

Review of Nutrient Reference Values for Fluoride

Administrative Report

Background

The current Nutrient Reference Values (NRVs) for Australia and New Zealand were published in 2006 after a comprehensive review process of the Recommended Dietary Intakes (the only type of nutrient reference value that had been produced at the time), commissioned by the Australian Government Department of Health (Health) in conjunction with the New Zealand Ministry of Health (NZ MoH).

The review resulted in a new set of recommendations known as the NRVs for Australia and New Zealand (2006). The National Health and Medical Research Council (NHMRC) carried out the 2006 review and recommended that these guidelines be reviewed every five years to ensure values remain relevant, appropriate and useful.

Scoping study

In 2011 Health, in consultation with the NZ MoH, commissioned a scoping study to determine the need and scope for a review of NRVs. The scoping study considered developments in comparable countries, expert opinions, stakeholder consultation and public submissions. The scoping study concluded there was sufficient justification for conducting a review and as a result, Health and the NZ MoH engaged the Nous Group and a technical team led by Baker IDI to develop a Methodological Framework to guide future NRV reviews.

The scoping study also identified the rationale and triggers for reviewing specific nutrients including changes or developments to NRVs in comparable OECD countries, emergence of new evidence, impact on public health priorities and/or concerns regarding the strength of the underlying methodology or evidence. Fluoride, iodine and sodium were identified in the scoping study as priority nutrients for review.

Methodological Framework

In 2013, the Nous Group was contracted to develop the *Methodological framework for the review of NRVs* (the Methodological Framework) to outline the overarching principles, methodologies, and approaches to ensure consistency of application and transparency in the NRV reviews across all nutrients. The Methodological Framework was developed through multiple rounds of consultations with technical experts and relevant stakeholders in Australia and New Zealand.

The Methodological Framework is designed for application across a range of nutrients and provides high level guidance that should not be impacted by characteristics unique to specific nutrients.

Governance and stakeholder involvement

This review is funded by the Department of Health and the NZ MoH. The recommendations have been developed by independent experts, and the funding bodies have not influenced the content of the recommendations. A Steering Group is overseeing the review process and is responsible for all strategic and funding decisions for the review. It consists of representatives from both funding agencies. The Steering Group is also responsible for the ongoing monitoring of triggers for a new review, and ensuring nutrient reviews are conducted in a timely manner. Membership is held by the following positions:

Health:

- Assistant Secretary - Preventive Health Policy Branch, Population Health and Sport Division.
- Director – Food and Nutrition Policy Section, Population Health and Sport Division.

NZMoH:

- Team Leader & Senior Advisor (Nutrition), Clinical Leadership, Protection and Regulation Business Unit.

The Steering Group appointed an Advisory Committee as an expert reference and advisory group that also acts as an independent moderator of nutrient recommendations. The Advisory Committee comprises members with a broad range of expertise, including experts in the areas of micronutrients, toxicology, nutrition risk assessment, public health, end user needs, research, chronic disease, and nutrition.

The Steering Group, with advice from the Advisory Committee determined that fluoride, iodine and sodium are priority nutrients and first to be reviewed, with the dual purpose to pilot the Methodological Framework.

The Steering Group, with the advice of the Advisory Committee established a group of experts to conduct this fluoride review. The Fluoride Expert Working Group (EWG) was primarily responsible for examining scientific evidence and establishing nutrient values. Membership of the groups involved in the development of the fluoride NRV guidelines is listed below.

Membership of the Nutrient Reference Values Advisory Committee

Professor Samir Samman (Chair)

Head of the Department of Human Nutrition, University of Otago, New Zealand

Expertise: micronutrients, biomarkers and the role they play in informing nutritional status and disease risk in humans. Professor Samman's interest in micronutrients has involved him in a range of national and international committees including the US National Institutes of Health and UN International Atomic Energy Agency committees that considered nutrient biomarkers.

Role: Chair the Advisory Committee meetings and provide expert reference and advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports including on micronutrient research components, and responses to methodological and independent expert reviews.

Ms Janis Baines

Manager, Food Data Analysis Section, Food Standards Australia New Zealand

Expertise: nutrition; chemistry; food regulation; nutrient risk assessment including dietary exposure assessment methods and nutrient fortification assessments; NRV end-use; and food composition. Ms Baines has been an expert member (and chair) of a number of Joint FAO/WHO expert committees in relation to dietary exposure assessment methods for food chemicals, including nutrients.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on end user needs and dietary exposure assessment aspects. Chair of the Fluoride Expert Working Group.

Associate Professor Marijka Batterham

Director of Statistical Consulting Service in Informatics, University of Wollongong

Expertise: statistics and nutrition research. Dr Batterham is an accredited statistician and advanced accredited practising dietitian. Dr Batterham is the Director of the Statistical Consulting Service in Informatics and works across the University of Wollongong to assist students and staff members with the statistical design and analysis of their research.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on nutrition research and statistical elements.

Professor Michael Fenech (until March 2016)

Professor, CSIRO Food & Nutritional Sciences

Expertise: micronutrients, genetic toxicology, genome health, nutrition research. Dr Fenech has written reviews relating to biomarkers of genome damage relevant to cancer risk and the role of folate and B12 in prevention of DNA damage.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on nutrition research elements.

Professor Mark Lawrence

Professor, School of Exercise and Nutrition Sciences, Deakin University

Expertise: public health, food and nutrition policy, and food systems. Professor Lawrence is a technical adviser to the World Health Organisation, a member of the FSANZ Public Health Dialogue and a member of the 2013 Australian Dietary Guidelines Working Committee.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on public health and end user needs.

Professor Jim Mann

Professor in Human Nutrition and Medicine, University of Otago and Consultant Physician (Endocrinology), Dunedin Hospital

Expertise: nutrition epidemiology; research and public health; chronic disease; endocrinology; and medicine. Professor Mann is the Director of Edgar Diabetes and Obesity Research and the WHO Collaborating Centre for Human Nutrition; the Principal Investigator

for the Riddet Institute at Massey University; and has chaired several WHO/FAO Expert Advisory Groups and Scientific Update Groups.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on nutritional epidemiology, public health and chronic disease elements.

Professor Murray Skeaff

Professor in Human Nutrition, University of Otago

Expertise: nutritional epidemiology and nutrition research. Professor Skeaff is a member of the FSANZ Health Claims Scientific Advisory Group, the New Zealand Heart Foundation's Scientific Advisory Committee and has been a member of the technical advisory groups for the Eating and Health Activity Guidelines and a number of FAO/WHO nutrition expert groups.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on nutritional epidemiology and research elements.

Professor Linda Tapsell AM

Senior Professor, School of Medicine, University of Wollongong

Expertise: nutrition and dietetics, nutrition research translation, evidence based review and guideline development. Professor Tapsell is a member of the FSANZ Health Claims Scientific Advisory Group, the 2013 Australian Dietary Guidelines Working Committee and several international science advisory committees. Professor Tapsell worked in health services before becoming an academic.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on nutrition research, evidence based guideline development aspects, and end-user needs. Chair of the Sodium Expert Working Group.

Associate Professor Sheila Skeaff (proxy member from March 2015)

Professor, Department of Human Nutrition, University of Otago

Expertise: nutrition research. Associate Professor Skeaff's expertise is in trace element research with a particular emphasis on iodine. Associate Professor Skeaff is particularly interested in assessing the iodine status of vulnerable groups of the population including children and pregnant women. Associate Professor Skeaff is the current President of the Nutrition Society of New Zealand.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on nutrition research. Deputy Chair of the Iodine Expert Working Group.

Emeritus Professor Christine Thomson (until February 2015)

Professor, Department of Human Nutrition, University of Otago

Expertise: nutrition research and public health. Professor Thomson's research involved studies of the nutritional importance of selenium and iodine for New Zealand residents, which has gained international recognition. This research identified a re-emergence of mild iodine deficiency in New Zealand.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on nutrition research and public health elements. Chair of the Iodine Expert Working Group until February 2015.

Professor Lynne Daniels (2013)

Head of School, Exercise & Nutrition Sciences, Queensland University of Technology

Expertise: nutrition research. Professor Daniels was appointed to a newly established capacity building research chair within the Institute Health and Biomedical Innovation. Professor Daniels research interests include nutrition and feeding in infancy and early childhood, childhood obesity, selenium status of infants and nutrition assessment and support of older adults.

Role: Contribute expert advice to the Steering Group and guidance to the Expert Working Groups on the development of the reports, including on nutrition research elements.

Membership of the Nutrient Reference Values Fluoride Expert Working Group

Ms Janis Baines (Chair)

Manager, Food Data Analysis Section, Food Standards Australia New Zealand

Expertise: nutrition; chemistry; food regulation; nutrient risk assessment including dietary exposure assessment methods and nutrient fortification assessments; NRV end-use; and food composition. Ms Baines has been an expert member (and chair) of a number of Joint FAO/WHO expert committees in relation to dietary exposure assessment methods for food chemicals, including nutrients.

Role: Chair EWG meetings, report on progress in Advisory Group meetings, contribute to the development of the report, including on end user needs and dietary exposure assessment aspects. In conjunction with the EWG and Advisory Committee, develop responses to the public consultation and methodological and independent expert reviews.

Dr Michael Foley

Director, Brisbane Dental Hospital, Queensland, Australia

Expertise: dentistry, epidemiology and public health. Dr Foley graduated with a bachelor of Dental Science and holds Masters degrees in epidemiology and public health, and lectures at the University of Queensland and Griffith University Schools of Dentistry.

Role: contribute to the development of the report, including advise on population dental health and fluoride NRV end-use.

Emeritus Professor Andrew John Spencer

Emeritus Professor, Australian Research Centre for Population Oral Health, School of Dentistry, the University of Adelaide

Expertise: dentistry; child and preventive dentistry; oral health policy and dental health care; and research in population strategies for prevention of oral diseases. Professor Spencer has had a long involvement in informing policy on oral and dental care in Australia. He was the Deputy Chair of the 2012 National Advisory Council on Dental Health to the Australian Government's Minister to Health.

Role: contribute to the development of the report, including advise on population dental health elements.

Professor Marco Peres

Professor in Population Oral Health and Director of the Australian Research Centre for Population Oral Health, School of Dentistry, the University of Adelaide

Expertise: population oral health research; oral health surveillance; use of fluorides; inequalities in oral health; life course epidemiology and the relationship between oral health and general health. Professor Peres is the coordinator of the 2016-18 National Study of Adult Oral health and is International Dental Association for Dental Research Global Oral health Inequities Research Network counsellor for Asia and Pacific region.

Role: contribute to the development of the report, including advise on population dental health elements.

Dr Utz Mueller

Principal Toxicologist and Manager Risk Assessment – Chemical Safety and Nutrition Section, Food Standards Australia New Zealand

Expertise: toxicology and risk assessment for food additives, processing aids, nutritive substances and food contaminants. Dr Mueller is a member of the Joint FAO/WHO Expert Committee on Food Additives and has served as rapporteur on the WHO (toxicology) panel. Dr Mueller has extensive experience in reviewing the toxicological data which underpins the development of NRVs.

Role: contribute to development of the report, including advise on toxicological frameworks and tools for use in undertaking risk analysis and on end-user needs.

Observers

Associate Professor Loc Do

Principal Research Fellow, Australian Research Centre for Population Oral Health, School of Dentistry, the University of Adelaide

Expertise: dentist and oral epidemiology with special interest in social and clinical oral epidemiology. Professor Do is a member of various committees of the International Association of Dental Research. He has been the recipient of several international and national awards for his work.

Role: Observer for experience and future succession planning.

Fluoride Research Assistants

Dr Judy Cunningham

Consultant

Expertise: scientific editor; risk assessment, dietary exposure assessment methods, food technology, food composition.

Role: update the systematic literature review and edit draft reports for consideration by the EWG.

Mr Emmanuel Gnanamanickam

Australian Research Centre for Population Oral Health, School of Dentistry, the University of Adelaide

Expertise: population oral health research.

Role: undertake the comprehensive literature review process and develop draft reports for consideration by the EWG.

Dr Najith Amarasena

Australian Research Centre for Population Oral Health, School of Dentistry, the University of Adelaide

Expertise: population oral health research.

Role: undertake the comprehensive literature review process and develop draft reports for consideration by the EWG.

Administrative Assistants

Ms Rose Thomas

Australian Research Centre for Population Oral Health, School of Dentistry, the University of Adelaide

Expertise: population oral health research.

Declarations of interest process

Declarations of interest were made by all members of the Advisory Committee and EWGs during the review process in accordance with the requirements of the *National Health and Medical Research Council Act 1992*. A record of interests was made publicly available on Health's website to ensure transparency. See [NRV Advisory Committee Membership](#) and [NRV's Fluoride Expert Working Group Membership](#).

Members were required to update their information as soon as they became aware of any changes and there was a standing agenda item at each meeting where declarations of interest were called for and recorded in the meeting minutes. Should a member have identified as having a significant real or perceived conflict of interest, a requirement was that the member would be requested to leave the room or not participate in discussions on matters where a conflict was identified.

End user (consumer) representation

The Advisory Committee and the Fluoride EWG comprised of experts with NRV end use expertise including clinical practitioners, food regulators and public health representatives.

Evidence and Recommendations

The purpose of the review was to ensure the currency of the fluoride NRVs with scientific methods and knowledge, particularly with relevance to population health. An additional purpose was to test the Methodological Framework. The Fluoride EWG used the Methodological Framework as the basis for the review of the NRVs. The Methodological Framework outlines the overarching principles, methodologies, and approaches to ensure consistency of application and transparency in the NRV reviews across all nutrients. The current NRVs for fluoride for all age groups were not able to be reviewed in the time allocated for this pilot review. The Fluoride EWG narrowed the scope of its review to an Adequate Intake (AI) and Upper Level of Intake (UL) for fluoride for infants and young children, as the critical age groups to consider for dental caries and fluorosis. Young children aged 0-8 years of age are considered the critical group for these biomarkers because this is the period of time in which permanent teeth are formed. The Fluoride EWG conducted several literature reviews, with the focus of the reviews being data available upon which to build NRVs and the method adopted. Full details of the method used for the assessment and consolidation of the evidence are provided in section 5 – Evidence Review (Technical Report) of the report on Australian and New Zealand Nutrient Reference Values for Fluoride; and appendix 1 – Summary of findings – GRADE assessment; and the Supporting Documents 1-4. This includes the research question development, PICO (population, intervention, comparator, outcomes) criteria, search strategy, study eligibility, data extraction, and assessment of the body of evidence.

Referencing

As all nutrients were not reviewed at the same time (as was the case with the 2006 NRVs), it is intended that the main reference for the revised NRVs would continue to be *NRVs for Australia and New Zealand (2006)*.

Approval Process

The draft NRV review report for fluoride was submitted to the Advisory Committee in mid-2015 and was approved for public consultation.

Public consultation

The draft NRV review report for fluoride was released for public consultation from 30 October 2015 to 11 December 2015. Public consultation is a requirement for this review under the *National Health and Medical Research Council Act (1992)*.

For more information on the public consultation process and on submissions received please refer to the Review of NRVs for Fluoride Public Consultation Report.

Following the public consultation period the Advisory Committee and the Fluoride EWG met to consider the comments received. The Fluoride EWG revised the report where appropriate and provided responses to a summary of the comments received.

Following this, the Advisory Committee approved the draft report for submission to the NHMRC for independent methodological and independent expert review on 8 July 2016.

Independent Methodological Review

The NHMRC contracted the University of Adelaide (UofA) to perform the independent methodological review. The role of the UofA reviewers was to evaluate the methodology and transparency and completeness of reporting of the Fluoride Report, to provide the NHMRC with a quality assessment. A response to the methodological review comments and a revised report to incorporate the review comments where relevant was provided to the NHMRC.

Independent Expert Review

The NHMRC facilitated three independent expert reviews of the draft NRV review report for fluoride. The reviews were completed by Dr Jaynath Kumar, State Dental Director, California Department of Public Health; Professor Sandra Capra, Professor of Nutrition, University of Queensland; and Professor Andrew Rugg-Gunn, Professor of Preventative Dentistry and Head of Department of Child Dental Health, Newcastle University, UK. A response to the independent expert reviews and a revised report and supporting documents to incorporate the review comments where relevant was provided to the NHMRC.

Council of NHMRC Approval

The recommendations within the NRV review report for fluoride were considered by the Council of the NHMRC on 3 November 2016 and recommended to the Chief Executive Officer of the NHMRC for issuing. The CEO approved the revisions on 21 November 2016, under Section 14A of the National Health and Medical Research Council Act 1992.