Chair
Cabinet Economic Development Committee

A1-A2 MILK: ARRANGEMENTS FOR UPCOMING REVIEWS

Proposal

1. This paper advises Cabinet of arrangements for two reviews to address ongoing issues related to the hypothesis that there are differences in the safety of A1 and A2 milk. The paper describes the processes that have been followed to date by the regulator, the New Zealand Food Safety Authority (NZFSA), in responding to these issues and provides a summary of planned arrangements (Terms of Reference and reviewer) for the review of NZFSA's risk assessment and communication processes generally and in regard to the safety of A1 and A2 milk specifically. The paper also advises on progress being made on arrangements for an expert survey of the available scientific research on A1 and A2 milk.

Executive Summary

2. The difference between A1 and A2 milk rests on two forms of beta-casein (a kind of protein) found in milk. Some groups claim that the A1 form of beta-casein in milk may be associated with serious disease in humans. Available evidence in regard to this hypothesis is inconclusive and there is no scientific consensus.

3. Issues concerning A1-A2 milk were subject to scientific review in 2003-04 and emerged again with the publication of a book by Professor Keith Woodford presenting further hypotheses on the matter in September 2007.

4. The New Zealand Food Safety Authority (NZFSA) announced on 10 October 2007 that a further review of the science related to A1-A2 milk would be commissioned, together with a review of the NZFSA risk management decision-making process. The latter will include an evaluation of the process applied by the agency in making statements about the importance of milk in the diet and its safety.

5. The reviews of the NZFSA risk management decision-making process and the science behind A1-A2 milk are very different and require different Terms of Reference and expertise.

6. The Terms of Reference for the review of NZFSA's risk management decision-making process have been considered by the State Services Commission, Audit New Zealand and the Treasury. These agencies advised they have no comments to make on the Terms of Reference. The Terms of Reference for the review of the science concerning A1-A2 milk remain under development in consultation with the Ministry of Health.

7. A reviewer of the NZFSA decision-making process requires particular regulatory expertise and international standing; attributes held by a very limited pool of potential candidates. Officials have identified Dr Stuart Slorach and have tentatively secured his agreement to undertake the review. Dr Slorach has extensive experience in the area. This experience includes being Chair of the Management Board of the European Food Safety Agency (EFSA) when it was first established and Chair of the international food standards setting agency, the Codex Alimentarius Commission. Cabinet is asked to note that I have agreed to the Terms of Reference for the review and that I have confirmed Dr Slorach as the reviewer.

8. The review of the science is more difficult and resource intensive and will potentially require a longer period to undertake and conclude. Discussions with potential reviewers are continuing and advice on this aspect will be provided to Cabinet in the New Year, 2008.

Background

9. Milk contains six major proteins: four casein and two whey proteins. Casein proteins comprise approximately 80 per cent of the protein in milk. Beta-casein is the most common of these. Milk high in beta-casein A1 has been described as 'A1 milk' and milk high in beta-casein A2 has been described as 'A2 milk'. The New Zealand dairy herd produces predominantly A1 milk. The principal technical issue in regard to A1-A2 milk is the proportion of beta-casein A1 and beta-casein A2 milk available to the consumer.

10. In November 2002, NZFSA was alerted to the A1-A2 milk issue as a result of a dialogue between Fonterra and A2 Corporation,[1] from claims being made in the press, and from a court case involving Fonterra and A2 Corporation. In January 2003, an article in the *New Zealand Medical Journal* (vol. 116 no. 1168) triggered greater media interest in the issues around A1-A2 milk. The article and subsequent advertising applied to A2 milk products (on labelling and on websites) made claims associating A2 milk and effects on heart disease, diabetes, schizophrenia and autism. NZFSA's prime interest at the time was in ensuring the claims applied by industry to A2 milk were compliant with New Zealand law.

Regulator response

11. Following public interest in the Fonterra-A2 Corporation dialogue and the claims made by the A2 Corporation, NZFSA became aware that some consumers were concerned that the milk they were drinking was not safe. This raised the potential risk that some people would substitute high-sugar drinks for milk. Acknowledgement of this risk prompted NZFSA to issue a press statement in January 2003 entitled "Milk still part of balanced diet".

12. As a result of the claims that were being made regarding A2 milk, and as there was growing consumer concern, NZFSA decided that the responsible step to take was to commission an independent review of the literature to assess the scientific validity of the statements being made.

13. NZFSA worked with the Ministry of Health on a review brief and potential reviewers were identified and approached. Professor Boyd Swinburn from Deakin University in Melbourne (formerly the Medical Director of the New Zealand Heart Foundation) agreed to undertake the review in late March 2003. Matters relating to the issue of truthfulness in labelling were referred to the Commerce Commission. NZFSA's message at the time remained that "milk is nutritious and beneficial and should remain part of a balanced diet".

14. The draft final report was completed by October 2003 but peer reviewers (again identified with the assistance of the Ministry of Health) took some months to secure. Peer reviewers were confirmed in February 2004. The peer reviewers were:
    - Dr Paul Shattock, Autism Research Unit University of Sunderland UK
    - Professor Inga Thorsdottir, Unit for Nutrition Research, University Hospital, Iceland
    - Professor Norman Sharpe, Medical Director, National Heart Foundation of New Zealand
    - Professor Robert Scragg, Auckland University

[1] A2 Corporation specialises in collecting, processing, and selling milk that is high in beta-casein A2.

The peer review was completed and the paper finalised by Professor Swinburn in July 2004. One of the peer reviewers expressed a view that it would be important that a clear lay summary be provided.

15. NZFSA released the report and its executive summary on 3 August 2004. The report, *Beta-casein A1 and A2 in milk and human health*, made it clear that the current state of research was inconclusive in terms of identifying risks of illness from drinking A1 milk and that further research is needed. In the executive summary Professor Swinburn stated that he "[did] not believe there is sufficient evidence to warrant the government agencies taking further specific public health actions such as changing dietary recommendations, requiring labelling of products containing A1 beta-casein, or encouraging changes in the dairy herd composition in order to promote and protect the health of the population." On this basis NZFSA considered it important to allay public fears by stating that milk was an important source of nutrition and was safe to drink.

16. NZFSA's statements to this effect were followed by public release of the lay summary. As the executive summary in the peer reviewed report was clear and comprehensive and as NZFSA determined that the lay summary substantively repeated the recommendations set out in the executive summary (including the statement that "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"[2]), the Authority decided not to release it with the report.

17. It has been suggested that NZFSA's delayed release of the lay summary and the Authority's communications about the safety of milk indicate problems with the application of NZFSA's decision making processes to food safety issues. It is for this reason the Terms of Reference for the proposed review into NZFSA risk management decision making process (see below) will specifically cover how NZFSA handled the lay summary.

Developments in 2007

18. On 15 September 2007, Keith Woodford, Professor of Farm Management and Agribusiness at Lincoln University, published a book entitled *The Devil in the Milk: Illness, Health and Politics, A1 and A2 Milk.* The book describes a hypothesis about the 'devil in the milk', a peptide called beta-casomorphin-7 (BCM7), which is a protein fragment of A1 beta-casein that is formed by digestion. Professor Woodford avers that BCM7 is a causative element in a wide range of human diseases. There is no scientific consensus on this hypothesis and the material presented in the book is open to scientific debate.

19. Considerable media interest prompted by the publication of Professor Woodford's book has led to questions about NZFSA's handling of A1-A2 issue. This prompted NZFSA to propose two reviews: a review of the science concerning A1-A2 milk and a review of the risk management decision-making process used by NZFSA in its work concerning food safety.

Comment

20. The reviews of the risk management decision-making process and the science are very different and require different Terms of Reference and different expertise.

[2] This must be considered in tandem with the statement, which is also made in the lay summary, that "public health actions, such as changing dietary advice or requiring labelling of milk products, are not considered to be warranted at this stage."

Review of decision-making processes used by NZFSA

21. NZFSA has a mandate to protect and promote public health and safety and enhance New Zealand's position as a trusted supplier of food. The credibility of NZFSA's risk management decision-making process is central to maintaining this position.

22. The Terms of Reference for the review of NZFSA's risk management decision-making process are at Attachment A. NZFSA prepared these Terms of Reference on the basis of the Risk Management Framework[3] initially published in New Zealand as a joint paper between the Ministry of Health and the Ministry of Agriculture and Forestry to describe the approach to be taken in consideration of food safety matters. The framework has been refined by, and is fundamental to the work of, NZFSA. Its application in relation to the A1-A2 issue specifically and to other food safety matters[4] is at the core of the Terms of Reference of the NZFSA decision-making review.

23. The Terms of Reference for the review of the NZFSA decision-making process have been considered by the State Services Commission which advised that while it did not have expertise in this particular area the Terms of Reference appeared to be adequate. Audit New Zealand and the Treasury both received copies of the draft Terms of Reference and had no comment to make.

24. A reviewer of the NZFSA risk management decision-making process requires particular expertise and international standing. Such credentials are held by a very limited number of people. Ideally, the reviewer would have knowledge of national food safety authorities, have knowledge of best practice in the decision-making of such agencies and be available to undertake the review. A number of potential candidates were considered. These were Andrew Wadge from the United Kingdom Food Standards Agency, Patrick Wall who was Chief Executive of the Irish Food Safety Authority and is now Chair of the European Food Safety Authority (EFSA), George Davey of the New South Wales Food Safety Authority, Tom Billy former Administrator of the United States Department of Agriculture's Food Safety and Inspection Service and Dr Stuart Slorach, former chair of EFSA.

25. Of these, Patrick Wall and Stuart Slorach were directly approached by NZFSA. They were approached because, to the best of NZFSA's knowledge, neither is currently employed in full time senior management or public service positions nor involved in time critical consultancy work. Patrick Wall indicated he was unavailable because of other commitments while Stuart Slorach indicated his availability beginning late 2007.

26. Stuart Slorach has extensive experience in the areas of risk management and food regulation (his curriculum vitae is provided as Attachment B) which includes his management of EFSA when it was first established and his chairing of the international food standards setting agency, the Codex Alimentarius Commission. Cabinet is asked to note that I have agreed to the Terms of Reference for the review and I have confirmed Dr Slorach as the reviewer.

Review of the science concerning A1-A2 milk

27. The Terms of Reference for the review of the science concerning A1-A2 milk remain under development in consultation with the Ministry of Health. Preliminary discussions with potential reviewers concerning the requirements are also underway. This review is

[3] The Risk Management Framework provides a systematic process whereby knowledge of risk and evaluation of other factors relevant to the control of hazards are used to choose and implement regulatory standards or other measures. It involves four generic steps: evaluating the issue and bringing the science together to determine the level of risk; assessing the options available to manage the risks to human health and selecting the most appropriate food controls; putting those controls into practice; and monitoring and reviewing the human health and other outcomes, such as the level of hazard remaining in the food chain, to see if the chosen controls have worked as expected.

[4] Matters such as the strategy for control of *Campylobacter* in poultry, aspartame as a food additive, the imported foods regime and food from China, and the standard development for Roquefort cheese made from raw milk.

more difficult and will potentially need a longer time period to undertake and conclude. It is intended that a further noting paper will be provided to Cabinet with details of the science review in the New Year, 2008.

Consultation

28. In preparing this paper, NZFSA consulted the State Services Commission, Audit New Zealand, the Treasury and the Ministries of Foreign Affairs and Trade, Agriculture and Forestry and Economic Development, Health and the Department of the Prime Minister and Cabinet.

Financial Implications

29. There are no financial implications for the Crown associated with this paper.

Human rights implications

30. 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

31. There are no legislative implications relating to this paper.

Regulatory impact analysis

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

Publicity

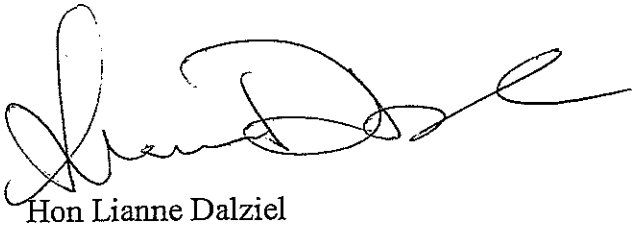
33. I have agreed to NZFSA making public the Terms of Reference for the review of NZFSA decision-making processes and the identity and credentials of the reviewer as soon as possible.

Recommendations

34. It is recommended that the Cabinet Economic Development Committee:

1. **note** that as a result of ongoing interest and new hypotheses concerning A1-A2 milk, two reviews are to be undertaken: one concerning the New Zealand Food Safety Authority's risk management decision-making processes on food safety matters and one concerning the science of A1-A2 milk
2. **note** that the two reviews require very different expertise and Terms of Reference and will therefore be undertaken separately
3. **note** to the Terms of Reference for the review of the New Zealand Food Safety Authority's decision-making process on food safety matters have been agreed by me and are set out in Attachment A
4. **note** that Stuart Slorach has been identified as the reviewer with the necessary expertise to undertake this review, that his curriculum vitae is at Attachment B, and that I have confirmed his appointment
5. **note** that I have agreed to the New Zealand Food Safety Authority publishing the Terms of Reference for the review of its risk management decision-making process on food safety matters, the details of the reviewer, and this Cabinet Paper
6. **note** that the Terms of Reference for the review of the science concerning A1-A2 milk are currently under development in consultation with the Ministry of Health and that

those Terms of Reference, together with further details of the review, will be advised to Cabinet in the New Year, 2008.



Hon Lianne Dalziel
Minister for Food Safety

Date: 27/ 11 /2007

Terms of Reference

Review of NZFSA's Risk Management Framework for making decisions on consumer protection

The expert consultant will

(i) Assess the appropriateness and applicability of NZFSA's Risk Management Framework for making decisions on consumer protection.

(ii) Undertake an evaluation of the applicability and appropriateness of the NZFSA Risk Management Framework in regard to:

a) varying levels of uncertainty in available scientific information and/or risk assessments;

b) establishing priorities for policy development and risk management action;

c) balancing scientific information on risks with other risk management inputs such as the health expectations of society and the likely cost/benefit of potential control measures;

d) the establishment of food safety standards where appropriate;

e) the context of international trade rules and New Zealand's international obligations; and

f) allocation of decision-making and standard development functions within the organisation, and the business structure for such activity.

(iii) Compare the Risk Management Framework as applied in New Zealand with international (Codex) guidelines on best practice.

(iv) Compare the application of the NZFSA's Risk Management Framework in New Zealand with similar risk management systems in other countries.

(v) Consider and report, in light of the report *Beta-casein A1 and A2 in milk and human health* prepared by Professor Boyd Swinburn, on the application of the principles of the Risk Management Framework in respect of the process by which NZFSA came to the decision to continue to take the position that milk is a good source of nutrition and is safe to drink.

(vi) Assess the transparency and communication of decisions made in regard to A1-A2 milk, particularly in light of the delayed release of the lay summary prepared by Professor Boyd Swinburn and his non-availability to respond to media queries resulting from the release of his report.

(vii) Consider whether, in light of the Swinburn report, further steps should have been taken by NZFSA (e.g. referring the report to relevant government agencies highlighting the need for further research).

(viii) Consider and report on the application of the principles of the Risk Management Framework in respect of other recent high-profile risk management and standard setting activities undertaken by NZFSA; in particular the strategy for control of *Campylobacter* in poultry, aspartame as a food additive, the imported foods regime (including for food from China), and the standard development for Roquefort cheese made from raw milk.

The expert consultant will take into account:

(ix) Published and internal NZFSA documentation of systems and processes

(x) Current New Zealand legislation and guidance

(xi) Published documents on risk management systems for (and of) other national food agencies

A review report is to be prepared and presented that contains:

(xii) A description of the NZFSA system

(xiii) A description of international best practice in the area

(xiv) A comparative analysis of the NZFSA system against best practice

(xv) Commentary on the application in recent risk management decision-making matters.

CURRICULUM VITAE

Dr Stuart Alexander Slorach

Place of birth: London, England
Citizenship: Swedish, previously British

Academic background and other qualifications

- Bachelor of Pharmacy (First Class Honours in Pharmacology and Pharmaceutical Chemistry), University of Nottingham, England, 1960 (graduated 1961).
- Doctor of Philosophy (Pharmaceutical Chemistry), University of Nottingham, 1963. Thesis entitled "Polyazapolycyclic compounds and carcinogenesis"
- Post-doctoral research worker and Lecturer in Pharmacology at the Department of Pharmacology and Therapeutics, University of St Andrews, Scotland. 1963-1966.
- Post-doctoral research worker, Department of Pharmacology, Karolinska Institute, Stockholm, Sweden, 1966-1972. Docent in Pharmacology, Karolinska Institute, 1971.
- Associate Professor of Toxicology, National Food Administration, Sweden, 1972-1983.
- Professor and Head of the Food Research Department, National Food Administration, Sweden, 1983-1990.

Languages

My mother tongue English and I am fluent in Swedish, having lived in Sweden for more than 40 years. I have a fair knowledge of French and can read and understand Danish and Norwegian fairly well.

Positions held

1. 1963-1966. Lecturer in Pharmacology at the Department of Pharmacology and Therapeutics, University of St Andrews, Scotland. Taught medical and pharmacology students and carried out research into histidine decarboxylase inhibitors.
2. 1966-1972. Post-doctoral research worker, Department of Pharmacology, Karolinska Institute, Stockholm. Carried out research on the storage and release of histamine and other biogenic amines and took part in the teaching of medical students.
3. 1972-1983. Associate Professor of Toxicology and Deputy Head of the Toxicology Laboratory, Swedish National Food Administration (NFA). Risk assessment of a wide variety of chemicals in food, especially food additives and contaminants (metals, nitrosamines, dioxins, PCBs, vinyl chloride, etc). Research into the assessment of human exposure through biological monitoring - measuring the levels of contaminants in human tissues and body fluids.
4. 1983-1990. Professor and Head of the Food Research Department, NFA. Responsible for managing a scientific department with a staff of about 160, comprising biology, chemistry, nutrition and toxicology divisions. Responsibilities included planning and evaluating research and development work related to food safety and food control and setting priorities. As head of department I was also responsible for co-ordination with the Food Hygiene and Administative Departments.
5. 1990-2005. Member of the Executive Committee of the NFA and Deputy Director-General (DDG) 1991-2005 (Acting Director-General Jan-April 2004). The NFA is an autonomous government agency with responsibility for looking after the interests of consumers in the food area, in particular working for safe food, fair practices in the food trade and healthy dietary habits. It has a staff of about 500. As DDG, I was responsible for

running the NFA in the absence of the DG and my work included risk assessment, risk management (especially the NFA's contribution to the development of food legislation in Codex and in the European Community) and risk communication. Much of my work involved international contacts with FAO, WHO and other international organisations the European Commission. I was chairman of the NFA's Expert Committee on Diet and Health for many years.

6. 1987-2000. Member of the Board of the National Institute for Environmental Medicine at Karolinska Institute, Stockholm.
7. 1991-1998. Member of the Steering Group for the Swedish Environmental Protection Agency's research programme "Persistent Organic Pollutants" (dioxins, PCBs, etc.).
8. 2000 - 2001. Member of the UK Food Standards Agency's Research Review Group
9. 2002 - 2006. Member of the UK Food Standards Agency's Advisory Committee on Research.
10. September 2002 - June 2006. Chairman of the Management Board of the European Food Safety Authority (EFSA).
11. 2004-present. Member of the World Organization for Animal Health's (OIE's) Working Group on Animal Production Food Safety (chairman since 2005).
12. May-December 2006. Chairman of the independent enquiry set up by the Norwegian government into the handling by the authorities and industry of the outbreak of food poisoning caused by Verocytotoxin-producing *Escherichia coli* O103:H25 in Norway in early 2006.
13. December 2006- present. Member of the Scientific Committee of the Abu Dhabi Food Control Authority.

Codex, FAO/WHO and other international activities

- Participated actively for many years in Codex work, especially in the Committee on Food Additives and Contaminants, the Committee on General Principles, the Co-ordinating Committee for Europe (previously as chairman and Codex Co-ordinator for Europe) and the Codex Executive Committee. I also took part in several of the earlier meetings of the Codex Committee for Food Import & Export Inspection and Certification Systems. I was elected a Vice-Chairperson of the Codex Alimentarius Commission in 1999 and re-elected to that position in 2001. Elected Chairperson of the Codex Alimentarius Commission in 2003 and relected in 2004.
- Participated in two meetings of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- Participated three Joint FAO/WHO Expert Consultations on risk analysis. I was Rapporteur at the first consultation (1995) on the application of risk analysis to food standards issues and chairman of the Expert Consultation on Risk Management and Food Safety in 1997.
- Worked for four months in 1974 at WHO in Geneva setting up the UNEP/FAO/WHO Global Environment Monitoring System (GEMS) Food Programme and the Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme. Prepared "Guidelines for establishing or strengthening national food contamination monitoring programmes" (1978) for FAO/WHO. Responsible for running a series of analytical quality assurance exercises for organochlorine compounds in GEMS/Food. Since then I have taken an active part in GEMS-Food Programme, most recently as chairman of the GEMS-Food EURO Steering Committee meeting in Rome in 2001.
- Responsible for development, execution and co-ordination of the organochlorine compounds component of the WHO/UNEP Pilot Project on Assessment of Human Exposure to Pollutants Through Biological Monitoring. The project involved measurement of persistent organochlorine compounds in human milk in nine countries around the world.

- One of the principal investigators in the UNEP/WHO Human Exposure Assessment Locations (HEALS) Programme which was co-ordinated by Sweden and measured human exposure to lead and cadmium in seven countries (1986-1991).
- FAO consultant in India (1978, food contaminant monitoring and control), China (1990, food control), Lithuania (1999-2001, improving food control).
- WHO consultant in China (1980,1981, monitoring human exposure to pollutants).
- In 2002-2006 taken part in the organisation and implementation of five training courses, supported by the Swedish International Development Cooperation Agency (SIDA), aimed at improving food safety and quality in countries in Africa, Asia and the Middle East, Jamaica and the Balkan region, respectively.
- For more than 25 years participated in, and in several cases been responsible for, Nordic projects in the food area, especially concerning food additives and contaminants, including the toxicological evaluation of dioxins.
- Speaker at the First FAO/WHO Global Forum of Food Safety Regulators in Marrakesh in January 2002 and at the Second Global Forum in Bangkok in 2004. Rapporteur for the FAO/WHO Pan-European Conference on Food Safety and Quality in Budapest in February 2002.
- Chair of Joint FAO/WHO Workshop on the Provision of Scientific Advice to Codex and Member Countries, 27-29 January 2004, Geneva, Switzerland

European Community and Council of Europe

- Participated for many years in two Council of Europe expert committees carrying out risk assessments of materials coming into contact with food and flavouring substances.
- Represented Sweden for many years on the European Commission's Working Group on Scientific Co-operation (SCOOP).
- Speaker at the European Commission's International Conference on Risk Analysis and its Role in the European Union in July 2000.

Publications, etc

Approximately 180 publications of various kinds including:

- Results of research published in refereed scientific journals
- Results of monitoring projects and programmes
- Publications intended for the general public on food safety issues
- Chapters in books on food safety, food legislation and exposure to environmental pollutants.
- Coordinated production of Volume 25 (2) (August 2006) of the *OIE Scientific and Technical Review* devoted to "Animal production food safety challenges in global markets".
- Presentations at international conferences, seminars, workshops, etc. on food toxicology, risk management, risk analysis, etc.

Conflicts of interest

I have no financial or other interests in the food industry or trade.