

FOI_NHMRC_2007_REVIEW_RFT_STATEMENT_REQUIREMENT

Document obtained by NHMRC Freedom of Information Request
No. 075-0708

The 6 pages (page B1 to page B6) are Part B of the RFT 99/0607 (Request For Tender) - STATEMENT OF REQUIREMENT that was supplied to 3 selected parties invited to submit a Tender for the 2007 NHMRC Review of Fluoridation .

On Page B3, in the Health Considerations section (which starts on Page B2) the NHMRC has acknowledged in a section titled *“Risks for those with kidney impairment”* *“People with kidney impairment have a lower margin for safety for fluoride intake. Limited data indicate that their fluoride retention may be up to three times normal”*

NOTE: This is basically the same wording in the NHMRC’s 2004 Australian Drinking Water Guidelines (ADWG) (and reported again in the 2011 ADWG)

PART B – STATEMENT OF REQUIREMENT12
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12**1. INTRODUCTION**

The National Health and Medical Research Council is seeking a consultant to:

- undertake a systematic review of national and international literature on fluoride and health, with specific attention to the health benefits and risks related to fluoride, and
- provide a Scientific Paper, comprising
 - an analysis of this review, and
 - evidence-based statements or recommendations.

2. CONDITIONS OF PARTICIPATION (PART A SECTION 5.4)

In compliance with the Commonwealth Procurement Guidelines (CPGs), the Commonwealth will exclude a Tender from further consideration if the Commonwealth considers that the tenderer does not comply with the following condition(s):

- (a) Capacity to comply with the draft contract conditions from a commercial, financial or technical perspective (Part A Section 4.6):
- (b) Tenderers must have the following levels of insurance and indemnity coverage in place for this project assignment (refer attached contract clauses referring to insurance and indemnity) at time of submitting a Tender:
 - Workers Compensation to an amount required by law
 - \$10,000,000 Public Liability, and
 - \$5,000,000 Professional Indemnity.
- (c) Capacity to comply with the draft contract conditions to a high quality, within the timeframe agreed to.

3. MINIMUM CONTENT AND FORMAT REQUIREMENTS (PART A SECTION 5.3)

In compliance with the CPGs, the Commonwealth will exclude a Tender from further consideration where the minimum content and format requirements have not been met. Subject to Part A section 3.4, tenderers are required to satisfy the format and content requirement including provision of the information listed in Part A section 5.3.

4. BACKGROUND**Fluoride**

Fluoride is a normal part of the human body, involved in the mineralisation of teeth and bones. Concentrations of fluoride in these parts of the body are about 10,000 times that in body fluids and soft tissues. Because of its role in the prevention of tooth decay, fluoride has been classified as essential to human health. Fluoride intake can occur through drinking water, food sources, dietary supplements, dental products and inhalation.

Fluoride occurs naturally in seawater, soil and air. Naturally occurring fluoride concentrations in drinking water depend on the type of soil and rock through which the water drains. Generally, concentrations in surface water are relatively low (<0.1 – 0.5 mg/L), while water from deeper wells may have quite high concentrations (1-10 mg/L).

Inorganic fluorine compounds are used in aluminium production, as a flux in the steel and glass fibre industries, and in phosphate fertilisers, bricks, tiles and ceramics.

Fluoride is used to protect teeth against dental caries. It is present in most brands of toothpaste, and it is often added to drinking water supplies. The World Health Organization states in a review of chronic disease and diet, that there is convincing evidence that both locally applied and systemic fluoride are preventative for dental caries.

Typical values in Australian drinking water

In unfluoridated supplies, fluoride concentrations are typically less than 0.1 mg/L, but can range from less than 0.05 mg/L up to 1.5 mg/L, with the higher values reported from groundwater sources.

In fluoridated supplies, the target fluoride concentration is between **0.7 and 1 mg/L**, with the lower concentrations applying where the climate is hot, to allow for a higher average consumption of water.

Values in food sources

Fluoride intake from most foods is low, with food generally having concentrations below 0.05mg/100g. Water in fluoridated areas, as well as beverages, some fish and some infant formulas (especially those reconstituted with fluoridated water) may have higher concentrations.

Virtually all foodstuffs contain traces of fluoride. In particular, high amounts can be found in dried tea leaves because of natural concentration by the tea plant. Total daily intake from all sources varies considerably, but has been estimated at 0.46 mg to 5.4 mg, with about 10% coming from unfluoridated drinking water.

Recommendations for fluoride intake by life stage and gender can be found in the NHMRC publication *Nutrient Reference Values for Australia and New Zealand (May 2006)*.

Health considerations

Absorption and excretion

Because fluoride is widely dispersed in the environment, all living organisms are exposed to it and all tolerate modest amounts. It has been claimed that fluoride is an essential trace element for humans, but this is difficult to establish conclusively, and no data are available on the minimum amount needed. Fluoride is absorbed quickly following ingestion. It is not metabolised, but diffuses passively into all body compartments. About 40% is excreted in urine within 9 hours, and about 50% over 24 hours. Fluoride has an affinity for mineralising tissues of the body: in young people, bone and teeth; in older people, bone. Thus excretion is somewhat greater in adults because they have proportionately less mineralising tissue than children.

Prevention of dental caries

Fluoride has been shown to prevent dental caries very effectively, and knowledge of its anti-caries effect came from the observed association of low caries prevalence with naturally occurring fluoride in drinking water (at about 1 mg/L).

Dental fluorosis

Concentrations above 1.5 mg/L may disturb tooth mineralisation in children up to about 6 to 8 years, leading to dental fluorosis - a mottling of the teeth which can occasionally occur to an unsightly degree.

Skeletal fluorosis

Skeletal fluorosis, characterised by hypermineralisation and thus brittle bones, has occurred in association with high fluoride concentrations in drinking water, and also with occupational exposure to fluoride-containing dust. It generally occurs after prolonged exposure (several years) and is reversible: if the exposure is removed, the fluoride levels in bones gradually decline.

Regular consumption of water with fluoride concentrations above about 4 mg/L involves progressively increasing risks of skeletal fluorosis. The USEPA has set this level as the maximum acceptable for drinking water: above it, communities are required to lower the fluoride concentration by treatment to remove it, or by dilution.

Risks for those with kidney impairment

People with kidney impairment have a lower margin of safety for fluoride intake. Limited data indicate that their fluoride retention may be up to three times normal.

Cancer

There is no substantiated epidemiological evidence that fluoride or fluoridation causes cancer. One animal study showed an increased incidence of bone tumours in some male rats that were exposed to very high concentrations of fluoride in water, but female rats and mice were not affected.

Tests for mutagenicity with strains of bacteria have been negative. Chromosome aberrations have been reported in tests with mammalian cells but only at extremely high fluoride concentrations.

The International Agency for Research on Cancer has concluded that fluoride is not classifiable as to its carcinogenicity in humans (Group 3, inadequate evidence in humans and in animals) (IARC 1987).

NHMRC activity and publications

Research into fluoridation and the fluoridation of drinking water in particular, was initiated in 1998 by HAC. The Royal Melbourne Institute of Technology - Key Centre for Toxicology, in conjunction with the Monash University Medical School's Centre for Epidemiology and Preventive Medicine was contracted to do the work, and reached the stage of producing a paper for public consultation. Due to a lack of resources, however, this work was abandoned.

The NHMRC has two current publications that refer to fluoride. The *Australian Drinking Water Guidelines (2004)*, and the *Nutrient Reference Values for Australia and New Zealand (2006)*. These documents are available on the NHMRC website <http://www.nhmrc.gov.au/publications/index.htm>.

5. CONTEXT

The National Health and Medical Research Council is seeking a consultant to:

- undertake a systematic review of national and international literature on fluoride and health, with specific attention to the health benefits and risks related to fluoride, and
- provide a Scientific Paper, comprising
 - an analysis of this review, and
 - evidence-based statements or recommendations.

The Scientific Paper will update the NHMRC on the broad issue of fluoride and health. The most current NHMRC publications that refer to fluoride quote scientific evidence prior to 2000. The NHMRC is in a pivotal position to provide health advice relating to fluoride, and it is important that that advice is based on current scientific evidence. The Paper will also inform the NHMRC in its participation in a Fluoride Workshop, hosted by Queensland Health, in February 2007.

6. OBJECTIVES

The objectives of this tender are:

1. the undertaking of a systematic review of the national and international literature on the topic of fluoride and health, and
2. the provision of a Scientific Paper comprising an analysis of the literature review, and evidence-based statements and recommendations relating to fluoride and health.

7. REQUIREMENT

The NHMRC requires a written Scientific Paper based on a systematic search, collation, and analysis of the national and international scientific literature covering the search term 'fluoride and health'.

Literature review content

When undertaking the literature review the consultant will cover local and international research, and must:

- include but not be limited to the scientific disciplines of medicine, pharmacy, social work, psychology, psychiatry, sociology, and nursing through databases including but not limited to Medline, PsychLit, Sociofile, and APAIS-Health;
- cover the years 1996 to 2006. The majority of references to fluoride in previous work by the NHMRC reflect scientific activity prior to 1995, and the Scientific Paper must reflect current evidence;
- cover the broad issue of fluoride and health, including but not limited to issues relating to dental and skeletal effects;

Conducting the Review

In preparing the Scientific Paper, the NHMRC must be satisfied that standards relating to quality and process for conducting the systematic literature review have been met. The systematic literature review must be conducted by complying with the standards as set out in the NHMRC publication '*A guide to the development, implementation and evaluation of clinical practice guidelines, 1999*', and the following companion handbooks:

- How to review the evidence: systematic identification and review of the scientific literature, 2000;
- How to use the evidence: assessment and application of scientific evidence, 2000;
- How to put the evidence into practice: implementation and dissemination strategies, 2000;
- How to present the evidence for consumers: preparation of consumer publications, 2000;
- How to compare the costs and benefits: evaluation of the economic evidence, 2001; and
- Using socio-economic evidence in clinical practice guidelines, 2003.

Full details of these publications are available on the NHMRC website at: www.nhmrc.gov.au/publications/cphome.htm

Analysis of the review

The analysis must include levels and grades of evidence as set out in

- *A guide to the development, evaluation and implementation of clinical practice guidelines*, available at <http://www.nhmrc.gov.au/publications/synopses/cp30syn.htm>, and
- *Additional levels of evidence and grades for recommendations for external developers of guidelines* (a pilot program), available at http://www.nhmrc.gov.au/publications/files/levels_grades05.pdf

Scientific Paper

The final Scientific Paper will comprise all of the scientific articles, a systematic review of the literature, and an analysis. It will be presented in a report form, with clear recommendations, and be suitable for publication as a stand-alone document.

8. ESSENTIAL REQUIREMENTS (PART A SECTION 5.5)

In compliance with the Commonwealth Procurement Guidelines, the Commonwealth will exclude a Tender from further consideration if the Commonwealth considers that the Tender does not comply with an essential requirement identified in the RFT by the use of the word "must".

9. SPECIFIC ISSUES

The Contractor will be required to liaise with the Commonwealth, through the Project Officer over the course of the project regarding any issues/concerns relating to fulfilling the terms of the contract, and adhering to the agreed timeline.

10. TIMEFRAMES

It is expected that the literature review will commence in November 2006. The draft report will be provided to the NHMRC by end January 2007, with a final report provided by mid February 2007.

11. REPORTING REQUIREMENTS

The successful contractor will be required to:

- Submit the search strategy for searching the literature from 1996 onwards to the Project Officer, for approval within 3 weeks of commencement;
- Provide a progress report to the Project Officer mid to late December 2006, and if required, participate in teleconferences with the Commonwealth staff to report on progress and discuss issues arising;
- Ensure that the Draft and Final reports are comprehensive, succinct and user friendly and are provided both in hard copy and electronically in Microsoft Word 2003 format, edited to publication standard including a summary table of all references (both included and excluded, with the rationale for exclusion); and
- Provide hard copies of all cited references to the Commonwealth. The cited references must be collated in alphabetical order (by author), as part of the contract materials of the Project. In addition, an alphabetical listing (by author) of all cited references should be provided both electronically in Word 2003 format and in hard copy to the Health Advisory Secretariat.

12. COMMUNICATION ISSUES

Regular liaison with the Project Officer about the progress of the literature review and development of the Scientific Paper is required. This could be achieved either through phone contact or emails, as agreed and as seems appropriate.

13. CULTURAL, COMMUNITY OR ORGANISATIONAL ISSUES

Tenderers will be required to demonstrate that they have an understanding of cultural, community and organisational issues relevant to the assignment.

14. CONFIDENTIALITY ISSUES (PART A SECTION 4.4)

Tenderers **must** indicate any element of their Tender which may become part of any subsequent contract, which they regard as confidential and provide reasons for requiring confidentiality. Further information regarding confidentiality in this context can be sought from the Department of Finance and Administration's Procurement Guidance publication "Confidentiality of Contractors' Commercial Information" available from http://www.finance.gov.au/ctc/confidentiality_of_contractors.html.

15. RECORDS AND RECORD KEEPING

Tenderers should be familiar with the requirements of record keeping in an outsourced environment, particularly the National Archives publication "Records Issues for Outsourcing". Copies can be downloaded from <http://www.naa.gov.au/recordkeeping/disposal/authorities/gda/pdf/gda25.pdf>

16. ELECTRONIC COMMERCE INITIATIVE

As part of NHMRC's adoption of electronic commerce principles, the NHMRC has a preference to make all payments by electronic funds transfer ("EFT"). Tenderers are required to advise their acceptance of the use of EFT.