

Review of Nutrient Reference Values for Sodium

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:

- Director/Deputy Director of Public Health, Protection Regulation and Assurance Business Unit
- 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 sodium review. The Sodium 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 sodium 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 Sodium Expert Working Group

Professor Linda Tapsell AM (Chair)

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: Chair EWG meetings, report on progress in Advisory Committee meetings, contribute to the development of the report, including on nutrition research, evidence based guideline development aspects, and end-user needs. In conjunction with the EWG and Advisory Committee, develop responses to the public consultation and methodological and independent expert reviews.

Dr Barry Fields

Senior Toxicologist, Food Standards Australia New Zealand

Expertise: toxicology and risk assessment of food additives, contaminants and processing aids. Dr Fields obtained his PhD in chemistry from the University of Sydney. He has worked as a research fellow at the University of Sydney and a senior toxicologist at the Therapeutic Goods Administration.

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.

Professor Vicki Flood

Professor of Allied Health, Faculty of Health Sciences, Charles Perkins Centre, University of Sydney

Expertise: nutrition epidemiology and public health nutrition interventions, micronutrient research including folate, vitamin B12 and sodium. Research areas include chronic disease, food security of vulnerable population groups and micronutrient research. Professor Flood has represented Australia at international meetings, such as the World Health Organisation.

Role: contribute to development of the report, including advise on public health context relevant to guidelines and nutrition research elements.

Professor Dorothy Mackerras

Chief Public Health Nutrition Advisor, Food Standards Australia New Zealand

Expertise: nutritional epidemiology and dietary methods, public health nutrition, critical appraisal of scientific evidence, statistics, and food standards and guidelines development. Professor Mackerras obtained her PhD in epidemiology in the United States and is well known in Australia for her expertise in nutritional epidemiology and dietary methods.

Role: contribute to development of the report, including preparing supporting documents containing statistical analyses and dietary modelling underpinning the development of the NRVs and on end-user needs.

Dr Rachael McLean

Public Health Physician & Senior Lecturer in Public Health Nutrition, University of Otago

Expertise: medical endocrinology and public health, evidence based review and guidelines development. Research interests include monitoring population dietary sodium intake, public health approaches to dietary sodium reduction, and the relationship between dietary sodium and cardiovascular disease.

Role: contribute to development of the report, including advise on public health and clinical aspects relevant to the use of the NRVs.

Dr Jacqui Webster

*Director, WHO Collaborating Centre on Population Salt Reduction, George Institute
Senior lecturer in public health, University of Sydney*

Expertise: nutritional epidemiology and public health nutrition interventions. Her primary research interest relates to the development and evaluation of population strategies to reduce salt intake. Dr Webster previously established and implemented the UK Government's salt reduction strategy. Dr Webster regularly contributes to national and international policy development.

Role: contribute to development of the report, including advise on public health context relevant to guidelines and nutrition research elements.

Observer

Ms Xenia Cleanthous

Manager of Nutrition Data and Analysis, National Heart Foundation of Australia

Expertise: nutrition and dietetics, food and nutrition data analysis, and NGO functions including policy development, program planning and advocacy.

Role: to serve as an observer of process as a community member and for a learning opportunity for future reviews.

Research Assistants

Dr Elizabeth Neale

Director, Landmark Nutrition Australia

Expertise: nutrition and dietetics and systematic literature review (SLR) methods for evidence based guidelines development.

Role: to undertake the SLR process and develop draft reports for consideration by the Sodium EWG.

Dr Deborah Nolan-Clark

Director, Landmark Nutrition Australia

Expertise: nutrition and dietetics and systematic review methods for evidence based guidelines development.

Role: to undertake the SLR process and develop draft reports for consideration by the Sodium EWG.

Dr Judy Cunningham

Consultant

Expertise: food regulation, risk assessment including dietary exposure assessment methods and nutrient fortification assessments, NRV end-use and food composition.

Role: scientific editor.

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 Review Advisory Committee](#) and [Sodium Expert Working Group](#).

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 Sodium 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 sodium NRVs with scientific methods and knowledge, particularly with relevance to population health. An additional purpose was to test the Methodological Framework. The Sodium 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 sodium for all age groups were not able to be reviewed in the time allocated for this pilot review. The Sodium EWG narrowed the scope of its review to the Suggested Dietary Target (SDT) and Upper Level of Intake (UL) for sodium for adults. The Sodium EWG conducted systematic literature reviews and independent searches. Full details of the methodology used for the assessment and consolidation of the evidence are provided in section 5 – Evidence Review (Technical Report), of the *Australian and New Zealand Nutrient Reference Values for Sodium* and the Supporting Documents 1-3. This includes: research question development; PICO (population, intervention, comparator, outcomes) criteria; selection of evidence, 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 sodium was submitted to the Advisory Committee in mid-2015 and was approved for public consultation.

Public consultation

The draft NRV review report for sodium 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 Sodium Public Consultation Report.

Following the public consultation period the Advisory Committee and Sodium EWG met to consider the comments received. The Sodium 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 clinical 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 Sodium 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 Clinical Expert Review

The NHMRC facilitated two independent expert reviews of the draft NRV review report for sodium. The reviews were completed by Dr Barbara Schneeman, Higher Education Coordinator, USAID and Professor Emerita of Nutrition, University of California; and Dr Johanna Dwyer, Senior Nutrition Scientist, US National Institute of Health and Professor at Tufts University School of Medicine. A response to the independent expert reviews and a revised report to incorporate the review comments where relevant was provided to the NHMRC.

Council of NHMRC Endorsement

The recommendations within the NRV review report for sodium were considered by the Council of the NHMRC on 21 June 2017 and recommended to the Chief Executive Officer of the NHMRC for issuing. The CEO approved the revisions on 13 July 2017, under Section 14A of the National Health and Medical Research Council Act 1992.