Australian Government

National Health and Medical Research Council

Review of the 2013 Australian Dietary Guidelines

Evidence review strategy

December 2023

Contents

1. Introduction

The Australian Dietary Guidelines (the Guidelines; NHMRC, 2013a) provide guidance on foods, food groups and dietary patterns that provide the nutrients required for optimal health and wellbeing. Along with the companion Eat for Health resources, the Guidelines support healthy food choices and eating behaviours for Australians. The Guideline recommendations underpin Australia's public health nutrition policies and practices.

In July 2020, the Australian Government announced a review of the Guidelines (the 'Review'). The current guidelines were issued in 2013 and are based on evidence reviews conducted between 2009 and 2012 (NHMRC, 2011a; NHMRC, 2013b). There is significant recent literature, as well as public interest and media commentary on food based dietary guidelines, so the Review is timely.

The Review will include a review of the evidence underpinning the guidelines, focused on high priority areas, with guideline recommendations to be updated as necessary to reflect the updated evidence. This will ensure that the Australian Dietary Guidelines and their recommendations remain a current, reliable and comprehensive resource for Australians and for public health nutrition policies and practices.

1.1. 2013 Australian Dietary Guidelines and companion documents

The 2013 Guidelines consist of five (5) high-level guidelines with recommendations, supported by evidence statements summarising the evidence underpinning recommendations. A number of companion documents were also based on the 2013 Guidelines. This includes pamphlets and implementation tools, such as the Australian Guide to Healthy Eating (NHMRC, 2013c).

The 2013 Guidelines, and associated companion documents, were developed as an evolution of the 2003 edition of the dietary guidelines (NHMRC, 2003) and built upon the established evidence base. New evidence for priority areas was assessed to determine whether associations between food, dietary patterns and health outcomes had strengthened, weakened or remained unchanged.

Development of the 2013 Guidelines and their recommendations was informed by the following sources of evidence:

- The previous series of dietary guidelines and their supporting documentation (NHMRC, 2003)
- A 2011 evidence review to address targeted research questions relating to diet and health (NHMRC, 2011a)
- A 2013 review on nutritional requirements and dietary advice for pregnant and breastfeeding women (NHMRC, 2013b)
- The 2006 Nutrient Reference Values (NRVs) for Australia and New Zealand (NHMRC et. al., 2006)
- A Food Modelling System developed in 2011 to translate the NRVs into dietary patterns (NHMRC, 2011b)
- Key authoritative reports from government and international bodies.

1.2. Review process and scope

The Review will comprise the following stages:

- *Scoping and prioritisation activities:* A range of activities aimed at collating a list of potential research questions and identifying priority research questions for review.
- *Evidence review:* In line with previous iterations of the Guidelines, the revised Guidelines will build on the evidence base underpinning the current 2013 Guidelines. The evidence review will focus on identifying new evidence for targeted, priority research questions.
- *Update to the 2013 Guidelines:* The 2013 Guidelines will be updated to reflect the current evidence base. Judgements about the evidence underpinning recommendations, and other contextual factors considered during decision-making, will be transparently recorded via an evidence-to-decision process.

The Review's limited resources do not allow for systematic reviews to be commissioned to address all the prioritised research questions likely to be identified by the Expert Committee, nor to update the body of evidence for all research questions previously reviewed in the 2013 Guidelines.

To ensure a manageable scope and make efficient use of review resources, the Review will focus on updating the evidence for the highest priority research questions. These research questions will be addressed using existing, published systematic reviews, where a suitable review (e.g. current, comprehensive and methodologically robust) is identified. A limited number of *de novo* reviews (up to 5) will be commissioned to target key gaps in the evidence base, where resources allow.

Updates to the 2011 Food Modelling System (NHMRC, 2011b) and NRVs (NHMRC et al, 2006) are outside the scope of the Review.

The 2013 Guidelines will be updated to reflect the current evidence base, based on the following sources:

- findings from the evidence review
- the previous series of dietary guidelines and their supporting documentation (NHMRC, 2013a)
- key authoritative national and international government reports
- the current Nutrient Reference Values (NRVs) for Australia and New Zealand, inclusive of updates to select NRV recommendations published since 2006 (NHMRC et al, 2006)
- the 2011 Food Modelling System (NHMRC, 2011b).

1.3. Relevant NHMRC and International standards

NHMRC's 2016 Standards for Guidelines (NHMRC, 2016a) were developed to align with international best practice. These Standards are underpinned by the NHMRC Guidelines for Guidelines (NHMRC, 2021), which provide guidance to support production of high-quality guidelines that meet the 2016 NHMRC Standards. The Guidelines for Guidelines reference a range of internationally accepted tools and frameworks to support the review of evidence and development of recommendations in line with these standards.

The Review will be undertaken in accordance with the NHMRC Standards (NHMRC, 2016), and associated Guidelines (NHMRC, 2021). Where relevant, these standards may require modification or adaptation to the nutrition context. NHMRC will also incorporate methods applied by other key international groups involved in the development of evidence-based dietary guidelines and advice, where these approaches align with the NHMRC Standards.

1.4. Key developments since 2013

Methods for evaluating evidence and guideline development have evolved significantly since 2013. Key changes are reflected in the 2016 NHMRC Standards, including NHMRC's adoption of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Schünemann et. al., 2013). The GRADE approach provides a framework for evaluating a body of evidence and developing evidence-based recommendations in guidelines. It has replaced the NHMRC's FORM framework (NHMRC, 2009) previously used in NHMRC guidelines, including in developing evidence statements underpinning the 2013 Guidelines.

Adopting the GRADE approach for the review of the Guidelines will improve consistency and transparency, and aligns with NHMRC Standards. However, this presents a challenge for the use of existing evidence statements, which will remain in the previous (FORM) format. An approach for addressing this issue in the revised Guidelines is outlined under '*5.1 Integrating new evidence – GRADE vs FORM'.*

1.5. Governance

1.5.1. Expert Committee

NHMRC has established the Dietary Guidelines Expert Committee (the Expert Committee) under section 39 of the *National Health and Medical Research Council Act 1992* to advise on the Review. The Expert Committee includes individuals with expertise in evidence translation, epidemiology, research methods, food and health relationships, nutrition communication, Aboriginal and/or Torres Strait Islander health and consumer behaviour.

The role of the Expert Committee includes advising on:

- priority topics for review
- the development and conduct of evidence reviews, including providing comments on draft evidence evaluation reports and evidence statements
- evidence submitted by NHMRC stakeholders relating to the review topics.
- updates to the 2013 Guidelines, based on the evidence, ensuring an Australian context.
- stakeholder consultation and engagement
- feedback received during public and targeted consultation
- any other matter requested by the CEO of NHMRC on this project.

1.5.2. Governance Committee

NHMRC has established the Dietary Guidelines Governance Committee (the Governance Committee) under section 39 of the National Health and Medical Research Council Act 1992 to advise on conflicts of interest that may arise during on the Review. The Governance Committee includes individuals with expertise in conflicts of interest management, guideline development and review processes, research methodology, health ethics and stakeholder influence on health research and policy.

The Governance Committee will:

- review the declared interests of individuals before appointment to the Expert Committee to determine any potential, perceived or actual conflict of interest related to the work of the Expert Committee, in line with NHMRC policy on *Disclosure of Interests Requirements for Prospective and Appointed NHMRC Committee Members (2019).*
- assess the declared interests of contractors involved in the Guideline review.
- advise on management strategies for conflicts of interest on a case by case basis.
- advise on strategies to manage potential bias related to conflicts of interest in the evidence review.
- attend Expert Committee meetings determined to be relevant by NHMRC, to provide support and advice in relation to managing conflicts of interest and bias in the evidence.

1.5.3. Management of Interests

Committee members are required to disclose their interests on an ongoing basis. Members are asked to consider perceived interests as well as actual interests. A summary of the interests disclosed by each member is listed on the NHMRC website.

Disclosed interests are considered at each committee meeting to determine if any management strategy is required, consistent with NHMRC policy (NHMRC, 2019).

Contractors are required to disclose their interests prior to engagement and if circumstances change on an ongoing basis, consistent with NHMRC policy (NHMRC, 2019*).*

The Governance Committee can assist with assessment and management strategies for conflicts of interest on a case-by-case basis.

2. Purpose

2.1 Objectives

This document outlines the strategy for the conduct of the Review in line with the 2016 NHMRC Standards (NHMRC, 2016). It aims to ensure that:

1. the highest priority research questions are identified for evidence review, based on a rigorous and transparent process [*Scoping and prioritisation*]
2. the Review is informed by the most relevant and best quality evidence available for the priority research questions [*Evidence review*]
3. the Evidence-to-Decision process used to develop evidence-based recommendations is consistent and the factors considered in developing recommendations are reported transparently [*Update Guidelines*].

3. Scoping and prioritisation activities

3.1 Scoping activities

The initial step in the review is to conduct a series of scoping activities aimed at identifying a list of potential topic areas relevant to nutrition and food-based advice for prioritisation.

Scoping activities include:

- *A snapshot of recently published systematic reviews* relevant to the Guidelines to gain insights into 1) current topics of interest in systematic reviews of nutrition; 2) whether topics map to existing topic areas within the Guidelines or address new or emerging topic areas of interest; and 3) the general methodological quality of existing systematic reviews in food and nutrition. This scoping exercise will not consider individual systematic review findings.
- *A review of international nutrition guidelines and country specific food-based dietary guidelines* published since the 2013 Guidelines to 1) compare recommendations from key international groups with the 2013 Guidelines; and 2) examine the various approaches used to review evidence and develop recommendations.
- *Identification of nutrition & food-based advice by Australian Health Organisations* to identify 1) whether (and if so, which) recommendations in the 2013 Guidelines were being applied by Australian health organisations; and 2) identify where advice is being provided on topics not currently addressed by the 2013 Guidelines.
- *A survey of people who use the Guidelines* targeted at people who use the guidelines for work purposes or as a personal information source. This open public survey will aim to identify 1) how the 2013 Guidelines are used by stakeholders; and 2) nutrition topics of significant public interest.
- *Targeted stakeholder consultation survey* to understand the use and usefulness of the 2013 Guidelines and companion resources by those promoting the health of Aboriginal and Torres Strait Islander people.
- *Identifying diet related topics and themes in the Australian media* – to identify emerging, or trending, food and/or diet related topics where there is significant public interest.

The specific methodology for each of the scoping activities will be developed prior to conducting each scoping activity and published in an overall scoping report upon completion.

The outcomes of scoping will be provided to the Expert Committee to support decision-making about priority research questions for review.

3.2 Prioritising topics and research questions

A preliminary list of topics will be compiled, based on the research topics and questions underpinning the 2013 Guidelines, and the outcomes of scoping, including identification of new and emerging topic areas not captured in the 2013 Guidelines. Initially, research topics will be broadly defined, based on the intervention/exposure of interest, with outcomes to be determined later in the prioritisation process. The Expert Committee will then prioritise potential topics from

the preliminary list of topics identified through the scoping activities, using a modified Delphi approach.

Prioritisation will be determined by applying an agreed set of prioritisation principles to identify the highest priority research topics, including identifying the key outcomes of relevance/interest for each topic area. A list of priority research questions will then be developed for the highest priority topic areas, inclusive of Population Intervention/Exposure Comparator Outcome (PI/ECO) criteria.

Topics that are critical for national dietary guideline recommendations will not necessarily be the highest priority for review. Where the evidence base is unlikely to have changed enough to alter recommendations, existing evidence will be considered alongside the evidence underpinning key international food and nutrition groups during the Evidence-to-Decision process.

The outcomes of the prioritisation process, including the rationale and methods used for prioritisation and the priority PI/ECO criteria, will be published following completion of the prioritisation exercise. This information will be made available on the Review website to support transparency.

3.2.1 Principles for topic prioritisation

The following principles will be applied by the Expert Committee when prioritising topics:

1. Relevance
2. Importance
3. Type of impact
4. Degree of impact.

The principles have been modelled on the prioritisation pathways used for development of the Dietary Guidelines for Americans 2021-2025 (DGAC, 2020), the Nordic Nutrition Recommendations 2022 (Christensen et al, 2020), and Canada's Dietary Guidelines (Health Canada, 2019). The principles also take into consideration prioritisation criteria commonly used in the development of health practice guidelines.

The principles will be applied qualitatively through a survey and discussion process that iteratively cycles through the potential topics to achieve Expert Committee consensus.

3.2.1.1 Relevance

The principle of 'relevance' relates to the relevance of a topic area to the Guidelines. The scope of the 2013 Guidelines includes:

- foods, food groups and dietary patterns that protect against chronic disease and provide the nutrients required for optimal health and wellbeing
- guidance aimed at people of all ages and backgrounds in the general, healthy population, including people with common diet-related risk factors such as being overweight.

Accordingly, in determining relevance, the Expert Committee will consider whether the topic:

- relates to the Australian context
- applies to the general Australian population (recognising that a significant proportion have chronic conditions or risk factors for chronic conditions)
- relates to whole foods, food groups or dietary patterns
- relates to the promotion of health or prevention (rather than treatment or management) of a nutrition-related chronic conditions or nutrition-related risk factors.

Topics that are not considered relevant will be deemed out of scope for the Review.

3.2.1.2 Importance

The principle of 'importance' relates to whether a topic is important to current public health priorities and to what degree (i.e. low, medium, high). In determining importance, the Expert Committee will consider whether a topic:

- is of significant public health importance
- aligns with or addresses Australian Government health priorities
- is a long-standing issue or has the potential to change existing recommendations
- is likely to change a recommendation and if so, whether it would result in significant public health improvement
- addresses an area of rapidly changing evidence
- has significant public interest, including in media
- is an area of potential misinformation
- may inform (and to what extent) national food and health policies and programs.

Topics that are assessed as being of high importance will be considered a higher priority for review.

3.2.1.3 Type of impact

The Expert Committee will also consider the type of impact a topic has on public health, including broader societal, economic or environmental impacts. In assessing the type of impact, consideration will be given to whether the topic:

- has an associated health burden
- has the potential to impact health outcomes
- has associated health consequences
- impacts mortality, survival, longevity and life expectancy
- impacts morbidity and disability
- impacts disease burden or has the potential to reduce severity of disease
- relates to health biomarkers

- relates to food and dietary patterns
- addresses socioeconomic, demographic and cultural issues/needs
- relates to ethical sensitivities
- considers equity or human rights
- has societal impacts or impacts on non-health outcomes
- has environmental impacts
- has economic or financial impacts.

Topics that are assessed as being of higher or more wide-ranging, impact will be considered a higher priority for review.

3.2.1.4 Degree of impact

The degree of impact a topic may have will be assessed, including the magnitude of the issue and the size of the affected populations likely to be impacted.

In assessing the degree of impact, the Expert Committee will consider the:

- magnitude of the health burden associated with the topic
- magnitude of the potential impact on health outcomes
- degree to which a topic may impact financial, economic, environmental or societal areas.

Topics with high impact will be considered a higher priority for review.

4. Evidence Review

To make efficient use of the limited review resources, recent, high quality published systematic reviews will be used to update the evidence for priority research questions, where available. A limited number of *de novo* reviews will be commissioned, to target key gaps in the evidence base.

The evidence review component of the Review will comprise the following steps:

- ***Identifying existing systematic reviews for use:*** This includes scoping to identify suitable systematic reviews in the published literature, mapping suitable reviews to priority research questions and selection of the most suitable reviews for use in updating the evidence for priority research questions.
- ***Summarising evidence from existing systematic reviews:*** This involves developing GRADE evidence profiles based on the findings of existing systematic reviews.
- ***Identifying research questions and scoping for de novo evidence reviews:*** This involves identifying the specific research question to be addressed by each *de novo* review, along with the review methods, PI/ECO criteria and other key aspects to inform procurement of evidence reviewers.
- ***Commissioning and conducting de novo evidence reviews*** to target gaps in the systematic review literature. This includes commissioning an independent research group or groups with relevant expertise to develop a research protocol, conduct the review and report on findings, along with methodological review of the research protocol and final report.

4.1 Identifying existing systematic reviews

Potentially relevant systematic reviews will be identified and sourced via:

1. Literature searches, including database searching and searches of systematic reviews commissioned or conducted by key international groups
2. A public call for systematic reviews.

This process aims to identify suitable (current, comprehensive and methodologically robust) systematic reviews for each research question, with the aim of achieving good coverage for the highest priority research questions. It will not aim to comprehensively search for, and identify, all relevant systematic reviews for the priority research questions identified.

Where resources permit, lower priority research questions may be addressed using systematic reviews published by key international food and nutrition groups, where available. Additional supplementary searches will not be undertaken to address lower priority research questions.

Systematic reviews identified through the literature searches and public call will be collated and screened against the priority research questions eligibility criteria and minimum methodological criteria. The minimum methodological criteria will focus on identifying reviews:

- with a clearly defined research question and inclusion / exclusion criteria developed a priori
- with robust methods to search for and screen eligible studies, such as searching multiple databases, documenting search strategies, and screening full-text articles in duplicate.

- that clearly document outcomes from searching and screening (e.g. PRISMA flow diagram)
- that assess and report on quality or risk of bias of included studies.

Reviews that meet the eligibility criteria will be assessed for risk of bias to inform decision making about suitability. All suitable reviews will be mapped to the priority research questions, along with information about the review's scope, currency and risk of bias. This information will be used to support the Expert Committee in identifying the most relevant review for use in updating the evidence underpinning the Guidelines.

It is likely that for some priority research questions, multiple systematic reviews may be identified as potentially suitable. The evidence mapping process will include identification of the 'most relevant' review or reviews for each question. This will focus on identifying those reviews that are the most comprehensive, current and methodologically robust, based on:

- scope: the extent to which the systematic review eligibility criteria (including PI/ECOs and other criteria) align with the research questions of interest
- currency: the date that systematic reviews searched for included studies, with a focus on reviews conducted within the previous 5 years.
- methodological quality or risk of bias: based on ROBIS assessment, this encompasses a number of parameters, from how the search was conducted, how results were identified, assessed and synthesised from included studies, to how inclusion and analysis decisions may have impacted on the review's risk of bias.

Decisions about the 'most relevant' review will be made by the Expert Committee based on the abovementioned factors. No single factor carries primary weight when determining the 'most relevant' review, with judgements about the 'most relevant' review made by comparing and contrasting each review's overall characteristics. A rationale will be provided to support recommendations about the 'most relevant' review in these instances.

4.2 Summarising evidence from existing systematic reviews

Applying the GRADE approach (Schünemann et al, 2013), evidence from systematic reviews for each research question and PI/ECO will be presented in a GRADE Evidence Profile or Summary of Findings table. These tables summarise the overall body of evidence, including the number and type of studies, statistical results, and judgements about the certainty of evidence for each outcome. They also include an evidence statement describing the estimated effect and level of certainty.

Data will be extracted from included systematic reviews and entered into an Evidence Profile or Summary of Findings table format. These tables will then be used to inform revisions to the 2013 Guidelines, via an Evidence-to-Decision process (see *'5.2 Applying the Evidence-to-Decision Framework'*).

4.3 Identifying research questions and scoping for de novo evidence reviews

A limited number of *de novo* evidence reviews (up to 5) will be commissioned, to target gaps in the body of evidence for priority research questions. The Expert Committee will determine which research questions will be prioritised for *de novo* review, to target key gaps identified during scoping and evidence mapping. Priority questions unable to be addressed within the review resources will be documented in an Appendix to the Guidelines, to guide future review priorities.

Once a broad research question has been identified as a priority, the Expert Committee will work with NHMRC to identify and scope the specific research question, to support procurement of an Evidence Review Contractor. This includes:

- Determining the type of review to be commissioned
- Identifying key review inclusion and exclusion criteria
- Identifying and prioritising outcomes
- Identifying critical confounders and effect modifiers.

A protocol scoping template has been developed to support identification of key elements of the review prior to procurement (*Appendix A*). This template may be provided to prospective contractors during procurement, to inform their understanding of the review's scope and methods.

The parameters of the review (including review methods and inclusion/exclusion criteria, outcomes, and confounders) will be further refined by the Expert Committee in consultation with the evidence review contractor, during research protocol development.

4.3.1 Determining the type of review

A number of approaches exist for reviewing evidence, and these vary in the extent to which they systematically identify and synthesise the body of evidence. This includes systematic reviews, Overviews (systematic reviews of systematic reviews), rapid reviews, scoping reviews, and literature reviews. Definitions of the various review types are provided at *Appendix B*.

The Expert Committee will determine the most appropriate review type, based on the research question, with consideration given to the body of evidence, review objectives and available resources.

For many research questions, a systematic approach (systematic review or Overview) will be the most appropriate. This includes research questions examining the relationship between dietary intakes or eating behaviours and health outcomes. For other research questions, such as those exploring Australian-specific contextual factors, a broad, narrative evidence review or scoping review may be more suitable.

4.3.2 Identifying key review criteria

This step will involve identifying key inclusion and exclusion criteria relevant to the research question. This includes developing a clear description of the review objectives and rationale, methods, and inclusion/exclusion criteria including identifying:

- appropriate study designs for inclusion in the review
- PI/ECO criteria, including identification and prioritisation of critical and important outcomes
- critical confounders and effect modifiers.

4.3.2.1 Prioritising outcomes

A range of outcomes will be considered when evaluating evidence for the Guidelines. This may include:

- health outcomes, including outcomes relating to diet-related chronic disease, health and wellbeing, or healthy growth and development
- diet quality (eg. achievement of diets consistent with Guidelines).

A list of potentially relevant outcomes for each research question will be developed, based on the 2013 Guidelines, the outcomes of scoping, core outcome sets (such as COMET) or outcomes suggested by the Expert Committee.

Potentially relevant outcomes will be rated for priority using the GRADE approach (Schünemann et al, 2013), with outcomes rated from 1 (least important) to 9 (critical importance). Outcomes will be prioritised using the above prioritisation principles, and relative to the context of each specific research question. The Expert Committee will advise on prioritised outcomes.

4.3.2.2 Critical confounders and effect modifiers

Important variables that might confound or modify the effect of the exposure on the outcomes of interest will be identified and defined within the research protocol. A priori identification of confounders is particularly important given that the body of evidence will largely comprise observational studies. Important variables that may confound the effect include lifestyle or behavioural factors.

There may be many potential confounders for a question, and confounders are also likely to vary depending on the outcome being assessed. A list of potential confounders will be developed based on Expert Committee advice, initial (scoping) reviews of the literature, and confounders identified by international groups engaged in developing evidence-based dietary guidelines. The Expert Committee will advise on a final list of critical confounders to be included in the research protocol. Critical confounders will be considered during risk of bias assessment using tools such as ROBINS-I (Sterne et al, 2016) or ROBINS-E (ROBINS-E Development Group, 2023), and in interpreting the review's findings more broadly.

4.4 Commissioning and conducting de novo evidence reviews

Once the priority research questions have been identified and scoped for de novo evidence review, Evidence review contractors will be procured to conduct the evidence reviews. Procurement will be undertaken consistent with Commonwealth Procurement Rules. It is preferable that evidence review contractors include personnel with expertise in nutrition, alongside individuals with experience in conducting evidence reviews (in particular, systematic reviews and GRADE methodology). Contractors may be engaged to complete more than one review. Contractors, and their specified personnel, will be required to declare relevant interests in line with NHMRC processes for managing interests (refer to *'1.5.3 Management of Interests'*)

Under guidance from NHMRC (with advice from the Expert Committee), the contractors will:

- develop a research protocol to guide conduct of the evidence review
- execute the evidence review in line with the approved protocol and report on findings in accordance with NHMRC requirements.

4.4.1 Developing Evidence Review Protocols

A research protocol will be developed for each *de novo* evidence review, prior to review commencement. Protocols will specify review inclusion and exclusion criteria, along with comprehensive methods for the review's conduct.

Review methods will be guided by NHMRC Guidelines for Guidelines (NHMRC, 2021) and the internationally accepted approaches, tools and frameworks referenced therein. These methodological approaches may require adaptation to suit the nutrition- or review- context, depending on the type of review being undertaken and research question. Methods applied by key international groups involved in developing dietary guidelines and advice may also be adopted, where these approaches align with NHMRC Standards (NHMRC, 2016).

The proposed research protocol will undergo methodological review by an independent expert in evidence review methods. The evidence review contractor will be required to revise the protocol to address feedback to the satisfaction of NHMRC (as advised by the Expert Committee). The final research protocol will be approved by NHMRC, with advice from the Expert Committee, prior to commencement of the evidence review.

Protocols for all eligible review types (systematic reviews, rapid reviews or Overviews) will be registered on PROSPERO (the international Prospective Register of Systematic Reviews).

4.4.2 Conducting the review and reporting findings

The evidence review contractor will conduct the review in accordance with the approved protocol. Any deviations from the protocol must be justified with an explanation and approved by NHMRC with advice from the Expert Committee. Deviations from the protocol will be documented in the final Evidence Evaluation Report, along with a rationale.

The outcomes of the review will be reported in a comprehensive Evidence Evaluation Report, including detailed appendices with data extraction and risk of bias tables. The report will

summarise the body of evidence in GRADE Summary of Findings tables or Evidence Profiles, to support the Expert Committee in developing recommendations.

The draft Evidence Evaluation Report will undergo methodological review by an independent contractor. Methodological review will assess the conduct and reporting of the review against the agreed protocol, and best-practice standards such as the PRISMA statement (Page et al, 2021).

Evidence review contractors will be required to address feedback from methodological review to NHMRC's satisfaction (as advised by the Expert Committee), prior to finalising the Evidence Evaluation Report. A summary of methodological review comments, and the associated response, will be documented and published on the NHMRC web site for transparency.

The final Evidence Evaluation Reports will be approved by NHMRC, with advice from the Expert Committee. The final Evidence Evaluation Reports and associated appendices will be published on the NHMRC website alongside the revised Guidelines.

5. Update to the 2013 Guidelines

Upon completion of the evidence review stage, the Expert Committee will advise on integrating new evidence and determining whether the Guideline recommendations should be retained, revised, or rescinded. Decision-making will be guided by an Evidence-to-Decision process, as per the GRADE approach (Schünemann et al, 2013).

5.1 Integrating new evidence – GRADE vs FORM

Updated evidence identified during the evidence review will be presented in GRADE Summary of Findings or Evidence Profile tables. These include evidence statements that describe the effect for each outcome, and level of certainty in the evidence. Under GRADE, the level of certainty is described as very low, low, moderate, or high.

The GRADE approach (Schünemann et al, 2013) has replaced NHMRC's previous approach - the FORM framework (NHMRC, 2009) - used in developing evidence statements that underpinned the 2013 Guidelines. The FORM approach graded recommendations from A to D, based on the strength of the underlying body of evidence. Accordingly, evidence statements developed during the current evidence review will differ in format to those evidence statements developed in 2013 that have not been updated.

The resources available for this review do not permit evidence for all research questions to be reviewed and updated. It is also not possible to 'convert' a rating under the FORM framework to a GRADE rating, as the methods for deriving a rating differ across the two frameworks. Accordingly, the transition towards a set of Guidelines that are underpinned by GRADE evidence profiles and evidence statements will be achieved over a series of Guideline updates.

The revised Guidelines will draw on evidence from the current review, along with existing sources of evidence, including evidence underpinning the 2013 Guidelines not prioritised for review. Evidence Statements from the 2013 Guidelines that have not been updated in this Review will be described as per the 2013 Guidelines, and clearly labelled as such. This will also provide transparency about which evidence has been updated in the current Review.

5.2 Applying the Evidence-to-Decision Framework

The GRADE approach provides a transparent and structured approach for summarising evidence and developing recommendations based on that evidence. Included in this approach is the use of an Evidence-to-Decision Framework (EtD Framework), to facilitate decision-making, and ensure that all relevant criteria are considered and transparently reported. Relevant contextual factors include the balance of health benefits and harms; human rights and sociocultural acceptability; health equity; equality and non-discrimination; financial and economic considerations; feasibility and health system considerations.

The GRADE working group has developed several EtD Frameworks to support different types of health care decisions and recommendations, including health system and public health decisions (Moberg et al 2018). To address gaps in existing EtD Frameworks, the World Health Organisation (WHO) has also developed a framework – WHO-INTEGRATE - specifically for use in public health decision making (Rehfuess et al, 2019). The criteria used in the WHO-INTEGRATE framework

broadly map to the GRADE EtD criteria (see *Appendix C*), with the addition of 'human rights' and a 'societal implications' criterion that captures the social and environmental impact of decisions.

An EtD framework integrating key domains from the GRADE and WHO INTEGRATE frameworks will be applied in developing recommendations based on the updated body of evidence. Not all elements of the EtD framework will apply to all recommendations. The type of evidence required to inform considerations will also vary, depending on the decision-making context.

It will not be feasible to undertake comprehensive evidence reviews to inform every contextual factor considered when applying the EtD. However, contextual evidence reviews may be undertaken, where the need for evidence is deemed to be critical to decision-making, and subject to the limitations of available resources. The Expert Committee will provide advice about the priority of contextual reviews. Where a contextual evidence review is undertaken, it will be conducted in accordance with the process for *de novo* evidence reviews outlined above.

5.3 Adapting or adopting recommendations

In addition to developing a range of EtD Frameworks, the GRADE Working Group have also developed GRADE-ADOLOPTMENT: an approach that combines adopting or adapting recommendations from other guideline developers alongside *de novo* development of recommendations (Schünemann et al, 2017). Elements of this approach are also reflected in the NHMRC Guidelines for Guidelines (Adopt, adapt or start from scratch) (NHMRC, 2021).

For evidence not updated during the current review, consideration will be given to adopting or adapting recent recommendations from key national or international food and nutrition groups, where those guidelines have been developed in accordance with NHMRC Standards, and the process for guideline development is transparently reported. The process for adapting or adopting recommendations from eligible guidelines will be undertaken per NHMRC's Guidelines for Guidelines (NHMRC, 2021) and the GRADE-ADOLOPMENT framework (Schünemann et al, 2017).

5.4 Next steps

This document sets out the strategy for reviewing the evidence and recommendations for the Australian Dietary Guidelines. Following the development of draft recommendations, the Guidelines will follow standard NHMRC guideline development processes, including public consultation and peer review of the draft Guidelines.

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Appendix A – Protocol scoping template

This template is to be used to describe the scope and associated requirements for evidence reviews commissioned by NHMRC to inform the Review of the 2013 Australian Dietary Guidelines.

This document will be provided to prospective evidence evaluation contractors during procurement, alongside a detailed statement of requirement, to specify NHMRC's requirements for *de novo* evidence review.

1. Review Title

<<Insert Research question here>>

Research questions should clearly describe the focus of the review and include a brief description of the exposure (or intervention) and comparator, outcomes and population of interest.

For example, "What is the relationship between higher dairy intake (vs no- or lower- dairy intake) and risk of osteoporosis in adults?"

2. Introduction

A brief introduction, including rationale and objectives, to contextualise the issue and provide key background to the research question of interest.

Rationale

1-2 paragraphs describing why this particular review question was considered a priority. Include:

- *a description of the problem (public health and nutrition context)*
- *size of the problem (supported by population data, e.g. AIHW / ABS statistics).*

Objectives

State the aims of the review. E.g. to identify, evaluate and summarise the best available evidence on <<insert research question>>. Include any subgroups of interest.

3. Methods

Eligibility criteria

Participants / Population

- <specify the population (and any sub-populations) of interest>
- *This will be the 'general population', unless a review targets a specific sub-population of interest. The general population includes healthy people and people who have or are at risk of a common chronic disease (or health outcome of interest). However, studies that exclusively involve participants with a chronic disease (or health outcome of interest) will be excluded, as they are not representative of the general population.*

<Intervention(s) / Exposure(s)

- <describe and define the intervention / exposure of interest>

Include the following detail, where relevant, to fully define the intervention/exposure of interest:

- *level of exposure,*
- *exposure duration (e.g. minimum exposure duration),*
- *measurement of exposure*

Comparator(s) / Contrast(s) / Control

- <describe and define comparators of interest>

Include the following detail, where relevant, to fully define the comparator of interest:

- *level of exposure,*
- *exposure duration (e.g. minimum exposure duration),*
- *measurement of exposure*

Outcome(s)

- <describe and define the outcomes of interest>

Include outcome domain name, acceptable outcome measures, and timepoints of interest (including specifying any minimum follow up period).

Only the outcomes deemed critical or important to decision making should be selected for inclusion in the review. A limited number of outcomes should be selected to limit the review to a feasible scope. See 'Prioritisation of outcomes' below.

Provide a rationale for selection of specific outcomes, measures or timepoints

Types of study

- <describe inclusion and exclusion criteria for study designs>

Criteria should focus on methodological features of studies (e.g. prospectively designed and controlled) rather than study labels (e.g. RCTs, cohort studies)

Eligible study designs will vary depending on the research question, but may include randomised controlled trials (including individual, cluster and cross-over trials), non-randomised trials, Mendelian randomisation studies, prospective cohort studies, retrospective cohort studies and nested case control studies.

Provide a rationale for the inclusion or exclusion of particular study design features.

Setting

- <specify the setting inclusion and exclusion criteria, relative to the context and objectives of the review>

For example, whether to include:

- *Participants in any setting, or specific settings such as schools, or community settings*
- *Studies conducted in any country, or only in those countries with comparable Human Development Indices*

Publication status and language

- Only those studies published in English or for which an English-language translation is available will be included.

NHMRC does not have the resources necessary to identify and accurately translate studies reported in languages other than English.

Consider inclusion of grey literature and publications identified via pre-print servers, and specify rules for inclusion or exclusion.

Publication date

- <specify any limitations to publication date>

Provide a supporting rationale where limitations are applied.

Prioritisation of outcomes

Describe the outcomes of outcome prioritisation using the GRADE outcome rating scale (rated from 1 to 9, where 1 is low importance and 9 is critical for decision making). All outcomes considered for inclusion in the review should be listed, in ranked order, along with their rating (1 not important -9 critical).

Only those outcomes deemed critical or important to decision making should be selected for inclusion in the review, with a focus on identifying up to 7 critical or important outcomes.

Key confounders and other factors to be considered

Identify any important variables that might confound the effect of the exposure. e.g. lifestyle or behaviour factors.

Any co-exposures (or co-interventions), confounders or effect modifiers should also be identified. Critical confounders should be distinguished from those confounders that are desirable to consider, but not critical.

Choose whether to define subgroups that may be relevant to the review question such as lifecourse stage, age, gender, and pregnant or lactating women.

Consider the relevance and potential impact of the criteria in the Evidence-to-Decision (EtD) framework on the review, to ensure that relevant criteria or considerations are captured within the protocol.

Appendix B – Types of reviews and their definitions

Source: Covidence (2022). *What are the different types of review?* Available from: https://support.covidence.org/help/types-of-review-explained (Updated 28 June 2022)

Systematic reviews

Systematic reviews attempt to collate all empirical evidence that fit pre-specified eligibility criteria in order to answer a specific, clearly formulated research question. A systematic review uses explicit and reproducible systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made.

The process starts with a research question and a protocol or research plan. A review team searches for studies to answer the question using a highly sensitive search strategy. The retrieved studies are then screened for eligibility using pre-specified inclusion and exclusion criteria (this is done by at least two people working independently). Next, the reviewers extract the relevant data and assess the quality of the included studies. Finally, the review team synthesizes the extracted study data and presents the results.

A systematic review may contain meta-analyses (statistical analysis). A systematic review which is continually updated, incorporating relevant new evidence as it becomes available is often known as a living systematic review.

Rapid reviews

Rapid reviews aim to produce a rigorous synthesis quickly (due to time constraints/urgency), based on a pre-defined research question. The review process for rapid reviews is the same as for a more traditional systematic review: the emphasis is on a replicable pre-specified search, and screening methods that minimize the risk of bias, although potentially isn't as stringent as a formal systematic review.

The process operates within pre-specified limits (for example, by restricting searches to articles published during a specific timeframe) and is usually run by a multidisciplinary team with expertise in systematic review methods.

Umbrella reviews or Overview of reviews

An umbrella review is a review of multiple systematic reviews. The process uses explicit and systematic methods to search for, and identify, systematic reviews on related research questions in the same topic area. The purpose of an umbrella review is to synthesize the results of the systematic reviews across important outcomes.

Scoping reviews

Scoping reviews are exploratory, and they typically address a broad question compared to a systematic review that typically has a more targeted question.

Researchers conduct scoping reviews to assess the extent of the available evidence, to organize it into groups and to highlight gaps. If a scoping review finds no studies, this might help researchers to decide that a systematic review is likely to be of limited value and that resources could be better directed elsewhere.

Literature reviews or narrative reviews

Literature, or narrative, reviews provide an overview of what is known about a particular topic. They evaluate the material, rather than simply restating it, but the methods used to do this are not usually prespecified and they are not described in detail in the review. The search might be comprehensive, but it does not aim to be exhaustive. Literature reviews are often topic based and can take the form of a discussion. Literature reviews lack precision and replicability and can present their findings in the context of what has come before. Often, this sort of synthesis does not attempt to control for the author's own bias. The results or conclusion of a literature review is likely to be presented in a narrative format rather than statistical methods.

Appendix C – Mapping the WHO INTEGRATE EtD to the GRADE EtD

WHO INTEGRATE criteria and their application			Mapping to GRADE EtD Criteria
Criteria and abbreviated definitions	**Sub criteria**	**Implications for a recommendation**	
Balance of health benefits and harms			
The balance of health benefits and harms reflects the magnitude and types of health impact of an intervention on individuals or populations, taking into account how those affected value different health outcomes	• Efficacy or effectiveness on health of individuals. • Effectiveness or impact on health of population. • Patients'/beneficiaries' values in relation to health outcomes. • Safety risk profile of intervention. • Broader positive or negative health-related impacts.	The greater the net health benefit associated with an intervention, the greater the likelihood of a general recommendation in favour of this intervention.	*Balance of benefits and harms*
Human rights and sociocultural acceptability			
Human rights refers to an intervention's compliance with universal human rights standards and other considerations laid out in international human rights law. Sociocultural acceptability is highly time-specific and context-specific. Decisions are based on on anticipated or experienced cognitive and emotional responses to the intervention	• Accordance with universal human rights standards. • Sociocultural acceptability of intervention to patients/beneficiaries and those implementing the intervention. • Sociocultural acceptability of intervention to the public and other relevant stakeholder groups. • Impact on autonomy of concerned stakeholders. • Intrusiveness of intervention.	All recommendations should be in accordance with universal human rights standards and principles. The greater the sociocultural acceptability of an intervention to all or most relevant stakeholders, the greater the likelihood of a general recommendation in favour of this intervention.	*Acceptability^* *^Human rights not incorporated in GRADE EtD*

WHO INTEGRATE criteria and their application			Mapping to GRADE EtD Criteria
Criteria and abbreviated definitions	**Sub criteria**	**Implications for a recommendation**	
Health equity, equality and non-discrimination			
Health equity and equality reflect a concerted and sustained effort to improve health for individuals across all populations, and to reduce avoidable systematic differences in how health and its determinants are distributed. This includes ensuring that individuals or population groups do not experience discrimination on the basis of their sex, age, ethnicity, culture or language, sexual orientation or gender identity, disability status, education, socioeconomic status, place of residence, or any other characteristics.	• Impact on health equality and/or health equity. • Distribution of benefits and harms of intervention. • Affordability of intervention. • Accessibility of intervention. • Severity and/or rarity of the condition. • Lack of a suitable alternative.	The greater the likelihood that the intervention increases health equity and/or equality and that it reduces discrimination against any particular group, the greater the likelihood of a general recommendation in favour of this intervention.	*Equity*
Societal implications			
Societal implications recognise that health interventions do not take place in isolation and may enhance or inhibit broader social, environmental or economic goals in the short or long term. It also reflects the fact that many regulatory, environmental or other population-level health interventions are directly aimed at system-level rather than individual-level changes.	• Social impact. • Environmental impact.	• The greater the net societal benefit associated with an intervention, the greater the likelihood of a general recommendation in favour of this intervention.	*Nil^* *^No equivalent GRADE EtD domain; unique to WHO INTEGRATE*

WHO INTEGRATE criteria and their application			Mapping to GRADE EtD Criteria
Criteria and abbreviated definitions	**Sub criteria**	**Implications for a recommendation**	
Financial and economic considerations			
Financial and economic considerations acknowledge that available financial (budgetary) resources are constrained and take into account the economic impact of an intervention on the health system, government or society as a whole.	• Financial impact. • Impact on economy. • Ratio of costs and benefits.	The more advantageous the financial and economic implications of an intervention, the greater the likelihood of a general recommendation in favour of this intervention.	*Resource use*
Feasibility and health system considerations			
This criteria recognises that the most appropriate and feasible interventions may vary significantly across different contexts, both across countries and across jurisdictions within countries. Legislation and governance, the structure of the health system and existing programmes, as well as human resources and infrastructure, should be taken into account.	• Legislation. • Leadership and governance. • Interaction with and impact on health system. • Need for, usage of and impact on health workforce and human resources. • Need for, usage of and impact on infrastructure.	The greater the feasibility of an option from the perspective of all or most stakeholders, the greater the likelihood of a general recommendation in favour of the intervention. The more advantageous the implications for the health system as a whole, the greater the likelihood of a general recommendation in favour of the intervention.	*Feasibility*

WHO INTEGRATE criteria and their application			Mapping to GRADE EtD Criteria
Criteria and abbreviated definitions	Sub criteria	Implications for a recommendation	
Quality of evidence			
Quality – or certainty - of evidence, reflects the confidence that the available evidence is adequate to support a recommendation. In principle, it can be applied across all criteria in the WHO-INTEGRATE framework. As a large number of criteria are integrated in the decision-making process, 'evidence' is interpreted in the broadest sense and allows for relevant contributions from a variety of disciplinary approaches. Moreover, decision-making under uncertainty often involves stakeholder experience and judgement, in the absence of strong evidence.	–	The greater the quality of the evidence across different criteria in the WHO-INTEGRATE framework, the greater the likelihood of a general recommendation.	*Certainty of the evidence*