

Chair
Cabinet Economic Growth and Infrastructure

Proposal to rescind a decision of Cabinet relating to the response to the European Food Safety Authority's Review of the Science on A1 milk

Proposal

1. This paper seeks the Committee's agreement to rescind a decision made by Cabinet in September 2008 that the New Zealand Food Safety Authority (NZFSA) convene a group of experts to discuss the European Food Safety Authority's (EFSA) report on the review of the science on A1 milk, possible actions, and the possible need for further research in this area [CAB Min (08) 36/8 refers].

Executive Summary

2. This paper sets out the basis for the recommendation that a previous decision of Cabinet is rescinded. The decision, as it stands, requires NZFSA to bring together a group of experts to at first instance discuss the EFSA review of the science on A1 milk (the review was published in February 2009). This paper sets out the background to the A1 issue, the basis for the original recommendation relating to the groups of experts (as agreed by Cabinet) and the matters I have considered in making the recommendation to rescind that decision; including (not in priority order) the costs to NZFSA relative to the food safety benefits, practical difficulties associated with a potentially very limited pool of experts; and the value such an exercise could add to the comprehensive EFSA review which concluded that a risk assessment of the safety of A1 milk is not recommended. The Committee is also recommended to note my intention to publish this paper, with an associated media release (if the recommendation to rescind the previous Cabinet decision is agreed).

Background

3. Between December 2007 and September 2008, Cabinet noted and made a series of decisions relating directly and indirectly to concerns that have been raised in recent years about the safety of A1 milk. The decisions included approval in December 2007 of a Terms of Reference for a review of NZFSA's risk management decision making process (referred to as the Slorach Review), which covered NZFSA's risk management and communications decisions in respect to the safety of A1 milk. Cabinet also noted in February 2008 that EFSA would be undertaking a comprehensive review of the existing science associated with A1 milk (referred to as the EFSA Review).
4. The Slorach Review was completed in the first quarter of 2008, and in September 2008 Cabinet agreed to a Government response to the recommendations made by the reviewer. The Government response included agreement that on completion of the EFSA Review (at that stage still in train), NZFSA would bring together a group of experts to discuss the EFSA report, possible actions, and the possible need for further research in this area.
5. The EFSA Review was published in February 2009, and concluded that a formal EFSA risk assessment of A1 milk is not recommended.
6. In light of the findings of the EFSA Review, and other relevant factors discussed in this paper, it is my view that it is neither necessary nor appropriate that a group of experts is so convened. As Cabinet agreed to the course of action however, it is necessary for the decision to be formally rescinded by Cabinet.

The A1 milk issue – the Science and the background to the EFSA Review

7. Milk contains six major proteins: four casein and two whey proteins. Casein proteins comprise approximately 80 percent of the protein in milk. β -casein is the most common of these proteins. Milk high in β -casein A1 has been described as A1 milk, and milk high in β -casein A2 has been described as A2 milk. The New Zealand dairy herd produces varying proportions of A1 and A2 milk, but A1 is the most common.
8. The EFSA Review looked at the available scientific literature that addresses the possible health effects (as per paragraph 9 below) of β -casomorphins and related peptides (proteins), and in particular β -casomorphin-7 (BMC7) which is a peptide sequence present in the milk protein β -casein.
9. Since 2002, matters going to the safety of A1 milk and alleged benefits of A2 milk have been on the food safety agenda. Initially, NZFSA was involved in ensuring advertising (including labelling) claims about the positive health effects of A2 milk, made by some in the dairy industry, were compliant with New Zealand law. The publicity on that issue, and an article published in the New Zealand Medical Journal, triggered further media interest and consumer concern about the safety of A1 milk. The concerns related to claims made that A1 milk contributes to increased risk of certain non-communicable diseases such as autism, cardiovascular diseases and type 1 diabetes.
10. In response to the concerns, NZFSA decided that the responsible step to take was to commission an independent review of the literature to assess the validity of claims being made.
11. The independent review was undertaken in 2003/2004 by Professor Boyd Swinburn, and was published in 2004. The report made it clear that the current state of research was inconclusive in terms of identifying risks of illness from drinking milk.
12. On that basis, NZFSA considered it appropriate to allay public fears by stating that milk was an important source of nutrition and was safe to drink given there was no food safety issue with either A1 or A2.
13. In September 2007, Keith Woodford, a professor of farm management and agriculture at Lincoln University, published a book titled “The Devil in the Milk: Illness, Health and Politics, A1-A2 Milk”. The book described BMC7 (as per paragraph 8 above) as the ‘devil in the milk’ and as a causative element in a range of human diseases. Professor Woodford also criticised NZFSA’s response to the 2004 Swinburn Review.
14. Considerable media interest preceded and followed the publication of “The Devil in the Milk” and in response, NZFSA announced it would commission two reviews: those being a further review of the science associated with A1 milk (the EFSA Review) and a more general review of NZFSA risk management decision making processes (the Slorach Review). The Slorach Review covered a range of food safety issues within the ambit of NZFSA, but it essentially arose as a consequence of debate around the A1 issue and included an assessment of how NZFSA’s risk management framework had been applied to the issue. The Slorach review did not however extend to any analysis of the science on A1 milk nor to whether concerns raised have basis.
15. As noted at paragraph 4 above the Slorach Review included a recommendation relating specifically to the outcome of the EFSA Review, which at the point the Slorach Review was concluded, was still in its early stages.

Comment

The basis for the recommendation being made in the Slorach Review

16. In the section of the Slorach Review report covering the A1/A2 milk issue, the reviewer noted that NZFSA's response to the recommendations made in the Swinburn Review (refer paragraph 11 above) did not extend to taking up Professor Swinburn's suggestion relating to the need to fund further research.
17. The response NZFSA made in 2004 to the Swinburn report is substantively beyond the scope of this paper (and for the record, NZFSA's justification for not undertaking such action at that time is set out in the Slorach Review). However, the recommendation relating to the EFSA Review could be reasonably understood as a means of rectifying a perceived failing on the part of NZFSA (and the Ministry of Health) in respect to actively engaging in identifying or filling research gaps and limitations. (It should be noted that funding of clinical research into the possibility of an adverse health effect previously unrecognised in a food is beyond the mandate of NZFSA and the Ministry of Health).
18. Within his overall conclusions Professor Swinburn stated "In my opinion, the warranted actions at present by the relevant government agencies involve: Funding further research, especially clinical research...". In the Slorach review it is noted that "neither NZFSA nor the Ministry of Health took any specific action to gather research workers in relevant disciplines for a discussion about support for new research to investigate a possible causal relationship between A1 milk and certain non-communicable diseases".
19. NZFSA recommended to the previous Minister for Food Safety that the Slorach recommendation relating to the bringing together of a group of experts be accepted by Government. To have not accepted the recommendation at that time could have been perceived as taking an a priori and closed approach to the outcome of the EFSA review (which at that time had not commenced, nor the Terms of Reference finalised).
20. The conclusion and recommendation of the EFSA review is definitive and not subject to conjecture. In comparison, the Slorach recommendation relating to a group of experts discussing, among other things, the possible need for future research, is inconclusive and was based on limited scientific material, as well as predating the EFSA Review report.

Factors considered in the recommendation to rescind Cabinet's decision

21. My view that a group of experts should not be convened to discuss the EFSA Report is best expressed by way of response to four questions. These being:
 - a) *What would such an exercise add to the review already undertaken?*
 - b) *What are the practicalities or difficulties (eg the availability of suitable experts)?*
 - c) *Would such an exercise represent value for money?*
 - d) *What risks arise in not taking this course of action?*

a) Addition to assessment already undertaken

22. The EFSA Review covered in detail an extensive range of research, if not all available scientific evidence, relating to the existence and robustness of an association between peptides originating from food (including β -casomorphins in milk) and non-communicable diseases. The Review was conducted by a highly erudite group of experts, including one of the people who originated the hypothesis that there was a link between the peptides in A1 milk and a range of non-communicable diseases. As noted above, the Review came to the conclusion that further scientific evaluation in the form of a risk assessment is not needed.
23. Given the scope and outcome of the EFSA Review, it is difficult to envisage a productive Terms of Reference for a group of experts charged with discussing the report, possible actions, and the possible need for further research in this area. Effectively, an expert panel would serve only as second reviewers to the EFSA Review, which would arguably defeat the purpose of the EFSA Review. Further, the level of scientific expertise that could be made available is likely to be less than that already applied in the EFSA review. In terms of making any recommendations or decisions on further actions arising from the EFSA Review, the panel of experts would be limited to evaluating the same information as has been rigorously (and very recently) assessed by EFSA.

b) Practical difficulties and obstacles

24. The main practical difficulty in bringing together a group of experts would be finding people with the relevant expertise; who have not previously been associated with such reviews; who have not expressed particular views on the A1/A2 issue; and who would be available at short notice. As it stands, there is a very small pool of people with the expertise required to reassess the scientific EFSA Review and of those, there may be few who would meet the threshold of little or no previous engagement with the issue. The composition of the group of experts would be closely scrutinised by stakeholders and it would be imperative that no doubts could be raised as to independence and impartiality; a challenge that would be very difficult to meet in Australasia
25. The experts would also need to be drawn from academia, and not from any of the food regulatory bodies with whom NZFSA has recently communicated (refer paragraph 39 below). It would also be preferable that the experts were drawn from outside Australasia, and this would add to the costs.

c) Value for Money

26. Without terms of reference, or identification of potential members, it is difficult to estimate the total cost of bringing together a group of experts. Based on a panel of six experts, all drawn from outside Australasia, a conservative cost of \$60,000 has been estimated. This would cover travel, and consultation fees (which would need to be paid for meeting preparation, meetings, and the collation of the group's review report), but does not factor in internal costs including the indirect costs of deferring or foregoing other NZFSA work. In the event the group made recommendations of further actions or research, the costs are at this point incalculable.
27. Given the lack of a body of evidence suggestive of causality, the food safety issue in question ranks well below the many food safety issues with measurable and highly significant health effects that are currently being addressed by NZFSA. While a major driver of decisions going to the appropriate management of different food safety risks

should not be cost to the Crown, it is critical that NZFSA's expenditure across a range of food safety issues is justified and represents value for money. The recessionary environment places greater emphasis on this exigency, and needs to be taken into account.

28. Given that further consideration of the A1/A2 milk issue by a new group of experts would not, in the view of NZFSA (the food safety regulator), add to the assessment already undertaken by EFSA, the monies expended would deliver no recognisable value in terms of the food safety goals of NZFSA.

d) Risks arising if the group of experts is not convened

29. The main risk that Government needs to take into consideration is that of the safety and health of consumers. The comprehensive EFSA Review of all the available science on the A1 protein concluded that a full risk assessment is not recommended. This is a clear message from a reputable and internationally respected food safety body that based on what is currently known there is no reason for concern as to the safety of A1 milk. Further, the EFSA Review did not signal that there are problematic gaps in the existing science. A decision to not convene the group of experts cannot therefore be interpreted as failing consumers by not pursuing or re-examining a 'live' food safety matter. It is also noteworthy that notwithstanding the then approved Slorach Review recommendation relating to the convening of a group of experts on the completion of the EFSA review, key industry stakeholders (the A2 Corporation and Fonterra) were consulted at the time arrangements for the EFSA review were being finalised and both acknowledged that the results of the EFSA Review would be definitive.
30. Given the history of the A1/A2 issue in the New Zealand context, and the publicly profiled criticisms of NZFSA in respect to its previous management of the A1/A2 issue, a further risk is a public and/or stakeholder concern that NZFSA (or the Government as decision maker) has failed to meet a commitment. In my view, rescinding the decision to form a group of experts, would not be a 'failure' of commitment but would reflect a revised position based on information not available at the time the initial decision was made.
31. The previous administration agreed to the Slorach recommendation (and NZFSA's previous advice on the same), with no expectations as to the Review's definitive conclusion. In terms of an appropriate risk management response to concerns about the A1 protein, the relevance of the Slorach recommendation has therefore significantly reduced.
32. It is also important to note that at various times over the past 7 years, NZFSA has been actively dealing with the A1/A2 issue. As per its mandate, NZFSA made an assessment as to the safety of A1 milk and has subsequently sought several external reviews (Swinburn, Slorach, and EFSA) – none of which have given cause for the NZFSA assessment of risk to be revised.
33. In respect to NZFSA's ongoing awareness of new or emerging scientific evidence as to the safety of A1 milk, NZFSA will continue the intelligence gathering and horizon scanning activities that are a day-to-day component of the Science Group's work. If new and compelling research was to arise, NZFSA would evaluate such research, and if appropriate take a precautionary approach in terms of consumer messages about milk.

Industry Reaction

34. A decision not to convene a group of experts may be viewed unfavourably by those who continue to hold the view that A1 milk carries public health risks and/or conversely, that A2 milk has innate health benefits. The available science (as recently and comprehensively reviewed by EFSA) does not support the former hypothesis but the possibility of further consideration of the issue by a group of experts would no doubt be welcomed in some quarters.
35. A decision not to bring together the group of experts, and effectively close the issue in terms of active engagement by NZFSA, may be seen as a failure to carry out an undertaking. In my view, the Government is entirely justified in considering decisions made by the previous administration in light of current priorities and new information; particularly internationally recognised scientific information.
36. Such a decision would not however affect the possibility of interested parties (industry, scientists, and/or academics) initiating or undertaking further work in this area. Researchers are able to put proposals for funding of research to the Health Research Council of New Zealand (HRC), the Crown agency responsible for the management of the Government's investment in public good health research. The HRC invests in health research through an annual contestable funding round and through joint initiatives with a range of non-Government (and Government) agencies.

Consultation

Consultation with Government departments

37. In the preparation of this paper, consultation was undertaken with the Department of the Prime Minister and Cabinet, the Ministry of Health, the Treasury, the Ministry of Economic Development, the Ministry of Agriculture and Forestry and the State Services Commission.

Consultation with other food safety regulators

38. Prior to providing the advice on which I made the decision to submit this paper, the Chief Executive of NZFSA sought from his counterparts at the food safety regulatory bodies in the United States, Ireland, the United Kingdom and Canada, their views on and intended response to, the EFSA review. The response of Food Standards Australia New Zealand (the body responsible for setting trans-Tasman food standards) was also sought. The consulted parties had no concerns or issues with the conclusion reached in the EFSA Review and at this point, none intend to take further action on the A1 issue.

Financial Implications

39. There are no financial implications arising from a decision to rescind Cabinet's previous agreement that a group of experts be convened to consider the EFSA report. If the Committee does not agree with the recommendation, and the commitment to convene the group of experts remains live, costs to NZFSA at first instance have been estimated at \$60,000.

Human rights implications

40. Officials are not aware of any implications relating to the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993.

Legislative implications

41. There are no legislative implications relating to or arising from this paper.

Regulatory impact analysis

42. A regulatory impact statement is not required for this paper.

Publicity

43. The A1 milk issue (and Government decisions relating to it) has previously been the subject of media attention and is of interest to the New Zealand dairy industry, particularly those producing or promoting A2 milk.

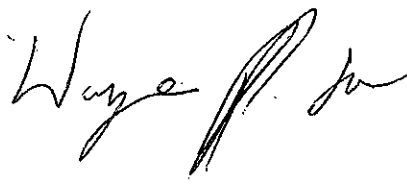
44. The Cabinet papers on the decisions to undertake the Slorach and EFSA Reviews were released by the previous Minister for Food Safety, as was the Government response to the recommendations made in the Slorach Review. Ongoing openness and transparency is important to maintaining public and industry confidence that the A1 issue is being appropriately managed. In the event Cabinet agrees to rescind the decision of the previous administration vis a vis the convening of a group of experts, it is therefore my intention to publish this Cabinet paper and to issue an associated media release.

Recommendations

45. The Minister for Food Safety recommends that the Committee:

1. **note** that on 15 September 2008, Cabinet agreed on a Government response to recommendations made in the review of the New Zealand Food Safety Authority's risk management framework and its application
2. **note** that the Government response included that on the completion of the European Food Safety Authority's review of the safety of A1/A2 milk, the New Zealand Food Safety Authority should bring together a group of experts in relevant fields to discuss the report, possible actions and the possible need for further research in this area [CAB Min (08) 36/8: Recommendation 8.2 refers]
3. **note** that the European Food Safety Authority is a highly resourced, competent, and internationally respected authority with a wealth of expertise in the areas of risk assessment and food safety
4. **note** that in February 2009 the European Food Safety Authority published its detailed review of the available scientific literature that addresses the possible health effects of, in particular β -casomorphin-7, a peptide sequence which is found in the milk protein β -casein
5. **note** that claims have been made that β -casomorphin-7 may contribute to increased risk of certain non-communicable diseases, such as autism, cardiovascular diseases and type 1 diabetes
6. **note** that the European Food Safety Authority review concluded that a cause and effect relationship is not established between β -casomorphin-7 and non-communicable diseases and that a formal risk assessment is not recommended
7. **note** that the previous decision of Cabinet (at recommendation 2 above) has been considered in relation to the following:
 - 7.1 the comprehensiveness of the European Food Safety Authority's review and its conclusion

- 7.2 the extent to which the bringing together of a group of experts would add value to the recent work by the European Food Safety Authority
- 7.3 practical difficulties and obstacles associated with convening a group of appropriate experts; and
- 7.4 whether, given the conclusion of the European Food Safety Authority, there is an imminent food safety issue relating to milk consumption that requires further research and attention at Government level
8. **note** that having considered the matters at recommendation 7 above, I am of the view that the New Zealand Food Safety Authority should not be required to convene a group of experts to discuss the European Food Safety Authority's report, possible actions, and the possible need for further research in this area
9. **agree** to rescind the 15 September 2008 decision of Cabinet that on the completion of the European Food Safety Authority's review on the safety of A1/A2 milk, the New Zealand Food Safety Authority bring together a group of experts in the relevant fields to discuss the report, possible actions, and the possible need for further research in this area [CAB Min (08) 36/8 Recommendation 8.2 refers]
10. **note** that interested parties wanting to pursue research in this area can submit research proposals to the Health Research Council, which manages the Government's investment in public good health research
11. **note** that subject to Cabinet agreeing to recommendation 10 above, I intend to publish this paper and issue an associated media release.

 for Hon K. Wilkinson
Minister of Food Safety

Hon Dr Wayne Mapp
Acting Minister for Food Safety

Date: 16 / 06 /2009