

# The Role of the NZFSA in Investigating Health Issues Concerning A1 and A2 Milk

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*Note: This document was sent to the NZ Minister of Food Safety and selected media on 7 October 2007. It led to the subsequent announcement by the Minister of Food Safety that Dr Stuart Slorach from Sweden would undertake a review of NZFSA risk management procedures, including specific consideration as to how these procedures were applied to the issue of A1 and A2 milk.*

# Summary

The approach of the NZFSA has been one of sustained misinformation. The outcome has been a major failure to objectively assess food safety issues for at-risk individuals.

Since at least 2002 NZFSA has had a stance that 'all milk is safe'. Consistent with this, the starting strategy for the 2003/2004 investigation into A1 and A2 milk was to 'deal with maintaining drinking milk'

The NZFSA sought a report from Professor Swinburn that was authoritative. The proposed outcome was that 'at the end, [we] can say we have checked'. However, there was a fundamental flaw in the NZFSA approach because the expected outcome was essentially predetermined.

The NZFSA then provided guidance to Professor Swinburn that the term 'precautionary principle', as it is normally understood, was to be avoided.

Throughout the review process the relationship between NZFSA and Fonterra was informal. It included advice from Fonterra as well as lobbying by Fonterra as to how the report should be used. In contrast, the relationship with A2 Corporation was more formal.

A2 Corporation was unsuccessful in widening the scope of the review to include any of the underlying science, information in patent applications, and unpublished documentation from within Fonterra.

NZFSA's communication strategy included a press release that was 'authoritative' in style and with a key message that 'there is no evidence that either milk poses a food safety issue'.

However, the report that Professor Swinburn produced did not provide a message that 'all milk was safe'. Swinburn has subsequently been explicit that he purposefully avoided such a phrase. Indeed the message was totally contradictory of statements by Swinburn that the A1/A2 health issue was 'potentially very important for population health'.

For NZFSA to successfully communicate a message of certainty ('all milk is safe'), two issues then needed to be dealt with. One was that the Lay Summary could not be released at the same time. This was because the Swinburn message of uncertainty was particularly explicit in this Lay Summary.

The second issue was that it would be counter productive if Swinburn were available to talk to the media at the time the report was released. This was because his message of uncertainty would have been elicited by media questions.

The decision making processes that led to exclusion of the Lay Summary and release of the technical report at a time when Professor Swinburn had said he was not available, remain opaque. It is clear that some relevant information has not been provided as required under the OIA. However, some discussions may have been held without written documentation.

It is clear that NZFSA has made contradictory statements about the initial non release of the Lay Summary. What is not clear is which of their statements is true. Carol Barnao's written statement that it was excluded 'as we feel that the tone is inconsistent with the substantive report' is illuminating. There was indeed a difference in tone between the technical report and the Lay Summary, and it arose from the difference in the audiences. In the technical report Swinburn was addressing the issue of whether 'ordinary milk' should have a health warning on it and he was clear that the level of uncertainty was far too high for such an action. However, in the Lay Summary he was speaking to ordinary people about the measures they might wish to take as individuals, given that level of uncertainty.

NZFSA have said that their decision to release the report when Professor Swinburn had stated his unavailability was made in error. However, even allowing for this confusion, NZFSA have stated that they deliberately chose not to delay the report for a few days until they knew Swinburn would be available in NZ.

It is notable that NZFSA did nothing to subsequently bring their 'key message' in line with Professor Swinburn's position. When Swinburn expressed his disappointment to them they tried to justify their stance and re-asserted their previous position.

The NZFSA response to Woodford's book (Sept 2007) provided further clear evidence that NZFSA had 'bunkered down' and was in a state of denial. NZFSA stated in a press release on 13 September 2007, that 'media reports of issues with milk, based on a book release, are not backed by scientific evidence'. However, they also admitted at that time, in response to questions, that they had not seen the book. On 'Close-Up' (13 Sept) Carole Inkster said that Professor Swinburn would have kept them informed if there had been new evidence. However, Swinburn had no such contract and he has stated that he has not been working in this field in recent years.

The NZFSA also said that "We understand that this new book...is not presenting new science but is continuing to consider the material that was available to Professor Swinburn. The reality was that Professor Swinburn considered 38 papers whereas Woodford's book considers more than 100.

One can only surmise as to the motivations that have led to the NZFSA behaviours, and whether they arise from incompetence or something else. It would seem that at an early stage NZFSA chose to characterise the A2 issue as an attack on milk in general, rather than an opportunity to deal with some particular problems that were solvable through animal breeding. It may be that NZFSA did not appreciate that there were already in the order of one million A2 cows in NZ, that no company can own the A2 gene, and that any farmer can produce and any company can sell milk that is free of A1 beta casein.

There is a subtle but extremely important distinction between the stance of NZFSA and Food Standards Australia New Zealand (FSANZ). (NZFSA is the NZ implementing agency for FSANZ.) On 14 Sept 2007 FSANZ produced a new 'fact sheet' for A1 and A2 milk, stating 'FSANZ recommends that milk should continue to be regarded as a safe and nutritious component of the diet *for most people*'. [Italics added.]. This has received no publicity in NZ.

The A1/A2 saga also highlights generic issues as to whether the structure and culture within NZFSA is fundamentally flawed. According to NZFSA's own website;

'The New Zealand Food Safety Authority has two key functions:

-to protect and promote public health and safety

-to facilitate market access for New Zealand's food and food-related products.'

This structure makes it very easy for NZFSA to have a confused mandate.

## Background and Purpose

The NZFSA claims (24 Sept 07) that they do not believe ‘A1 milk is any more or less of a risk than A2 milk’. Presumably they are basing this claim on the report undertaken for them by Professor Boyd Swinburn in 2004, which is the only external review they have undertaken. Both the NZFSA position and the Swinburn Report can be accessed from their website ([www.nzfsa.govt.nz](http://www.nzfsa.govt.nz)).

The NZFSA also claims that the recent book, “Devil in the Milk”, written by the author of this report, has presented no new evidence that would cause them to change their position.

The purpose of this report is therefore to review whether or not the NZFSA position is consistent with the professional advice that they have received, and to analyse the processes that have led to any discrepancies between their position and this professional advice.

The report also addresses whether their current stated position regarding no further evidence being available is consistent with the facts, and how they have come to this conclusion.

Leading from this, the report analyses the behaviours that have led to the discrepancies that are found, and explores whether there are fundamental problems at NZFSA both in relation to the *specific* issue of A1/A2 milk and the *generic* issue of structure and culture within the NZFSA.

## Information Sources

This report draws on four key data sets

1. Information from the NZFSA website including NZFSA press releases
2. Information obtained from the NZFSA as a consequence of a request by the author of this report under the Official Information Act (OIA), relating to internal and external correspondence relevant to the Swinburn Report on A1 and A2 milk, and for the calendar years 2003 and 2004..
3. Information provided by NZFSA to NZ Farmers Weekly under the OIA in March 2004.
4. Correspondence from the NZFSA to the author of this report.

The information obtained by this author under the OIA was supplied on 28 Sept 2007 in response to a request made on 24 July 2007.

There is a requirement under the OIA for material to be provided within 20 working days of a request, unless there are unavoidable delays, in which case a plan for supplying the information is to be provided. The relevant Act and the office of the Ombudsman make it clear that responding to such requests is to be regarded as ‘core business’ and delays based on other staff commitments are not valid.

In this particular case, an official of the NZFSA finally advised orally on 12 Sept 2007 that the material had been collated but required ‘signoff’ from Policy Director Carole Inkster as to what

could be released and what would have to be withheld on various grounds. This then took another 11 days due to a 'lack of availability of the authorising Director'.<sup>1</sup> The total time was 47 days.

Various information was then withheld (and remains currently unavailable) on three grounds.

One was privacy under Section 9(2)(a) of the Act. There were 187 exclusions on this ground, including identification of various industry officials from Fonterra and A2 Corporation who wrote in their official positions. In the case of A2 Corporation it was possible to identify the officials because their official position was in general noted below the withheld official's name. However, in the case of the Fonterra officials, this identification of official position was not possible beyond identifying that the addresses were from Fonterra Head Office in Auckland.

The second set of eight exclusions was under section 9(2)(b)(2) of the Act citing 'commercial in confidence'. Apart from perhaps the specific remuneration paid to Professor Swinburn for his report, it is challenging to understand why a Food Safety Authority should be indulging in commercial discussions which are of a confidential nature.

There were an additional 18 exclusions on the grounds that information was 'patently not relevant'. It is not clear on what legislative grounds these exclusions were made and it would seem that they were on the judgement of Policy Director Carole Inkster (who was herself the central NZFSA figure in relation to the Swinburn Report). Given that the topic of the communications were indeed A1/A2, it is difficult to understand the legitimacy of these exclusions. One particular document (Briefing No 03/639) of 20 April 2004 had all of the first page excised except for the following headings; Background, Scientific Update, Market Developments, and Media Interest. It is indeed disturbing to see a Food Safety Authority providing briefings which include market considerations and even more disturbing when these communications are withheld.

If all documents had been supplied in response to this OIA request then there should have been no additional documents in the material previously supplied to NZ Farmers Weekly in March 2004, and relating to the 2003/4 period. However, this was not the case. For example, the material included in this report from Carole Inkster to Professor Boyd Swinburn about the NZFSA strategy in 'trickling out' with the terms of reference, was not included in the 2007 request. Similarly, a letter from Carol Barnao of 12 August 2004 to the author of this report (Woodford) was not included. This raises grave concerns as to what other information might remain undisclosed in NZFSA files.

## **NZFSA's Strategy**

The overall strategy was set out in a handwritten undated document by Carole Inkster. It is clear from the contents that this was before the appointment of Professor Swinburn (which was

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<sup>1</sup> Correspondence dated 27 Sept 2007 to Keith Woodford from Policy Director Carole Inkster, apparently referring to herself in the third person.

underway in March 2003). The document appears to have been written either in late January or early February 2003.

The 'strategy' as set out was 'to deal with maintaining drinking milk'.

This particular strategy would seem surprising for a Food Safety Authority. A more appropriate strategy would seem to have been to investigate the food safety issues and to communicate accordingly to Government and the populace in New Zealand. In contrast, the strategy of 'maintaining drinking milk' would indeed seem to be predetermining the stance and outcome.

The strategic outcome (as set out in the document) is stated thus: 'at the end, [we] can say we have checked'. However it is not clear whether this was the expected outcome, the hoped for outcome, or the required outcome, with any of these being a plausible interpretation. Once again, one can only express surprise at this strategic outcome being so narrowly described. The apparent exclusion of the possibility of a food safety issue being identified would seem remarkable.

The people at this meeting were 'Steve' and Carol B', and the planning was to include 'Lloyd at the next meeting'.

The immediate plan also included to 'click in with [deleted] etc about it not being dangerous'. The deleted person (deleted on privacy grounds) is presumably outside the NZFSA. One can only surmise as to what organisation this person might belong to, why they needed to be 'clicked into' and why they might need privacy.

## **Choice of Reviewer**

There was contention over the choice of reviewer. Subsequent to Professor Swinburn being approached by NZFSA to conduct the review, A2 Corporation expressed strong disagreement based on apparently negative comments that had been made (and reported on TV) by Professor Swinburn about Professor Bob Elliott, (who had produced some of the key A2 research). There was also some internal concern within NZFSA about the appointment (with some names of those making the comments deleted). (Professor Swinburn was himself proactive and totally 'upfront' in alerting the NZFSA to his public comments.) It is not clear where the initial nomination of Professor Swinburn came from, but it is evident that it was Carole Inkster who determined that Swinburn's public comments should not disqualify him.

## **Terms of Reference**

The terms of reference evolved over time, and were not finalised until Professor Swinburn had almost completed the report. Early on there was debate as to the limits on the information to be assessed.

During March 2003 there was various internal correspondence between officers of NZFSA over the terms of reference. However, it is also apparent that this correspondence involved people outside NZFSA whose names have been deleted. There is no indication as to what organisations these people represented.

On 5 May 2003 a communication from A2 Corporation requested that the terms of reference include 'the literature on beta-casomorphin7 and metabolites which have opioid like (morphine like) effects and which can be derived from A1 and B beta-casein but not from A2 casein'. In the same letter it was requested that the various patent applications (and hence the data within) from organisations such as the Dairy Board and A2 Corporation, and also unpublished documentation available from within Fonterra, be included in the review.

There is no evidence of NZFSA responding to this particular letter. Neither issue was included in the terms of reference.

It was also pointed out in this 5 May 2003 letter from A2 Corporation that in NZ 'we produce about 13 billion litres of milk [but in NZ] drink only 2.55% of that figure. However 27-28% of the NZ cows are A2 and hence supplying A2 milk 'is a relatively easy logistical problem'. This was relevant to some correspondence about this time between A2 Corporation and NZFSA whereby A2 Corporation believed that the NZFSA was characterising their position as 'anti milk'.

Internal correspondence within NZFSA about the terms of reference was still occurring on 22 May 2003. There was specific comment about whether or not a study investigating the effect of A1 and A2 beta-casein on heart disease parameters and undertaken at University of Queensland should be included. At that time the paper had been accepted for publication in the international journal 'Atherosclerosis' but had not actually been published. This study concluded that 'A1 beta casein is atherogenic [i.e. causes heart disease]'. Internal NZFSA correspondence of 22 May 2003 refers to this as the 'infamous rabbit study' and 'the infamous Campbell report'. It is puzzling as to why it should be described this way, although of course it was clearly a problem paper for those who wished to deny there were health issues associated with A1 beta-casein.

On 23 May 2003 the Chairman of A2 Corporation wrote again to the NZFSA requesting input into the terms of reference to ensure that the 'brief is full, rounded, and likely to lead to a truly independent and authoritative assessment of the present situation'. The NZFSA replied on 16 June saying that the contract has already been agreed by both parties [NZFSA and Swinburn].

In late May Carole Inkster advised Professor Swinburn that she hoped to 'go out (trickle out) with a summary of the terms of reference'.

However it was only on 17 July 2003 that Carole Inkster advised Professor Swinburn that she had signed the contract.

It is apparent, however, that others had been given some opportunity to influence the terms of reference. An internal email communication (29 April 2003) between 'H' and Carole Inkster stated that (s)he had a 'phone message re terms of reference for the review by Boyd Swinburn

from [name deleted] Porter Novelli, Sydney. It is not clear who Porter Novelli, a global public relations company, were representing.

The final terms of reference were not clearly marked as such within the OIA documents. Nor were they included in Professor Swinburn's report. The various draft terms of reference (one of which may have been the final version) are not specific as to whether the report should include investigations with animals, or whether the underlying science of beta-casomorphin should be explored. In fact the report did include some animal studies (limited) but there was no material on the science of casomorphins. (By September 2007 the PubMed database includes 235 published papers on casomorphins.)

## **The Precautionary Principle**

There was ongoing discussion between Professor Swinburn and Carole Inkster as to the way various issues should be addressed. In late April Carole Inkster wrote in an email:

'In relation to discussion of the precautionary principle our preference would be to not discuss it as the precautionary principle – this term has all sorts of baggage associated with it (especially European baggage) and our preference is to refer to the way we treat uncertainty in scientific assessments and exercise caution in reaching risk management based positions. Happy to expand on this if that would be useful.'

This communication raises important issues in relation to the way NZFSA was attempting to manage the situation. The precautionary principle, when properly applied, states that when there is uncertainty, and where the cost of making a mistake is high, then one should err on the side of caution. In essence, the precautionary principle says that one does not wait for final absolute proof before taking an issue seriously, in situations where there are large potential risks associated with ignoring that issue.

## **The Initial Report**

Professor Swinburn's initial report (before peer review) was submitted on 17 July 2003. It was not (and still has not been) made available. Arguably, this is reasonable. This is because the purpose of peer review is to try and avoid incorrect statements and it is not helpful to have a draft report still awaiting peer review in wide circulation. However, it does appear that the two key commercial parties (A2 Corporation and Fonterra) may not have been treated equally. I am advised by A2 Corporation's CEO at that time (Dr Clarke) that they did not receive any information about the report until late July 2004. However, there is an email from Fonterra dated 13 October 2003 which says (with punctuation and spelling retained as in the original);

Carole. you will recall that I mentioned that A2 is looking elsewhere to market its milk (see attached).

It is important that NZFSA keeps the momentum up on Boyd Swinburn's report and that its decision on the merits of A2's claims be published ASAP. This will go a long way to providing an independent view to other food/health authorities off shore (including US FDA??) and also to those in the food and dairy industry who are likely to be facing the problems we have been facing here in NZ and Oz

kind regards  
[blanked on privacy grounds]  
Fonterra Co-operative Group Ltd.

There are three issues raised by this communication.

The first is the opening statement 'you will recall that I mentioned'. If this previous communication was in written form then it should have been included in the OIA information. And if it was oral then this would seem to confirm a considerable level of informality in the communications (and hence close relationship) between Fonterra and the NZFSA.

The second issue is the lobbying that is inherent in the communication and whether this is appropriate behaviour between a commercial company and a FSA.

The third is that the communication is apparently based on some knowledge as to the contents of Professor Swinburn's report. How was this information obtained? And why and how had Fonterra received this information, given that it was not supplied to A2 Corporation?

## **The Peer Review Process**

An email from Fonterra on 18 November 2003 sets out eight potential reviewers of Boyd Swinburn's report. It is clear that this is email, which is simply headed 'Names', is in response to a request from NZFSA, but there is no documentation of that earlier communication. It may have been oral.

There is no evidence that A2 Corporation were asked to supply name of potential reviewers, and Dr Clarke, who was the CEO at A2 Corporation at the time has confirmed to me that they were not provided with this opportunity.

It is clear from correspondence obtained from NZFSA that there was considerable difficulty in finding appropriate reviewers, with some potential reviewers being unavailable for various reasons. In the end there were two reviewers from NZ, one from the UK and one from Iceland. It is obvious from the peer review documents that the peer reviewers varied considerably in regard to the effort they put into their review and their knowledge of the topic. The Icelandic reviewer stood out in terms of providing critical but constructive comments.

## Planning the Release of the Report

An undated Draft Communication Plan states that the style was to be ‘Authoritative’.

The first ‘key message’ was to be ‘there is no evidence that either milk poses a food safety issue’.

A ‘Comms briefing kit’ was to be prepared for the media consisting of the ‘Report, FAQs, Media Release, Terms of Reference, and Short Background on Boyd and Reviewers’.

Various stakeholders were to be given an embargoed report one week prior to release. The organisations to receive such a copy would be;

Ministry of Health,

A2 Corporation,

Fonterra,

FSANZ, and

the Commerce Commission.

This was the first time (approx 26 July 2004) that A2 Corporation had seen the overall thrust of Professor Swinburn’s report. They quickly replied to NZFSA, welcoming some aspects of the findings but also expressing great concern about information that had been omitted. Indeed they identified 39 research papers that they considered important but which Professor Swinburn had omitted.

Carole Barnao replied that ‘We will send through your comments to Boyd but will be publishing the report as it is, with an opportunity for discussion possibly later in the month when Boyd will be in New Zealand’ One can only wonder whether this approach was consistent with getting a quality report.

## Release of the Report

The report was released on August 3 2004 with an accompanying media package. However, despite Carol Barnao having said to A2 Corporation a few days earlier that ‘We will be publishing the report as is’, a significant change had in fact occurred. The Lay Summary had been removed. In doing this, some unidentified person had changed the Layout of the technical Executive Summary to create very large (indeed extremely large) paragraph breaks so that the overall document retained its original length in terms of the number of pages. *The motivation for this change, or indeed the decision to omit the lay Summary, is not recorded in any documentation released under OIA.*

The NZFSA press release of 3 August 2004 commenced:

Consumers are advised to keep drinking milk as a nutritious food no matter whether it is A1 or A2, as there is no food safety issue with either type of milk’.

Not surprisingly, it was this message that dominated media reports.

***A key issue is whether or not this safety message was consistent with the report that Professor Swinburn had presented.***

***A related key issue is whether or not the NZFSA could have sustained their position if Professor Swinburn had been available for media interviews. It will be documented below that Professor Swinburn had in fact stated his unavailability to do interviews on the specific days surrounding 3 August, but his availability at other times.***

## **The Issue of the Lay Summary**

The Lay Summary was written by Professor Swinburn in response to a reviewer's comment that such a report was needed. This is explicit in information obtained under the OIA. Professor Swinburn also made it explicit on Radio NZ National on 14 September that he was asked to provide this report. However Carole Inkster was also explicit on Radio NZ National on that day that this was not part of the contract and this was why it was omitted

The Lay Summary said *inter alia*:

‘The A1/A2 hypothesis is both intriguing and potentially very important for population health if it is proved correct. It should be taken seriously and further research is needed.’

‘Changing the dairy herds to more A2 producing cows may significantly improve human health.’

‘As a matter of individual choice, people may wish to reduce or remove A1 beta-casein from their diet (or their children's diet) as a precautionary measure. This may be particularly relevant for those individuals who have or are at risk of the diseases mentioned (type 1 diabetes, coronary heart disease, autism and schizophrenia).’

Indeed the overall tone of the Swinburn report was to emphasise the uncertainty. As a consequence, Swinburn was clear that there were insufficient grounds for warnings to be placed on milk containing A1 beta-casein. He was equally clear that there may be considerable benefits to some individuals by moving to A2 milk.

## **Why was the Lay Summary Removed?**

It is remarkable that there was no internal or external correspondence released under the OIA which helps understand how the decision to omit the Lay Summary was made. Indeed the existence of such a report would not have been known to the media if it were not for this author (Woodford) disclosing its existence. Woodford became aware of the Lay Summary because of an A2 Corporation press release that mentioned a statement by Swinburn which was not in the released version of the report. Woodford then obtained the original report from A2 Corporation and compared the documents.

The NZFSA has given contradictory reasons for the omission of the Lay Summary.

The first approach was to essentially pretend that it did not exist. Carole Inkster said on Radio NZ National: 'There is nothing being held back. The full text of the report is in the public arena. It is on our website.' Then in response to a specific question from presenter Kevin Ikin as to whether it included the Lay Summary, she replied: 'No, it doesn't include the Lay Summary because we felt it didn't add anything'.

However, Carol Barnao, in subsequently (12 August 2004) releasing the Lay Summary under an OIA request to this author, stated in writing, that the Lay Summary was 'not included in the final report, which was available on the website, as we feel that the tone is inconsistent with the main report.' (It is notable that this letter was missing from the OIA documents released in Sept 2007.)

Subsequently (Sept 2007), Carole Inkster has said on Radio NZ National that it was not released because it was not part of the contracted report. Inkster also stated to NZPA on 14 Sept 2007 that: 'What we do with the report that we commissioned is really our business'.

In fact the Lay Summary was subsequently placed on the NZFSA website. However, by this time the issue was 'stale' and it was not picked up by the news media.

It can be noted that the tone of the Lay Summary was indeed somewhat different than the main report. Swinburn explained this in a letter written jointly with the author of this report (Woodford) in an email letter to Fonterra CEO on 24 August 2004 and documented within 'Devil in the Milk'. In essence the main report was aimed at Government and addressed the issue of whether or not there should be a warning on milk. The Lay Summary focused on what ordinary people should do given the uncertainty.

## **Subsequent Responses from Professor Swinburn**

Professor Swinburn wrote to NZFSA on 13 August expressing his disappointment at the way NZFSA had released his report. He pointed out that it had been released at a time when he had previously advised he would be unavailable to take media calls. He also said:

'The NZFSA spin turned out to be a rather classic government agency response of trying to paint it as a non issue with a degree of certainty it didn't warrant. That is why I had recommended a balanced communication from government about the uncertainty, and I suspect it is why the Lay Summary was pulled.'

Professor Swinburn was also critical of ('amazed' and 'disappointed at') [name deleted, but an easily identifiable nutrition scientist] who had weighed into the debate by arguing against the need for more research'

The NZFSA response from Carole Inkster included taking responsibility for 'getting the availability of your dates wrong'. However, the NZFSA also indicated that it was a considered decision not to wait until when they believed Professor Swinburn would be available in NZ, some

10days later, as ‘we had decided we did not want to delay release until later in August’. It is indeed puzzling why a delay of a few days was so important to NZFSA given that there had already been more than 12 months delay since Professor Swinburn had first submitted his report for peer review.

Carole Inkster’s response on 16 August 2004 also contained the following remarkable comment in relation to Swinburn’s unavailability to the media.

‘...we did not believe that [your unavailability] was a distraction in so far as the media were not able to engage on points of science unnecessarily and potentially beat up the issue.’

The debate between NZFSA and Swinburn continued, with Swinburn stating

‘I think NZFSA could be subject to criticism if it is very definitive when the evidence is suggestive but not conclusive. I think the media or others can and should debate the science.’

Swinburn continued:

...if I had a child with Type 1 diabetes and was due to have another and I could easily obtain and afford A2 milk or formula, I would certainly use it for the next child because the cost/benefit is low because of the potentially very large benefit of preventing Type 1 diabetes.

Clearly these statements are inconsistent with the NZFSA key message that ‘there is no evidence that milk poses a food safety issue’.

Swinburn also made his position very clear on Radio NZ National on 14 Sept 2007 that his non inclusion of terms such as ‘milk is safe’ was very purposeful.

## **NZFSA’s ongoing position from 2004-2007**

Given the omitted evidence identified by A2 Corporation, the question immediately arose as to whether further updating was needed. Professor Swinburn’s position was that if he were to do further updating work he wished to ‘stick with human data’. This meant not looking at pharmacological data, such as the bizarre behaviour of rats when injected with beta casomorphin 7. For ethical reasons these types of trials are close to impossible to undertake in humans.

Carol Barnao wrote to Carole Inkster that she ‘would also push for limiting [update work] to human studies –the complexity if we broaden the scope (and probably get hit with a retrospective consideration) is too difficult.’

Although there was discussion within NZFSA as to the desirability of contracting Professor Swinburn to maintain a watching brief, there was apparently no action taken to set up such a contract.

## **NZFSA Responses to Woodford's book**

Woodford's book 'Devil in the Milk', based on more than 100 papers published in the scientific literature, was published on 14 Sept 2007. Some media had advance 'readers copies' some days before.

NZFSA's immediate response by press release on 13 September was: 'Recent media reports of issues with milk, based on a book release, are not backed by scientific evidence.' The spokesperson then admitted in response to a question that no-one at NZFSA had sighted the book.

NZFSA also stated (13 Sept 2007) that: 'We are not aware of any new research from anywhere in the world, and can only conclude that the world's medical researchers have not seen the A2 hypothesis as a high priority for investigation.'

Subsequently, on 24 September 2007, the NZFSA stated in a press release that their 'expert opinion' [is] that milk, whether A1 or A2` remains safe to drink'. This opinion was reached 'after careful consideration of Keith Woodford's book'.

## **NZFSA and FSANZ**

The relationship between NZFSA (NZ Food Safety Authority) and FSANZ (Food Standards Australia New Zealand) can be a source of confusion to those not closely involved. The FSANZ is a joint Australia/New Zealand organisation that harmonises food regulations across the two countries. In Australia the FSANZ regulations are implemented by state and territorial authorities and in NZ this implementation is undertaken by NZFSA.

On 14 September 2007 FSANZ produced a new fact sheet on 'A1 and A2 milk'. It stated 'FSANZ recommends that milk should continue to be regarded as a safe and nutrition component of the diet for most people'. This was the first time that FSANZ had qualified its nutritional advice by adding 'for most people'.

## **Reflections and Conclusions**

It is evident that NZFSA had a strategy prior to commencement of the Swinburn study which was to 'maintain drinking milk'. This was consistent with a range of NZFSA press releases on milk between 2002 and 2007 which emphasised that 'all milk is safe'.

The NZFSA sought a report from Professor Swinburn that was authoritative. However, there was a fundamental flaw in the NZFSA approach because the expected outcome was essentially predetermined.

The NZFSA then provided guidance to Professor Swinburn that the precautionary principle, as it is normally understood, was to be avoided.

It is notable that throughout the review process the relationship between NZFSA and Fonterra was informal and included input from Fonterra as to the process, as well as lobbying as to how the report should be used. In contrast, the relationship with A2 Corporation was considerably more formal and it seems that A2 Corporation were particularly unsuccessful in widening the scope of the review.

Despite terms of reference that led to most of the science (biochemistry, pharmacology, and immunology) being excluded, together with exclusion of some animal-based research and data contained within patent applications, the report that Professor Swinburn produced did not give a clear message that 'milk was safe'. Indeed Swinburn has been explicit that he purposefully avoided such a phrase.

For NZFSA to then successfully communicate a message of certainty, two issues needed to be dealt with. One was that the Lay Summary could not be released at the same time, because of the obvious contradiction between the NZFSA 'key message' of certainty and Swinburn's key message of uncertainty. The second was that it would be counterproductive to have Swinburn available to talk to the media at the time the report was released, because his message of uncertainty, which would have been elicited by media questions, was in obvious conflict to that key message.

The decision making processes that led to the exclusion of the Lay Summary and the release of the report at a time when Professor Swinburn had said he was not available, remain opaque. In regard to omission of the Lay Summary it is, however, totally clear that NZFSA has made contradictory statements. What is not clear is which statement is true. In this regard, Carol Barnao's written statement that it was not included in the final report 'as we feel that the tone is inconsistent with the substantive report is illuminating. There was indeed a difference in tone between the substantive technical report and the Lay Summary, and it arose from the difference in the audiences. In the technical report Swinburn was addressing the issue of whether 'ordinary milk' should have a health warning on it and he was clear that the level of uncertainty was far too high for such an action. However, in the Lay Summary he was speaking to ordinary people about the measures they might wish to take as individuals given that level of uncertainty.

It is unfortunate that the reasons for these differences in tone were not made more explicit within the Swinburn report itself. However, Swinburn did make it clear to NZFSA in the days following the report that their key message did not have his support. (This was also made explicit in a joint letter written by Professor Swinburn and the author of this report (Woodford) in a letter to Fonterra CEO on 19 August 2004 and documented in Woodford's book 'Devil in the Milk')

It is notable that NZFSA did nothing to subsequently bring their 'key message' in line with Professor Swinburn's position. Despite him pointing out his findings had been incorrectly communicated by them, they simply re-asserted their previous position.

The response to Woodford's book proved further clear evidence of NZFSA being 'bunkered down' and in a state of denial. How was it possible for NZFSA to state in a press release on 13 September 2007 that 'media reports of issues with milk, based on a book release, are not backed

by scientific evidence' when they also admitted that they had at that time not seen the book? NZFSA also said that 'We understand that this new book...is not presenting new science but is continuing to consider the material that was available to Professor Swinburn'. The reality was that Professor Swinburn considered 38 papers whereas Woodford's book considers more than 100.

***Quiet simply, the approach of the NZFSA has been one of sustained misinformation. The outcome has been a major failure to objectively assess food safety issues for at-risk individuals.***

One can only surmise as to the motivations that have led to the NZFSA behaviours, and whether they arise from incompetence or something else. It would seem that at an early stage NZFSA chose to characterise the A2 issue as an attack on milk in general, rather than an opportunity to deal with some particular problems that were solvable through animal breeding. It may be that NZFSA did not appreciate that there were in the order of one million A2 cows in NZ, that no company can own the A2 gene, and that any farmer can produce and any company can sell milk that is free of A1 beta-casein.

The A1/A2 saga also highlights generic issues as to whether the structure and culture within NZFSA is fundamentally flawed. According to NZFSA's own website;

'The New Zealand Food Safety Authority has two key functions:

-to protect and promote public health and safety

-to facilitate market access for New Zealand's food and food-related products.'

This structure makes it very easy for NZFSA to have a confused mandate.

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