its future should be determined early in 2015 and will depend on the outcome of external research into the efficacy of the product and the acceptability and scalability of AgResearch's immunisation protocol. However, despite this, the programme continues to offer significant potential benefits both from the projects themselves and possible spin offs. A key challenge remains proving real benefits from the compound products to a level that differentiates them from competitor products. Ultimately the level of tangible benefits will be a key determinant in proving to consumers in various potential markets that the compound products are materially better than alternatives.

Background

The Whai Hua programme is one of the Primary Growth Partnership (PGP) programmes designed to lead to greater market success for New Zealand's primary industries through long-term government and industry joint ventures. Key goals of PGP are to boost productivity and profitability across the primary industries, delivering long-term economic growth and sustainability.

The Whai Hua programme began in June 2013 and will run for 2.5 years to December 2015. It has 50:50 government and industry funding of \$1.75 million each. The government's commercial partners are Wairarapa Moana ki Pouakani Incorporation (WMI), Miraka Ltd and Kanematsu New Zealand Ltd. As set out in the Whai Hua outcome logic model (attached) it is seeking to develop new, added-value dairy ingredients, based on immune-enhancing dairy milk products. It involves working closely with industry partners in the target Asian and New Zealand markets and focusing on health-conscious consumers in those markets.

The business case noted a goal of creating premier immune-enhancing products. This would be supported by a significant body of scientific evidence directly linking its protective properties with those of human milk components and marketed to major international nutritional companies. It was intended that it should therefore be a leader in a new market as there would be no comparable products.

The Whai Hua programme contains five projects: target compound functionality, herd selection and management for product A, the development of product B, target compound processing and market intelligence. These are seeking to develop protocols for milk component production and processing and provide sufficient market knowledge and functional evidence so that two products can be taken to market once the Whai Hua programme is completed.

¹ Product A and product B are the names given to the two products under development in this programme. The actual names for each have been removed due to commercial sensitivity.

Target compound functionality: Results indicate that the target compounds in bovine milk act in a similar way to their counterparts in human milk, binding with a wide range of bacteria. In vivo studies will be conducted during 2014-15. Further study must include demonstration of activity of the target compound as an ingredient, dose response and comparison to other products, such as colostrum. This will form a crucial part of the information dossier needed to demonstrate the value and define its competitive advantage. It is also necessary for setting targets for herd selection and processing objectives. This objective should therefore receive the highest priority in the next stage of the programme.

Product A herds: The natural production profiles of the target compounds have been shown to be repeatable within and between years. Protocols for selecting cow replacements have been developed and options for genetic improvement are being pursued. The logistics required to maintain product A herds have been identified along with data showing it is possible to improve component concentrations without significantly sacrificing other production factors. This project offers some of the greatest scope for commercialisation.

Product B: The objective is to develop an effective and safe immunisation for future commercial application. Alternative adjuvants used in immunisation trials have proved to be acceptable from an animal ethics and welfare perspective. There have been delays in the testing of animal models. Assuming an acceptable level of functionality is demonstrated, there still remains the issue of whether the revised protocol will scale up and whether sufficient quantities of milk for commercial use can be produced. This project faces some significant hurdles before it could achieve what was originally planned.

Processing: This objective set out to design a process that makes a product suitable for market and provides test material for market evaluation. Optimal processing specifications that retain functional activity have been determined. Further development of low heat processing is necessary. However, good progress has been made towards achieving an acceptable retention rate. This project has a lot of commercial potential and its findings could improve the retention of other heat sensitive proteins in milk.

Market intelligence: The aim of this project was to develop market intelligence and new markets through desk research and early market engagement to understand market sizes, values and expectations for component dairy ingredients in Asia and New Zealand. The business case noted that market development would require strong business links with in-market partners that operated in the immune health food sector. The market studies undertaken so far have highlighted the need for better information about the product. When Whai Hua has a product ready to sell, few problems opening doors with potential customers were identified, though there are a number of competing products in the immune-enhancing market. The marketing work contained clear messages on the need to differentiate from other immunity enhancing products. The ability to do this is dependent on the scientific research showing functional activity. It also noted this could be challenging due to other products containing much higher levels of the compound. As a result providing evidence of functionality will be pivotal.

The degree of this evidence that can be identified in the Whai Hua programme will determine next steps. However, the marketing work indicates that there is very likely to be a significant effort needed to educate consumers about the compound due to little consumer awareness. In addition, MPI advice on regulatory requirements indicate that prototype

products produced by Whai Hua will face significant further scientific work if they are to achieve the ability to market these with higher level health claims in New Zealand. Regulatory approaches vary in overseas markets but the more promising sizeable markets will require further scientific validation and partnering with both local and in-market firms to reach longer term export sales volumes.

Spill Over Benefits

A number of positive collateral findings have been made as part of the Whai Hua programme. These could be taken up in future research and investment. The programme has also built a good working relationship between Japanese and New Zealand commercial partners. This rapport could lead to future projects. The spill-over benefits forecast in the business case are only likely to be achieved with successful completion of the programme.

Management and Governance

On the question of management and governance, the Whai Hua programme is well organised and well directed and has stuck closely to its budget. This is despite it having come up against some obstacles in particular projects. It has managed these flexibly by reallocating resources and reprioritizing as needed. The AgResearch science team appears well motivated and is appreciating the higher level of feedback from marketing and commercial partners that characterise Whai Hua compared to some other projects. The commercial partners are pleased with the effective project management of Whai Hua and with the focus and direction of the scientific work at AgResearch. Overall, the Whai Hua documentation and discussions with key participants indicated strongly to the reviewers that Whai Hua is a focused and well managed programme.

International Developments

The progress of the Whai Hua programme against international science, technology & industry trends was discussed with the research team and a limited review was undertaken. These indicated that there is some resurgence in interest in the literature about these compounds but that this tended to focus on human rather than bovine compounds. At least one company has made an attempt at commercialisation of immune-milk based products for the dietary management of intestinal infections. It would appear that this field of research remains largely unexplored.

Progress assessment towards achieving intended outcomes

Good progress has been made with Product A, although functionality is yet to be proven in product form and the animal trials also need to succeed. Product B is unlikely to achieve its original objectives in the time remaining in the programme. Progress with product B is awaiting the results of external research. The issues identified with processing the compound have been mapped out. Progress with the processing project is awaiting Food Innovation Waikato's (FIW) plant modifications which should allow prototype product to be manufactured. A high compound producing herd has been established but further progress is dependent on progress in research on product functionality. Good initial marketing scoping work has been completed. Further progress on identifying product formats and market potential awaits product functionality results and prototype production.

Overall there has been good progress from the technical/science aspects of the project, but further progress will be hampered until an optimal target level of the compound ingredient

powder is better defined. The science team requires more feedback from the market as to the ingredient specification and what supporting information is needed. Greater engagement with the market is needed to identify the end product applications and what secondary processing the ingredient will be subjected to. This will be important to a number of potential product lines.

Whai Hua should give priority to delivering a prototype product under semi-commercial conditions, with information on its composition, functionality and possible applications over the remainder of the programme. This is likely to require a continuation of the flexible approach to allocating programme resources taken to date.

Future

At the outset it was proposed that perhaps more time and resources were needed to accomplish Whai Hua's objectives. If key milestones are met over the next six months, such as product functionality, successful animal trials, FIW processing and the external research for Product B then extending the timeline for the programme may be sensible. If Whai Hua succeeds in providing evidence of functionality that can be retained through to the point of consumption over the next year, there is likely to be further worthwhile research that could follow on from Whai Hua. This is because the regulatory requirements for strong health claims would require more time and resources than is available in the current programme.

Recommendations

1. Focus efforts on development of a single prototype product, product A, with compositional data and robust evidence of functionality and efficacy relative to competitor products by the end of the Whai Hua programme.
2. Include the determination of dose response in the functional evaluation of the product A compound ingredient to establish the minimum effective dose of the compound. Confirm activity is due to the compound and not non-compound components and conduct a trial with spray dried compound powder to ensure it retains activity in the powder.
3. Repeat the in vitro efficacy experiments of biological properties of bovine compound to reconcile the difference in results from other published data.
4. Use the prototype for market evaluation to elicit feedback on the product and to get a sharper view of potential retail products, markets, channels and ingredient formats and to develop clearly defined targets for animal selection and processing modifications.
5. Conduct storage stability trials to determine shelf life of the ingredient and evaluate the ingredient in secondary processing based on better guidance from the market on how the ingredient will be used.
6. Ensure all data on functionality is robust and based on rigorous science to allow health claims to be made.
7. Extend the knowledge gained from the product prototype to development of other product applications to maximize potential spill over benefits.
8. Establish proof of concept and key specifications for product B before any further development of the vaccine, immunisation protocol and ACVM registration. Vaccine registration should be the last step only once this proof of concept has been

achieved, the immunisation protocol has been finalised and trialled with a larger number of cows.

9. Should the research external to Whai Hua on product B not show sufficient functionality, or the immunisation protocol not be able to be scaled up or provide acceptable immunisation responses in the test cows, the product B project should be stopped.
10. If key milestones are met over the next six months, such as product functionality, successful animal trials, FIW processing for product A or the external research for Product B, consider extending the timeline for the programme. This could allow the programme's original objectives to be achieved and compensate for some of the challenges encountered to date e.g. in product B and compound processing.
11. Review the potential for further work past the completion of the PGP programme should sufficient product functionality through to the consumer be proven over the next year. Examples could include:
 - Developing a proposal for research to identify factors causing inter-animal variation and whether these may be leveraged to further induce the levels in compound producing animals.
 - Assessing what clinical trials if any are needed in New Zealand and overseas to support product health claims.
 - Investigate whether the bovine compound could lead to the development of allergy related symptoms due to amino acid sequence differences with human compound as part of the safety assessment of the ingredient.

Progress review of Whai Hua PGP programme

Introduction

1. The Primary Growth Partnership (PGP) is designed to lead to greater market success for New Zealand's primary industries through long-term government and industry joint venture programmes. Key goals of PGP are to boost productivity and profitability across the primary industries, delivering long-term economic growth and sustainability.
2. MPI has a goal of doubling the value of exports by 2025 as part of the Government's Business Growth Agenda. This will require a significant improvement in both volume and value of exports.
3. PGP investment programmes are designed to target a range of points along the value chain which may include education and skills development, research and development, product development, commercialisation, market development and technology transfer. They will be aligned with, but additional to, existing initiatives and work programmes. Therefore the PGP investments must be new initiatives or initiatives that clearly improve on the pace or scale of existing initiatives.

Whai Hua programme for new dairy products and value chains

4. The Whai Hua PGP programme is seeking to develop new, added-value dairy ingredients, based on immune-enhancing dairy milk products. It involves working closely with industry partners in the target Asian and New Zealand markets and focusing on health-conscious consumers in those markets. AgResearch is the principal scientific research provider. Whai Hua also offers an opportunity to help develop Maori agribusiness strengths.
5. Whai Hua will do this by developing dairy herds which produce milk which has high immune-enhancing properties, product development, functionality testing and market research. At the outset of the Whai Hua programme it was estimated that Whai Hua could create \$8.6 million per year in economic benefits to New Zealand by 2021.
6. Whai Hua began in June 2013 and will run for 2.5 years to December 2015. It has 50:50 government and industry funding of \$1.75 million each. The government's commercial partners are Wairarapa Moana ki Pouakani Incorporation (WMI), Miraka Ltd and Kanematsu New Zealand Ltd.

Progress review

7. Sapere Research Group and Dr Colin Prosser were engaged by MPI in September 2014 to provide an independent, progress review of Whai Hua 16 months into the programme. This review is intended to provide the partners in the Whai Hua PGP programme with an independent assessment of how the programme is tracking towards its goals as set out in the original business plan, as modified from time to time and whether Whai Hua could be adjusted or improved. This report seeks to meet the terms of the review contract dated 10 October 2014.

Objectives of the review

8. The key objectives of the progress review were to:
 - Review progress made to date in each of the five programme objectives towards the intended programme outcomes set out in the programme's contract and Outcome logic model;
 - Identify any unintended consequences (positive and/or negative);
 - Review internal and external factors affecting the programme including management and governance;
 - Check progress and direction against international science/ technology/ industry trends; and
 - Make recommendations to improve the programme (if any).

Scope of the review

9. The review included:
 - All projects within the Whai Hua programme;
 - Management, governance and reporting systems.
 - Project resources – contractors, staff and research providers;
 - Appropriateness of programme funding to achieve targets;
 - Programme monitoring and outcome logic model; and
 - Other internal and external factors affecting the programme.
10. The review did not encompass:
 - Financial management - MPI conducted a financial management audit during the 2013-14 financial year; or
 - The rationale for PGP investment in the programme.

Review team

11. Sapere Research Limited provided the lead reviewers, Peter MacIntyre and David Moore. Dr Colin Prosser provided the technical expertise to evaluate the technical progress and science involved in producing the target compound in milk. Colin is the Chief Scientific Officer for the Dairy Goat Co-operative.

Methodology

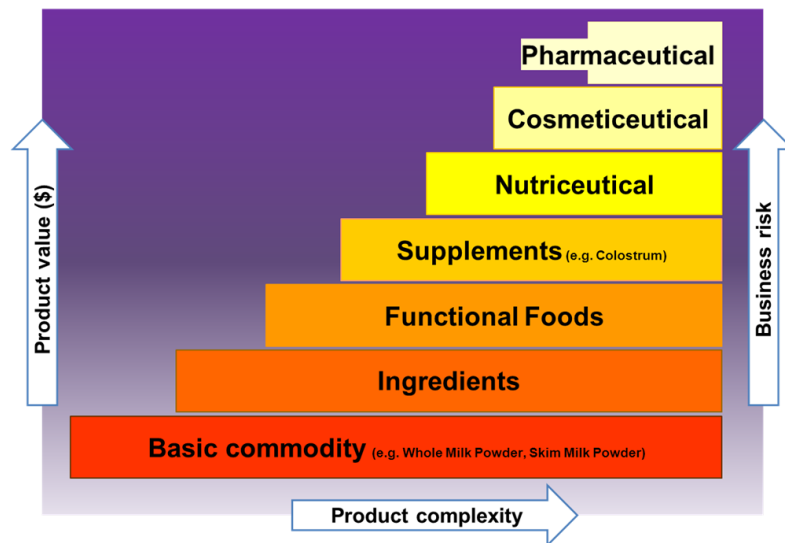
12. The review team reviewed information about the programme, including:
 - The Business Case (1 November 2012);
 - Quarterly reports for the Programme Steering Group (PSG) and MPI for July and October 2013 and January, March, July and September 2014;
 - The PSG minutes for meetings held in June, July and October 2013 and April and July 2014;
 - Whai Hua PGP Programme Annual Plan for 2014 –15;
 - Outcome logic model;
 - Schedule 5, Programme outcomes and milestones of the PGP contract between MPI and the co-investors; and
 - Market analysis and draft science research reports.
13. The team interviewed the Whai Hua programme manager, AgResearch staff, the members of the Programme Steering Group and Dr Kevin Marshall of the PGP Investment Advisory Panel (IAP). The interviews were a range of face to face interviews and some done by telephone. Through this process the review team sought to understand the factors affecting the programme, the efficacy of the project and identify possible opportunities for improvement.

Business Case

Whai Hua vision and objectives

14. According to the business case the target compound concept had advanced to the stage where significant business opportunities existed for the industry partners and the wider New Zealand dairy industry. However, critical R&D issues needed to be addressed before the compound concept could be turned into a commercial reality. These included:
 - More evidence on the biological functionality of these products was required to support product claims and engagement with potential in-market partners.
 - Greater surety was required in the ability to produce and process products that have consistently high functional activity.
 - Stronger business relationships were required with in-market partners who work in the immune health food sector.
15. Figure 1 illustrates the opportunity that exists to move up the dairy product value staircase. The product complexity and business risk rises as products move towards pharmaceutical levels of efficacy but the product value also increases.

Figure 1 Dairy products value staircase



Source: Business Case 12 November 2012

16. The business case noted that to overcome these barriers, a greater critical mass of capability and momentum was required. Without the PGP investment, the opportunity would not advance beyond the situation existing in early 2013.

Outcomes

17. The business case identified the following short-term outcomes from Whai Hua:
 - Two new added value dairy product ingredients being product A and B will be developed to a pre-commercial stage and be ready to take to market. The commercial partners would have an expanded product range while WMI and other suppliers would supply higher value milk for both products.
 - Accelerated development of products and potential market channels will mean new products are able to go to market in 2016/17. Speed to market was seen as important in a fast moving market.
 - Greater confidence to market and supply these products based on evidence of functionality, assembly of naturally high product A herds and retention of compound activity during processing.
 - Market research would identify outlets and potential partners including four to six potential market partners in marketing plans for Asia and New Zealand, in addition to Kanematsu's existing market channels.
18. Sales of product A were to increase 5 fold after five years. A price premium on standard Skim Milk Powder (SMP) was targeted. For product B the aim was to produce and market a smaller amount annually by 2021/22 (5 years after commercialisation). A market value significantly higher than the standard price of SMP was targeted which would be comparable with other hyper-immune products. The business case's projected earnings would cover all extra costs, provide a good return on incremental capital and pay suppliers of higher compound milk a premium per kg of milk solids.

19. Nationally, Whai Hua was predicted to provide a net economic benefit of \$172m over 20 years. This estimate was based on known in-market prices for similar products and sales ramping up as described above by 2021/22.
20. Whai Hua was also expected to result in several spill-over benefits. These included a boost to confidence in innovation initiatives, improving Māori capacity and confidence to invest in such initiatives and the potential to reduce productivity and environmental tensions with higher value added products.

Additionality

21. Providing value additional to existing initiatives and work programmes is a key objective of PGP investment programmes. The business case noted that the position prior to Whai Hua was:
 - WMI was a Māori farming business that supplied milk and sought to expand its activities both inside and outside the farm gate.
 - Miraka was a recently established dairy processing and exporting company and given its relatively small size, it needed to strengthen its competitive position by producing and selling higher margin products.
 - Kanematsu had a long standing role in the marketing of New Zealand produced, immune enhancing dairy products in Japan.
22. It noted that without the Whai Hua PGP investment:
 - WMI would continue to supply milk to Miraka and seek a marketing partner for the existing products. However, this would be done within the context of minimal evidence of function and processing protocols that did not retain sufficient compound activity.
 - Miraka would continue to search for new higher margin products that could overlay its core commodity products.
 - Kanematsu would continue its off-shore investment to identify immune-synergies and product opportunities.
23. The business case therefore emphasized that the Whai Hua investment would allow:
 - Industry partners to realise their vision and goals to commence commercialisation of the products in 2016/17.
 - Completion of all five projects covering new work areas required to overcome the identified technical and market barriers.

Product differentiation and health claims

24. Validating the functionality of the products to support product claims and engagement with potential in-market partners is a critical component of the Whai Hua programme. These products also need to be effective at the point of consumption so consistently high functional activity needs to survive production, processing and shelf life. Achieving this underpins the business case assumptions about the margin Whai Hua's products could attain in target markets.

25. The business case noted that health benefit claims or statements were regulated by Food Standards Australia New Zealand (FSANZ) and were under review. It noted that there were few food safety concerns from high and varied exposures to bovine compounds similar to product A and B.
26. The business case stated that existing immune milk products were dominated by colostrum. It had been marketed as a premier food for the young for growth and development without substantial scientific support. The business case noted that this left these products exposed to being seen as fashion food. Other immune products included Stolle hyperimmune SMP² which had some scientific support. The business case also pointed to Lactoferrin which was used as an ingredient in pediatric and nutritional formulas for its general immune and antimicrobial qualities. It noted that its human counterpart was a major protein in human breast milk. However, the business case related that many scientific studies had failed to clearly show relevant health benefits so it was generally stocked in health food stores as a supplement.
27. The business case noted a goal of creating premier immune-enhancing products. This would be supported by a significant body of scientific evidence directly linking its protective properties with those of human milk components, more concentrated than colostrum products and marketed to major international nutritional companies and would qualify to be added to medical foods. It was intended that it should therefore be a leader in a new market as there would be no comparable products.

Intellectual property

28. It was noted that the product functionality project would be made public through international peer reviewed scientific publications which were needed in order to establish credible, functionality statements for marketing purposes. It also envisaged that licensing and further joint ventures of the technology and practice to other milk suppliers and processors would be determined by the pace and extent of market growth.

Projects that make up Whai Hua programme

29. The PGP programme contains five projects:
 - Target compound functionality
 - Product A herds
 - Product B development,
 - Processing
 - Market intelligence

² Produced from cows immunised with a cocktail of antigens at fortnightly intervals (to maintain antibody levels in the milk) and contains only specific antibodies against the antigens used in the cocktail.

Target compound functionality

30. The stated goal of this project is to provide evidence of biological functionality (i.e. demonstrating that bovine compound performs in a similar manner to its human counterpart in human model systems). This evidence is essential for the purpose of functionality claims and engagement with in-market partners.
31. At the outset of the project the first critical stop/go point was identified as the need to indicate that bovine compound had some similar functions to human compound at an in vitro level. This was to be resolved by September 2014. At this point a draft science paper has been prepared and will be available at the end of December 2014.
32. Key findings
 - The compound purified from bovine milk bound similar levels of a range of bacteria as the human compound.
 - the effect of the compound on intestinal health was however, not clear cut.
33. It has been proposed to further assess compound function in two different animal models.
34. These are excellent initiatives and will form a crucial part of the information paper. The success of these experiments is a key stop/go point in the compound functionality project. Subsequent experiments along the lines outlined below should also be considered as a priority.
35. Using the animal testing model giving the most effective outcome with unprocessed milk:
 - Conduct trial with spray dried compound powder to ensure it retains activity.
 - Confirm activity is due to compound itself and not to other components.
 - Determine the minimal effective dose of the compound in powder.
 - Establish specification for product based on above information.
 - Compare the efficacy of the ingredient to a colostrum product.
36. In summary this project has made good progress in showing the equivalence of bovine and human compound in vitro. It must still prove functionality in the animal trials though. It should then address the points raised above. If these initiatives are successful a solid foundation will be established which will support the herd development project and the processing and marketing projects.

Product A Herds

37. The stated goal of this project is to optimise selection of naturally high target compound herds which will involve understanding the determinants of high compound production and then developing these herds without compromising other production traits. These herds will form the basis of the product A concept.

38. The critical stop/go point identified at the outset of the programme for this objective was that a naturally high target compound herd would be able to generate economic gains at the farm level. This was to be known by July 2014.
39. This project has achieved its stop/go point objective by assembling a superior herd of 500 cows which will be monitored during the 2014-15 season. However, whether it will generate economic gains at the farm level won't be able to be established until the Whai Hua programme is completed and any product prototypes are commercialised.
40. Key findings
- A herd of 500 cows was assembled and screened for the compound.
 - Correlations between the compound and other production variables identified.
 - The main criterion for selecting 'high' compound cows selected.
 - Heritability of compound was estimated.
 - The repeatability of animal compound levels between seasons was identified.
41. Another means to further enhance the compound is via genetic selection. A project to define genetic parameters was therefore added as a secondary outcome of this objective. The data indicate that it is possible to achieve genetic improvement in compound concentrations in the herd without significantly sacrificing other factors.
42. This project has made very good progress. A high compound herd has been formed and can be maintained. Genetic selection for the compound is also possible and future studies of environmental factors could be undertaken as a way to further induce the levels in low compound producing animals.

Product B

43. The stated goal of the product B project is to develop effective and safe multi-antigen immunisation, through determining the compatibility of the immunisation protocols and multi-antigen vaccines, and then achieve vaccine registration. An acceptable protocol is needed to underpin the product B concept.
44. The critical stop/go point identified in the business case for product B was that the multi-antigen vaccine would be ethically acceptable and produce elevated levels of the compound in milk produced from the immunised cows. This was to be known by April 2014. This has not yet been achieved.
45. Work on developing an acceptable and effective commercial vaccine is still ongoing. Ag Research successfully tested a new vaccine reformulation with acceptable animal safety results. This produced a variable response to the target antigens in initial trials. While the reformulated vaccine was found to cause acceptable site reactions, it is thought that the immunisation protocol will still need modification to achieve acceptance from a welfare and logistics perspective.
46. There are major difficulties and risks with producing the target antigen ingredient. The key issues still to be resolved are whether the:

- The product B compound imparts a significant biological advantage.
 - The AgResearch immunisation protocol will be acceptable for ACVM registration for commercial use.
 - Overall response to the vaccine will be sufficient for commercial production.
47. It is extremely important that the proposed functional studies are completed as soon as possible. This will be the next key stop/go point for this project. To assist PSG decisions, the results of the functional studies will need to be available by May 2015. This is an achievable target, but is dependent on the completion of the studies by providers outside of the PGP programme, within this time frame. There would be one year of the programme left at this point.
 48. Numerous trials have been done over the years with the AgResearch immunisation protocol. Various options exist but these also have all been trialled to some degree before. While it may be useful to do these again, it will involve considerable time and cost to undertake a full evaluation of these modifications.
 49. Another concern is whether the immunisation process can be scaled up to provide enough milk with an effective level for processing. For now, the work on registering the vaccine has been put on hold until functionality is confirmed. Realistically it will remain on hold until the immunisation protocol is finalised as registration also requires information on this protocol.
 50. The business case stop/go point for this project has some way to go before it will be reached. The expectations for this objective need to be scaled back to provision of proof of concept for the immunisation protocol and efficacy of the product. Vaccine registration should be the last step only once this proof of concept has been achieved, the immunisation protocol has been finalized and trialled further.
 51. Overall this project faces significant hurdles and is unlikely to achieve its goals by the end of the Whai Hua programme. Should the research external to Whai Hua not show sufficient functionality, or the immunisation protocol not be able to be scaled up or provide acceptable immunisation responses in the test cows, it should be stopped. Resources could then be reallocated to other the projects.

Processing

52. The stated goal of this project is to identify suitable milk processing parameters through developing and testing a process that will ensure the retention of an acceptable level of compound activity. Supplying safe product with consistently high functional activity will be essential to gaining market confidence.
53. The processing critical stop/go point identified in the business case was that the milk processing protocols needed to ensure product safety as well as retain high compound activity. This was to be determined by July 2014. This has not yet been achieved.
54. This objective set out to design a process to make a prototype of a market suitable ingredient and provide test material for evaluation by the science team. The project determined the thermal characteristics of the compound, identified which process steps caused the greatest problems and how to mitigate these.

55. Key findings
- Laboratory scale processing estimated the compound to be moderately heat stable.
 - The compound has proved to be quite susceptible to heat loss.
 - A small scale commercial run resulted in only a low percent retention. A higher level was attained after the plant was reconfigured to reduce heat load.
 - It is estimated that further process modifications may increase the retention rate.
 - Processing modifications will affect process efficiencies and costs of processing.
 - Alternative non-thermal technologies may be suitable, but will add significant cost to processing and hence product.
56. At this stage there has been no processing of milk from the high target compound herd to produce a prototype ingredient. While the optimum specifications have been established, they have not been validated at a commercial scale. This is planned to be achieved by September 2015 using the reconfigured FIW plant.
57. There is still a lot of work to do before the process can be deemed to be suitable for safe consistent production of the ingredient with high functional activity consistent with the business case stop/go point. There will be a need to conduct storage stability trials and some evaluation of the ingredient in secondary processing. There is some risk that secondary processing will lead to further loss of the compound activity in some product lines. There is a need for guidance from the market as to what product application the ingredient will be used in.
58. Overall good progress has been made addressing the initial problems encountered with compound retention, but it is unlikely that original targeted retention will be possible under standard processing conditions. Knowledge has been gained as to modifications to manufacturing process to reduce heat induced loss of compound. However, scaling up the processing of products will require significant investment into a purpose-designed plant configured with these capabilities. These same modifications could have positive spin offs to production of other heat sensitive products.

Market Intelligence

59. The stated goal of this project is to develop market intelligence and new markets through desk research and early market engagement to understand market sizes, values and expectations for target compound dairy ingredients in Asia and New Zealand. The business case noted that market development would require strong business links with in-market partners that operated in the immune health food sector.
60. The business case market intelligence critical stop/go point was that the results of the other projects were sufficiently positive to proceed with market engagement. This was to be known by November 2014. Although this hasn't been achieved at this point, achievement is looking possible for Product A but unlikely for Product B.

61. Market studies undertaken to date have highlighted the need for better information about the product function. One has shown that there should be few problems opening doors with potential customers when Whai Hua has a product ready to sell. It also investigated a number of products that provide good benchmarks for the target compound so, it concluded, this product could establish itself in the market for immune-enhancing foods.
62. Two marketing reports emphasised the difficulties of defending and profiting from investment in developing functional foods with high failure rates for new foods being typical. In the functional foods arena this stems from the challenges of proving specific efficacy and health claims given complex biological processes and often rigorous regulatory requirements. Investments in development of new foods and functional foods are exposed to being copied by others reducing the returns to the trail blazing investor. In addition, consumers tend to be jaundiced by many unsupported claims that have been made about a variety of products over the years.
63. The marketing work contained clear messages on the need to differentiate the target compound from other immunity enhancing products. The ability to do this is dependent on the scientific research showing functional activity in products A and B. The marketing reports emphasised that the levels of the target compound in these prototypes was significantly lower than those found in human milk and competitor products, such as bovine colostrum, which reportedly had as much as 20 times more compound. The question could therefore be the extent to which the bovine target compound beneficially supplemented that naturally produced by the human body. This could mean that it would be challenging to prove health claims so the scientific evidence needed to support the messages for consumers and enable nutrition and structure-function claims to be supported.
64. One report noted that the functionality science formed a go/no go point and suggested that if sufficient evidence was not available the products would not be consistent with the programme's vision and would require significant investment in market education and brand building.
65. The best strategy for retail products, markets, channels and ingredient formats of the products was not clear at this stage.
66. The degree of functional evidence that can be identified in the Whai Hua programme will determine next steps. The market intelligence project is doing further work on requirements for different segments/applications and scoping out the questions that need to be addressed when engaging with potential customers. Due to challenges faced by the other projects, particularly in determining functional evidence and retention in processing, the marketing effort is delayed relative to its business case stop/go point of November 2014.
67. MPI advice on regulatory requirements has shown that Whai Hua products would best fit within the self-substantiated claims category. The MPI advice also indicates that prototype products produced by Whai Hua would face significant further scientific work, including multiple animal and human trials of the product, if they are to achieve the clearance needed to market these with higher level health claims in New Zealand. The end application of the product will determine what clinical

trials are needed. A decision regarding this can be made and a plan developed when the animal trials demonstrating function of the products have been completed. Regulatory approaches vary in overseas markets, but the more promising sizeable markets will also require further scientific validation and partnering with both local and in-market firms to meet regulatory requirements and reach longer term export sales volumes.

68. In summary, the market intelligence work has provided good initial scoping and has challenged thinking about marketing options for these products. Further progress awaits the results of the functionality research and prototype production.

Progress towards achieving programme outcomes

Table 1 Progress against outcome logic model

Short term outcomes in outcome logic model (see Appendix 1)	Progress towards outcomes to date
Products A and B are developed and capable of being produced.	Good progress with Product A. Functionality yet to be proven in product form. Product B unlikely to achieve original objectives in remaining time.
Evidence of product function in supporting immunity in humans is established.	Good initial results found for Product A but animal trials also need to succeed. Product B testing awaiting external research results
PGP partners have capability and confidence to produce consistently high quality products.	Issues with processing compound mapped out. Awaiting FIW plant modifications to test produce prototype product.
Miraka & WMI have improved their competitive potential as diversified Māori agribusinesses.	High compound producing herd established but further progress dependent on progress in research on product functionality.
Market knowledge is increased & likely in-market partners are identified.	Good initial scoping work completed. Further progress on identifying product formats and market potential awaits product functionality results and prototype production.

Source: Sapere and outcome logic model

69. The medium and longer term outcomes set out in the outcome logic model are dependent on achieving the short term outcomes described above. The outcome logic model is attached as Appendix 1.

Unintended consequences & spillover effects

70. A number of positive collateral findings have been made as part of the Whai Hua programme. These could be taken up in future research and investment beyond the Whai Hua programme. The programme has also built a good working relationship between Japanese and New Zealand commercial partners. This rapport could lead to future projects. The spill-over benefits forecast in the business case are only likely to be achieved with successful completion of the programme. As discussed above, good progress is being made with product A but product B faces challenges.

Management and governance

71. After reviewing the Programme Steering Group minutes and quarterly reports and interviewing PSG members and others it is clear that the Whai Hua programme is well organised and well directed and has stuck closely to its budget. This is despite it having come up against some obstacles in particular projects, such as adverse adjuvant reactions in its work on the product B concept. It has managed these flexibly by reallocating resources and reprioritising as needed. This flexible approach to managing the process was appreciated by the commercial partners.
72. Feedback from those interviewed also emphasised the effective project management and facilitation of the good flows of information between MPI, the commercial partners and the research team. Whai Hua participants believed that this had been important in helping the programme achieve what it had to date.
73. The AgResearch science team appears well motivated and is valuing the higher level of feedback from marketing and commercial partners that characterise Whai Hua compared to some other projects. The commercial partners are pleased with the project management of Whai Hua and with the focus and direction of the scientific work at AgResearch. They also expressed appreciation for the practical, commercially oriented and outcome focused approach taken by MPI in the Whai Hua programme saying that it had helped to make the programme work smoothly.
74. The Programme Management Team (PMT) consists of Dr Sheath (Programme Manager), Dr Matthews (Programme Advisor), Dr Haigh (Project Manager for the science projects) and Mr Wyeth (Project Manager for market intelligence). The PMT reports to the PSG. The PMT meets regularly (primarily by teleconference) to keep track of milestone delivery and to report quarterly to the PSG. The PMT prepares the annual report of work conducted during the previous year and develops an annual work plan and budget for the upcoming year.
75. The Whai Hua programme documents made available to the reviewers provided a good record of its progress through time. Progress against milestones, problem identification, contract variations and decisions and action points to rectify problems were available for review. Overall, the Whai Hua documentation and discussions with key participants indicated strongly to the reviewers that Whai Hua is a focused and well managed programme.

Progress against international science, technology & industry trends

76. The progress of the Whai Hua programme against international science, technology & industry trends was discussed with the research team and a limited review was undertaken. These indicated that there is some resurgence in interest in the literature about these compounds but that this tended to focus on human compounds rather bovine compounds. At least one company has made an attempt at commercialisation of immune-milk based products for the dietary management of intestinal infections. It would appear that this field of research remains largely unexplored.

Conclusion

77. Overall the Whai Hua programme has made good progress with four of the five projects tracking close to where planned at the outset. As can be expected in innovation programmes there will be challenges. The product B project, which aims to develop a safe and effective vaccine for an immune-enhancing compound, is facing some difficulties which may mean it does not achieve its original goals. Its future should be determined early in 2015 and will depend on the outcome of external research into the efficacy of the product and the acceptability and scalability of AgResearch's immunisation protocol. However, despite this, the programme continues to offer significant potential benefits both from the projects themselves and possible spin offs. A key challenge remains proving real benefits from the compound products to a level that differentiates them from competitor products. Ultimately the level of tangible benefits will be a key determinant in proving to consumers in various potential markets that the compound products are materially better than alternatives.

Appendix 1 : Outcome logic model

