

Report of Consultation on Nutrient Reference Values in the Australia New Zealand Food Standards Code – a potential revision

Executive Summary

Background

In May 2006, the National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health (NZ MOH) released nutrient reference values for Australia and New Zealand (2006 NRVs). These nutrient reference values are a set of recommendations for nutritional intake based on available scientific knowledge at the time. They include measures of both adequacy and safety.

These 2006 NRVs expand and replace the *Recommended Dietary Intakes for Use in Australia* published in 1991 (1991 RDIs) that were formally adopted later by the NZ MOH.

The *Australia New Zealand Food Standards Code* (the Code) currently makes use of regulatory Nutrient Reference Values (rNRVs) for vitamins, minerals¹ and protein based on the 1991 RDIs and, where such values were unavailable, the 1989 United States Estimated Safe and Adequate Daily Dietary Intakes (ESADDI). The rNRVs for macronutrients and their components were drawn from other government recommendations.

These rNRVs are used in the Code as the basis for:

- label declaration of the nutrient content as % daily intake (%DI) (macronutrients and sodium) and %rRDI (vitamins and minerals)
- criteria for minimum content claims of vitamins and minerals (%rRDI and % rESADDI)
- criteria for maximum content claims of vitamins and minerals to regulate the voluntary addition of vitamins and minerals (%rRDI and %rESADDI) to foods.

Consultation

In the light of the 2006 NRVs, Food Standards Australia New Zealand (FSANZ) is considering the issues involved in, and potential approaches to, a revision of the current rNRVs in the Code. Any revision of the rNRVs in the Code is expected to be a complex process.

In July 2010, FSANZ released a Consultation Paper and invited comment from interested parties on the underlying principles, the relevant issues and potential approaches to revising the rNRVs in the Code. The approaches relate to the selection and derivation of the rNRVs based on the various and new aspects of the 2006 NRVs.

¹ In this Paper, sodium is considered separate from the minerals group.

In light of the detail and complexity of the issues discussed in the Consultation Paper, FSANZ also undertook targeted consultation with key stakeholders through a series of webinars. These were attended by seventy-three individuals including food industry and jurisdiction representatives, health professionals and academics.

Overall forty-two submissions were received in response to the Consultation Paper. This included six from government agencies, twenty-nine from the food industry and related organisations, six from health professionals/academics, and one from a consumer organisation.

Response to Consultation

Overall response

There was general agreement that a revision of the rNRVs to reflect the 2006 NRVs and contemporary science was appropriate.

Submitters identified several impacts that could result from a revision of the rNRVs including the cost to industry of label changes and possible reformulation of some foods, potential consumer confusion as a result of changes to food labelling, the cost of education campaigns, provision of support for public health strategies and some possible benefits to public health. It was also noted that the timing of a revision of the rNRVs in relation to other matters that might change labelling requirements, such as the independent Review of Labelling Law and Policy (the Labelling Review) might also influence these impacts.

Overarching issues that would need to be considered in a revision of the rNRVs included: an assessment of the costs to industry versus benefits to consumers and public health, the need for dietary modelling to ensure upper levels of intake (ULs) are not exceeded e.g. by children, the significance of change (to a value), the importance of values based on current science, the need for consumer education to reduce potential confusion, consumer research to understand how the rNRV information is currently used, and consideration of the potential to increase food fortification in the future. The need to align with other related matters such as the Labelling Review, including a common transition period to minimise costs to industry and to decrease consumer confusion where labelling requirements change, was seen as an important issue to be considered.

While many of these issues were common to the different stakeholder groups, industry submitters tended to emphasise the need for a cost benefit analysis, the transition period and consistency with international approaches. While industry submitters supported use of the best available evidence, it was suggested that in some cases this may not be the 2006 NRVs e.g. omega-3 fatty acids. Some industry submitters also noted that limiting changes to those values absolutely necessary to maintain the accuracy and intent of the Code could reduce the impact on stakeholders.

Jurisdictions, health professional and consumer submitters tended to emphasise public health issues as a priority including dietary modelling, consumer education, consumer research and also a review of fortification permissions.

Potential Approaches to the revision of rNRVs

The Consultation Paper identified a range of technical issues that would need to be considered in a revision of the rNRVs. Potential approaches and a preferred approach, with rationale where provided for each issue and are summarised in the table below. An overall summary of the submitters' responses to each issue is also provided.

It is noted that not all submitters commented on all issues; some commented only on a particular area of interest to them.

Generally, for many of the technical issues raised in the Consultation Paper, submitters supported FSANZ's preferred approach. However, various other issues were identified and further suggestions provided for FSANZ's consideration.

There were four main issues for which submitters expressed a range of differing views:

- selection of which 2006 NRV for sodium
- the rNRV for dietary fibre and method of analysis for resistant starch
- selection of new age- and life-stage categories for labelling purposes
- selection of the 2006 NRVs for carbohydrates and fats and calculation methods for their rNRVs.

In addition, different stakeholder groups sometimes reflected a different view for particular issues, for instance:

- Regarding the selection of the rNRV for sodium: jurisdictions and health professionals tended to support a reduction in the current rNRV with several preferring use of the AI. However many industry submitters tended to support retaining the status quo.
- Regarding the possible introduction of rNRVs for the new age categories and life-stages: most industry submitters supported the inclusion of new ages on a voluntary basis particularly a children's age category. Although some health professionals and jurisdictions supported this view, they considered more research on this issue was needed e.g. consumer research.
- Regarding the selection of the 2006 NRVs based on adequacy or the reduction of chronic disease: most jurisdictions and industry submitters tended to support adequacy. However, some specific industry submitters and health professionals tended to have mixed views noting adequacy was appropriate for some nutrients whereas the reduction of chronic disease was more relevant to other nutrients.

Overall submitter response to each issue raised in the Consultation Paper

ISSUE	CONSULTATION PAPER PREFERRED APPROACH	RATIONALE FOR PREFERRED APPROACH	SUPPORT FOR PREFERRED APPROACH AND KEY ISSUES RAISED
Selection of 2006 NRVs for subset of nutrients – nutrient adequacy or reduction of chronic disease risk?	<i>Establish rNRVs based on 2006 NRV measures of adequacy wherever possible</i>	<ul style="list-style-type: none"> • Majority of rNRVs can be underpinned by a consistent measure of adequacy. • Consistent with Codex 	<p>Supported</p> <ul style="list-style-type: none"> • However with some exceptions such as sodium and long-chain omega-3 fatty acids.

ISSUE	CONSULTATION PAPER PREFERRED APPROACH	RATIONALE FOR PREFERRED APPROACH	SUPPORT FOR PREFERRED APPROACH AND KEY ISSUES RAISED
Selection of 2006 NRVs for protein, vitamins and minerals: Which measure of nutrient adequacy – EAR or RDI?	Maintain the RDI as the basis of the rNRV	<ul style="list-style-type: none"> Greater certainty of meeting adequacy requirements. Consistent with Codex. Less confusion for consumers 	Supported <ul style="list-style-type: none"> Noted potential for an NRV to exceed the UL for children, or encourage increased fortification of processed foods and claims. Recommended dietary modelling, consumer research and cost benefit analysis
Selection of 2006 NRVs for several vitamins and minerals: Adequate intakes	Revise the basis of the rNRV from rESADDI to regulatory AI	<ul style="list-style-type: none"> Consistent with domestic NRVs rather than overseas values 	Supported <ul style="list-style-type: none"> Caution was noted as there is less certainty when there is no RDI or EAR available which may lead to overestimation and greater fortification.
Calculation methods for rNRVs for protein, vitamins, minerals and dietary fibre	Calculate rNRVs on the basis of a simple averaging of 3 or 4 adult age categories (either 19 – 70 or 19 – 70+ years) for males and females	<ul style="list-style-type: none"> Simplicity and comparability of result compared to more complex approaches. Consistent with Codex. 	Supported <ul style="list-style-type: none"> Some alternative combinations of adult age categories were suggested.
Selection and basis for reference energy value	Review the energy reference value for the general population	<ul style="list-style-type: none"> Consistent use of the 2006 NRVs as the basis of the rNRVs rather than drawing on a separate dietary intake data set 	Supported <ul style="list-style-type: none"> Recommended basing the value on energy requirements rather than intake. Noted the potential impact on %DI labelling, costs and consumer confusion. Recommended further consideration of children's products, and use of a physical activity level (PAL) between 1.4-1.8.
Calculation methods for rNRVs for carbohydrates and most fats	Base rNRVs for carbohydrate and fat within their respective AMDR percentage energy range and adapting for protein rNRV energy gap	<ul style="list-style-type: none"> Maximum use of measures of adequacy with inclusion of protein 	Some support <ul style="list-style-type: none"> A range of views were expressed The lower level of energy from fat was an issue for some submitters.
Selection of 2006 NRV for sodium	Base rNRV for sodium on SDT rather than AI	<ul style="list-style-type: none"> SDT provides a more 'reachable' rNRV in light of current sodium consumption 	Some support <ul style="list-style-type: none"> A range of views included basing the rNRV for sodium on the status quo, the SDT, or the AI. Some supported a reduction regardless of the level.
Units for niacin	Update rNRV to mg niacin equivalents (NE)	<ul style="list-style-type: none"> Consistent with the 2006 NRV units. Consistent with Codex. More accurate consumer information 	Supported <ul style="list-style-type: none"> Recommended dietary modelling to ensure safe levels of niacin and revision of the labelling criteria. Testing foods for NE was considered to be complex.

ISSUE	CONSULTATION PAPER PREFERRED APPROACH	RATIONALE FOR PREFERRED APPROACH	SUPPORT FOR PREFERRED APPROACH AND KEY ISSUES RAISED
Units for folate	Update rNRV to dietary folate equivalents (DFE)	<ul style="list-style-type: none"> Accounts for increased bioavailability of folic acid. Consistent with the 2006 NRV units 	Supported <ul style="list-style-type: none"> Caution was noted around the higher DFE of 400 micrograms, any risk of an excess intake to children, and the potential for fortified foods to replace nutrient rich unfortified food.
Dietary fibre rNRV and method of analysis	Adopt 2006 NRV for dietary fibre and update Code to add a method(s) of analysis for total resistant starch	<ul style="list-style-type: none"> Consistent with the basis of the 2006 NRVs for dietary fibre 	Supported <ul style="list-style-type: none"> A range of views was expressed on the definition, types and level of fibre, and the methodology.
New' nutrients not currently in the Code	Include rNRVs for all 'new' nutrients in the Code unless stakeholder comment indicates no support for particular nutrient e.g. total water.	<ul style="list-style-type: none"> Consistent with 2006 NRVs 	Supported inclusion of all or some 'new' nutrients <ul style="list-style-type: none"> Most excluded water Several supported using the rNRV as a basis for criteria for some new nutrients, although some did not support that for nutrients with an AI.
Potential new age and life stage categories for labelling purposes	No preferred approach	<ul style="list-style-type: none"> No preferred approach at this stage 	Some support <ul style="list-style-type: none"> A range of views were expressed. Many supported a voluntary category for children. There was less support for stages such as pregnancy and lactation. Noted limited label space, consumer confusion, and potential to encourage fortified foods. Further research was recommended.

Next Steps:

FSANZ is now considering the next steps for undertaking a revision of the rNRVs in the Code. Stakeholder views will help inform FSANZ's approach to any future action.

FSANZ is also aware of the impacts of other related matters, which may have implications for labelling changes, such as the Labelling Review. The Final Report, *Labelling Logic - Review of Food Labelling Law and Policy (2011)* was released by the Australian Government on 28 January 2011. The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) is responsible for developing a whole-of-government response to the recommendations of the Final Report.

The whole-of-government response to the recommendations in the Labelling Review is currently being developed and is expected to be released by the Ministerial Council by the end of 2011.

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1. Background

In May 2006, the National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health (NZ MOH) published nutrient reference values for Australia and New Zealand (2006 NRVs) (NHMRC and NZ MOH, 2006). These nutrient reference values comprise a set of recommendations for nutritional intake based on currently available scientific knowledge. They include measures of both nutrient adequacy and safety. The 2006 NRVs expand and replace the *Recommended Dietary Intakes for Use in Australia* published in 1991 (1991 RDIs) (NHMRC, 1991)² that were formally adopted later by NZ MOH.

The 2006 NRVs introduced several significant changes to the previous official nutrient reference values. In particular, the publication:

- expanded the range of nutrients assigned nutrient reference values
- introduced new types of reference values including for macronutrients
- revised many of the 1991 RDIs
- modified the age ranges
- modified the units for folate
- revised the presentation of energy requirements.

The *Australia New Zealand Food Standards Code* (the Code) currently makes use of regulatory Nutrient Reference Values (rNRVs)³ for vitamins, minerals and protein based on the 1991 RDIs and, where such values were unavailable, the 1989 United States Estimated Safe and Adequate Daily Dietary Intakes (ESADDI) (IOM, 1989). The current rNRVs for macronutrients and their components were drawn from other government recommendations.

In light of the 2006 NRVs, Food Standards Australia New Zealand (FSANZ) is considering the issues involved in, and potential approaches to, the revision of the current rNRVs in the Code.

2. Purpose of This Paper

This paper reports on the consultation undertaken by FSANZ in 2010 with regard to a potential revision of the rNRVs in the Code. The report outlines the consultation process, provides an overview of the response from submitters and includes an indication of the support for the various technical issues and approaches proposed in a consultation paper released in July 2010. While the report reflects the views of submitters and identifies key issues raised for further consideration, it is not intended to provide a detailed response to these issues nor provide the final approaches which will be used in any future revision on the rNRV in the Code.

3. The Consultation Process

In July 2010 FSANZ released a public Consultation Paper to invite comment on the underlying principles to guide consideration, the relevant issues and potential approaches to revising the rNRVs in the Code.

² The 1991 RDIs have been rescinded by the NHMRC and are available electronically for historical purposes only.

³ The term regulatory Nutrient Reference Value (rNRV) is used in this report to differentiate current and any future values in the Code from those provided in the 2006 NRV publication or from a conceptual discussion of nutrient reference values.

In light of the detail and complexity of the issues discussed in the Consultation Paper, FSANZ provided an Explanatory Guide to accompany the Paper and also undertook targeted consultation with key stakeholders through a series of webinars. The webinars were attended by seventy-three individuals including food industry and jurisdiction representatives, health professionals and academics.

A copy of the full Consultation Paper can be accessed at <http://www.foodstandards.gov.au/srcfiles/NRVs%20Consultation%20paper%20FINAL.pdf>

3.1 Objectives of the consultation

Given the extent of the changes in the 2006 NRVs and the differing approaches that could be taken to revise the rNRVs in the Code FSANZ sought to consult with interested stakeholders as a first step. Therefore, the objectives of the Consultation Paper were to explore the scope of the issues to be addressed, consider the issues and impacts of the potential approaches, and to inform future work, which could potentially include development of a proposal(s) to amend the Code.

3.2 Scope and exclusions

The consultation considered the current rNRVs and their implementation in the Code, the range of changes made in the 2006 NRVs, and the various approaches that could be taken to revise the rNRVs in the Code.

The following were identified as out of scope:

- evaluation of the 2006 NRVs beyond their use in the Code
- adoption of 2006 NRVs directly into the Code
- consideration of mandatory fortification requirements in the Code relating to folic acid, thiamin and vitamin D in Australia and to iodine in both Australia and New Zealand
- permission to add a particular vitamin or mineral to a food – however, the amount of a vitamin or mineral that could be added or claimed is within scope because such amounts (as mg or µg) are derived from a percentage of the rNRV (%rNRV)
- consideration of where and how declarations are made on the label (e.g. as part of Nutrition Information Panel (NIP), front of pack etc.), the outline and format of the NIP or the setting of tolerance levels for label declarations
- criteria for claims unless they were directly affected as a result of possible changes to rNRVs.

4. Consultation Response

Forty-two submissions were received in response to the Consultation Paper. This included six from government agencies, twenty-nine from the food industry and related organisations, six from health professionals/academics and one from a consumer organisation representatives.

4.1 Overall response to a potential revision of the rNRVs in the Code

In general, most submitters supported a revision to update the rNRVs in the Code to reflect the 2006 NRVs. However, a range of overarching issues were identified as important when considering a revision. These included the need for:

- a full cost benefit analysis (CBA) to assess the costs to industry versus benefits to consumers and public health outcomes.
- the impacts of a revision on public health to be the first priority.

- dietary modelling to determine the implications of increasing the rNRVs for many key nutrients.
 - revised values to be based on current science.
 - consumer research on how the NRV information is currently used e.g. on food labels and its impact on food consumption.
 - only those nutrients with a significant change being reviewed.
 - a widespread communication/ education campaign for health professionals and consumers to minimise confusion about label changes.
 - a cautious and guarded approach to including additional rNRVs because of a concern that this could potentially lead to increased food fortification in the future.
- alignment with other related labelling activity such as the independent review of Labelling Law and Policy (Labelling Review), to allow for a common transition period for labelling changes.

While many of these issues were common to the different stakeholder groups, industry submitters tended to emphasise the need for a cost benefit analysis, the transition period, limiting changes to those values absolutely necessary to maintain the accuracy and intent of the Code and consistency with international approaches. While industry submitters supported use of the best available evidence, it was suggested that in some cases this may not be the 2006 NRVs e.g. omega-3 fatty acids.

Jurisdictions, health professional and consumer submitters tended to emphasise the public health issues including dietary modelling, consumer education, consumer research and also a review of fortification permissions.

4.2 Underlying principles

To assist future decision making, stakeholders were asked to consider the following principles identified by FSANZ which could underpin a revision of the rNRVs:

- consistency where possible across the Code
- consistency with international approaches
- workable integration of approaches
- seeking balance between effective outcomes and unnecessary impact
- simplicity of future revisions.

Just over half of the submitters commented on these principles and generally supported them, providing the following comments:

- Seeking balance between effective outcomes and unnecessary impact: several submitters considered that a revision of the Code should be nutritionally significant to justify a change. The benefit of small and potentially insignificant changes was questioned and a risk benefit analysis was recommended once the proposed changes to the rNRVs are more clearly established. It was noted that the Principles provide a framework for developing regulations that are effective and proportional to the issues being addressed, and also a framework for demonstrating that the benefits outweigh the costs.
- Consistency with international approaches: while there was general support for this Principle it was noted that there is no consensus internationally with regard to applying the Codex NRVs (which are currently under review).
- Simplicity of future reviews: this Principle was considered particularly significant in relation to the future review of the NRVs by NHMRC.

In addition, nearly half of those providing comments considered that the first priority should be the impact of any change on public health outcomes. Several submitters recommended an additional Principle in line with FSANZ's objective to protect public health. It was suggested revising the rNRVs for energy, total fats, saturated fats, total sugars, sodium and dietary fibre was a first priority as these nutrients are of greatest public health significance. A concern was noted that some proposed approaches could potentially result in adverse health effects.

Some submitters also commented on the importance of using the latest, most current scientific information noting that the 2006 NRVs are based on scientific evidence available prior to that date. It was considered that nutrition-related developments since that date should be taken into account.

4.3 Potential approaches to the revision of rNRVs in the Code

The Consultation Paper outlined several approaches that could be used to update the range of rNRVs in the Code and identified FSANZ's preferred approach. Not all submitters commented on all issues discussed in the Consultation Paper and some commented only on their particular area of interest.

Many of FSANZ's preferred approaches were supported by most submitters who provided comment. However, some issues were more contentious with a range of views expressed, including:

- selection of which 2006 NRV for sodium
- the rNRV for dietary fibre and method of analysis for resistant starch
- selection of new age- and life-stage categories for labelling purposes
- selection of 2006 NRVs for carbohydrates and fats and calculation methods for their rNRVs.

These are discussed in more detail under the relevant sections below.

4.3.1 Selection of 2006 NRVs for a subset of nutrients – nutrient adequacy or reduction of chronic disease risk?

In the 2006 NRVs, either the Estimated Average Requirement (EAR) or RDI, or the Adequate Intake (AI) address nutrient adequacy for all listed vitamins and minerals and age categories. The 2006 NRVs also introduce Acceptable Macronutrient Distribution Ranges (AMDR) and Suggested Dietary Targets (SDT) (see Attachment 1) for some nutrients based on evidence of reduction of chronic disease risk. Protein has an EAR and RDI covering all age categories as well as an AMDR for youth and adults.

Possible approaches to the rNRVs

- 1 *Establish rNRVs based on 2006 NRV measures of adequacy wherever possible*
- 2 *Establish rNRVs based on 2006 NRV measures for reducing chronic disease risk wherever possible*

FSANZ's preferred approach at Consultation

At Consultation, Approach 1 was preferred because it enables the vast majority of rNRVs (i.e. micronutrients and protein) to be underpinned by a consistent measure of nutrient adequacy for all age categories that are or could be included in the Code. In view of the limited data in support of the health relationships for some SDTs and AMDRs, FSANZ regards Approach 1 as the one which can be applied more consistently into the future.

Issues raised by submitters

Most submitters supported FSANZ's preferred approach. A range of comments were provided about the appropriateness of this approach for specific nutrients.

Generally most jurisdictions and industry submitters tended to support adequacy. However, some specific industry submitters and health professionals tended to have mixed views noting that adequacy was appropriate for some nutrients whereas the reduction of chronic disease was more relevant to other nutrients.

Several submitters considered adequacy was not appropriate for sodium. Changes based on the reduction of chronic disease risk were supported where there is a compelling public health case such as for sodium, and also where there is a benefit for all age groups and subsections of the population. Several submitters also supported the use of AMDRs for carbohydrate, total fat and saturated-trans fats in line with the reduction of chronic disease risk. One submitter specifically considered that adequacy was not appropriate specifically for long chain omega-3 fatty acids.

It was noted that basing all macronutrients including protein on AMDRs would provide consistency across micronutrients, fibre and macronutrients. It would also overcome some problems associated with differing protein requirements and conversions to % energy.

It was also noted that the impact on industry would differ depending on the approach adopted. For example SDTs are generally higher than measures of nutrient adequacy and if adopted would therefore have a greater impact on fortification requirements and permitted nutrition claims (for those vitamins and minerals that have SDTs) i.e. if a higher level of a vitamin or mineral is present in a food, existing nutrition claims (either source claims based on 10% or good source claims based on 25% of the current rNRVs) could not be made unless the food is reformulated.

In addition, some considered SDTs should not be used as the basis for NIP requirements.

4.3.2 Selection of 2006 NRVs for protein, vitamins and minerals

Which measure of nutrient adequacy – EAR or RDI?

The Code has established rNRVs as rRDIs and rESADDIs (which are conceptually similar to AIs) but not EARs as this value was not described in the 1991 RDIs.

For about a third of listed nutrients, the 2006 EAR is the same or higher than the current rRDI for a single age and gender group.

Possible approaches

- 1 *Maintain the basis of the rNRV as RDI*
- 2 *Revise the basis of the rNRV from RDI to EAR*

FSANZ's preferred approach at Consultation

Approach 1 was preferred because it provides greater certainty that a nutrient intake that met the rNRVs would be adequate for the vast majority of the target population. It better supports the goal of the population as a whole having an adequate intake, and it is more appropriate for a smaller proportion of the population than the EAR. The risk of exceeding the UL for young children is expected to be very low but this will be further investigated before any decisions are made.

This approach maintains the concept of RDI for consumers, and is also consistent with the proposed Codex revision.

Both approaches are likely to place a similar burden on industry since the quantum of change appears to be about the same with very few numbers remaining unchanged.

Issues raised by submitters

Most submitters supported FSANZ's preferred approach noting it would provide greater certainty of meeting the dietary requirements of the majority of the population, maintain consistency with current use of rRDI in the Code which would minimise consumer confusion and impact on industry, and is consistent with the proposed Codex revision.

However, there was some concern that using the RDI might result in an rNRV that exceeds the UL for some nutrients for some population groups e.g. small children. Further investigation of nutrients that have a general population RDI that is similar to the UL for young children, such as zinc and iodine was recommended. These risks need to be considered before deciding to use the RDI.

It was also considered that using the RDI may encourage increased fortification, the increased use of nutrient content claims particularly where there has been a major increase in the RDI (such as phosphorus), and potentially the overconsumption of certain nutrients and food. Also, it was noted that any figure used can never be a meaningful target for individuals as it will not accurately reflect the RDI for any one specific gender and life stage group.

It was noted that many 2006 RDIs are greater than the current rRDIs which could potentially impact on the levels of nutrients in the food supply. It was recommended that modelling should be undertaken to test the effects of changing the RDIs on the intake of population groups such as young children.

It was also noted that use of the RDI would impact on industry in relation to meeting the requirements for a nutrition content claim and also for the %DI and %rRDI values on labels. Where the rNRV increases for vitamins and minerals, reformulation might be required to ensure a minimum claim criteria can still be met. It was noted that FSANZ will need to consider whether the proportion rRDI or the actual quantity should remain the same in relation to the maximum permitted claim per reference quantity (Standard 1.3.2). One submitter also estimates there would be more cost associated with adopting the 2006 RDI values (as compared to the EAR values) where they are higher than the current rNRV in the Code. It was also suggested that FSANZ seek the advice of the Australian Competition and Consumer Commission (ACCC) as to whether claims based on EARs would be considered misleading.

It was considered that further investigation is warranted and that a cost benefit analysis of EAR versus RDI might be beneficial.

Further research including consumer research to gain a better understanding of how the NRV information is used and if it determines consumption, was recommended prior to making decisions. Modelling to illustrate the potential impacts of adopting the EAR or the RDI was also recommended to assist decision making. Development and testing of appropriate messages for use on labels to assist interpretation of NRVs was also suggested. The diverging views on the use of EAR or RDA in the United States and Canada were also noted.

In addition, it was suggested that appropriate reference quantities (Standard 1.3.2) versus serving sizes be used so they more closely reflect current consumption patterns.

4.3.3 Selection of 2006 NRVs: Adequate intakes

The 2006 NRVs provide AIs for several vitamins and minerals instead of EARs and 2006 RDIs. These AIs were developed in cases where there was insufficient evidence to establish an EAR or where the evidence was conflicting. Two types of AI were developed based either on experimental evidence or according to population median intake assuming that neither the Australian nor New Zealand population was deficient. Because of the assumptions made or the uncertainties in the evidence base, AIs are not as reliable as EARs and RDIs.

As previously noted, the Code includes rESADDIs for micronutrients that were not allocated an RDI in 1991. Most rESADDIs are drawn from the US 1989 ESADDIs. Comparison of the rESADDIs in the Code with their 2006 NRV counterparts shows a downward trend (refer to Attachment 3 of the Consultation Paper).

Possible approaches

- 1 *Maintain current rESADDIs except for nutrients with EAR and 2006 RDI (i.e. molybdenum)*
- 2 *Revise the basis of the rNRV from rESADDI to regulatory AI*

FSANZ's preferred approach at Consultation

Approach 2 was preferred by FSANZ if other rNRVs are revised, to provide a total set of rNRVs that reflect contemporary official Australia New Zealand values. This approach promotes greater consistency across the Code in relation to rNRVs.

Issues raised by submitters

Of those submitters who commented on this issue, most supported FSANZ's preferred approach. However, submitters recommended caution when considering use of AIs to establish rNRVs as there is less certainty when there is no EAR or RDI.

It was noted that in deriving the rNRVs, as they relate to a single value to be used on a food label, the basis must reflect the best available evidence at the time and the most consistent approach i.e. where there is no established EAR or RDI, the adoption of the new AIs.

Concern was expressed that the AI may be higher than an RDI if one could be determined and that this may lead to overestimation of needs and may also allow for greater levels of fortification of currently permitted vitamins and minerals.

Further investigation into the effects on the downward trend in many of the vitamins and minerals from revising the rNRV from ESADDI to AI was recommended.

Comments were also made in relation to specific nutrients for example, sodium (see Section 4.3.8). The poor suitability of the AI for dietary fibre was noted by another submitter; the need for consumer education about how to use and interpret the % DI was also noted.

4.3.4 Calculation methods for rNRVs for protein, vitamins and minerals, dietary fibre for the general population 4 years and above

The 2006 NRVs maintain similar age groups for infants and children but expand the adult age groups from two to four: (19-30, 31-50, 51-70, >70 years). Of the thirty-seven nutrients with measures of nutrient adequacy, only seven have the same value for all adult age and gender categories i.e. vitamin A, folate, vitamin C, vitamin B12, iodine, molybdenum and phosphorus.

Most rNRVs for the general population in the Code were derived from a single value or from within a range of an age and gender category. No calculation methods were needed since in most cases only one value (adult males) was selected. The general population values are for ages 4 years and older excluding pregnancy and lactation. rNRVs are also given for infants and for young children.

Possible approaches

- 1 Calculate rNRVs on the basis of a simple averaging of the three or four adult age categories (19 – 70 or 19 – 70+ years) for males and females
- 2 Calculate rNRVs on the basis of one of the other methods

FSANZ's preferred approach at Consultation

Approach 1 was preferred because of its simplicity and comparability of result with more complex weighted approaches. Also, it better represents all age categories in the general population than the selection of the highest RDI.

Issues raised by submitters

Most submitters supported FSANZ's preferred approach to calculate these rNRVs on the basis of a simple averaging of 3 or 4 adult age categories.

Several different combinations of adult age categories were suggested as the basis for the average. The most preferred option was to calculate the average rNRVs from three or four age categories (19-70 or 19-70+ years) for males and females. Other suggestions from individual submitters were:

- average age groups 19-70 with the exclusion of older persons (70+) and menopausal women
- adults up to 50 years to exclude women of menopausal age and the 70+ age group, who have extreme requirements for some nutrients
- the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) derived values that are based on average values for adult males (19 to 65 years) and females (19 to 50 years) (yet to be adopted).

One alternative suggestion to an averaging calculation method was a population-weighted calculation of rNRVs; another was the highest adult male RDI value.

It was noted the latter would provide higher nutrient allowances and therefore increase the likelihood of addressing recommendations for other life stages, such as pregnancy and lactation and, in some cases higher recommendations during adolescence.

4.3.5 Selection of reference energy value

The 2006 NRVs include an Estimated Energy Requirement (EER) for adults at Body Mass Index (BMI) 22 kg/m² for a range of ages, heights and physical activity levels (PAL) for each gender.

An energy reference value of 8,700 kJ (2,100 kcal) is prescribed in the Code as the benchmark for nutrition labelling. This value of 8,700 kJ was derived from the average intake of adult males and females from national dietary surveys in Australia and New Zealand (ABS, 1997; Howarth *et al*, 1991). Energy reference values for other age categories are not set in the Code.

The rNRVs for total fat, saturated fat, (available) carbohydrate and total sugars are derived from a percentage of the energy reference value (refer to Table 5.1 of the Consultation Paper). These rNRVs may be used by food manufacturers to label the %DI of these nutrients in a serving of the food.

Where % DI is used, the following statement is required to be placed under the NIP:
**Percentage daily intakes are based on an average adult diet of 8,700 kJ. Your daily intakes may be higher or lower depending upon your energy needs.*

This statement was instituted in recognition of the wide range of energy intakes that are needed to support varying energy expenditures across the population.

Possible approaches

- 1 *Maintain the current energy reference value of 8,700 kJ*
- 2 *Review the energy reference value for the general population*

FSANZ's preferred approach at Consultation

Approach 2 was preferred because it would result in consistent use of the 2006 NRVs as the basis of the rNRVs rather than drawing on a separate data set as in Approach 1. The choice of appropriate BMI in Approach 2 needs further consideration.

Issues raised by submitters

Most submitters supported FSANZ's preferred approach to review the energy reference value for the general population. Basing the energy reference value on energy requirements rather than energy intake was recommended.

A number of issues were raised by submitters. It was recommended FSANZ determine how significantly values would differ between the preferred and alternative approach. Others recommended maintaining the current value if the new value is +/- 10% of the current value to reduce the impact on costs and consumer confusion.

The possible impact of a change on the voluntary %DI declaration in the NIP was noted, as was the cost to update packaging and to avoid consumer confusion.

It was noted that calculations based on the preferred approach may result in higher energy value than the current level. This could result in labels making foods appear as though they had less energy so more could be consumed, with unintended consequences.

Further consideration of children and children-specific products was recommended. It was suggested that the current energy value for NIPs and products specifically targeted at children aged 3-12 years be reviewed and an average child's energy rNRV for children's products be considered. It was noted that a review of energy requirements for infants should be done during the review of Standard 2.9.1 – Infant Formula Products.

Submitters' recommendations for an appropriate PAL to use ranged from 1.4 – to 1.8. Further modelling was recommended as it was considered that a PAL of 1.7 could overestimate requirements for a large section of the population but 1.2, which refers to bed/chair bound individuals, may be too low.

FSANZ also asked the specific question: *Are you aware of data that could appropriately serve as a basis for a review of the energy reference value?*

Suggestions included:

- Maintain the current value until data from the Australia National Health Survey (NHS) is reviewed then use the average of mean energy intakes for healthy weight adult males and females, weighted to reflect the adult population ages and activity levels.
- Use the NHS data to select the appropriate PAL and population-weighted height to calculate EER of adults.
- Use a population-weighted approach rather than averaging EERs for a range of age/sex groups.
- Designate energy values by gender.
- Average the 2006 NRV EER using adult age categories that correspond most closely with the current rNRV adult age i.e. categories of both genders <50yrs age and moderate activity (1.8) PAL.

4.3.6 Selection of 2006 NRVs and calculation methods for carbohydrates and most fats

The rNRVs for total fat and carbohydrates and their subcomponents in the Code are given as gram amounts which were derived from a percentage of the prescribed energy reference value. The rNRVs for carbohydrate and total fat have no alternative but to be based at a point along their respective 2006 AMDRs which are expressed in terms of percentage energy. An upper bound only is allocated to saturated-and-trans fat but no AMDR is given for sugars, nor is carbohydrate defined as total or available carbohydrate.

The 2006 AMDRs are:

Protein	15 – 25% energy
Carbohydrate	45 – 65% energy
Total Fat	20 – 35% energy
Saturated-and-trans fat	≤8 – 10% energy.

FSANZ's preferred approach at Consultation

The rNRV for protein is preferred to be based on its adequacy measure, the 2006 RDI even though it contributes dietary energy. Therefore, only carbohydrate and total fat would have rNRVs based on the AMDR ranges of percentage energy.

Setting of the energy percentage for the macronutrients needs to be undertaken in tandem with decisions on the reference energy value and protein rNRV. At consultation it was considered reasonable to suggest that only minor adjustments should be made to the current percentages, mostly to accommodate a revised % energy contribution from protein based on the RDI.

Issues raised by submitters

There were a range of views expressed on this issue, with around half of those commenting supporting FSANZ's suggested approach.

Submitters noted that the final figures will depend on the energy reference value determined. It was noted that making minor or no adjustments to current % of macronutrients is the most reasonable approach. Some submitters considered that if the revised values are similar to the Code, the values would not need to be changed.

Several submitters supported FSANZ's preference to use the RDI for protein. It was noted that the current approach is less than the lower end of the AMDR range for protein but that Australians easily achieve the required levels. Also, it was noted that treating protein as an RDI not an AMDR reflects the primary need for protein as a nutrient rather than an energy source.

However, others considered the AMDR to be the appropriate basis for carbohydrate, fats and also for protein, as this would be a consistent approach for all macronutrients and there would not be a need to consider the EAR/RDI for protein. One submitter considered that an intake of dietary protein above the RDI is required to meet micronutrient recommendations within reasonable energy intakes. Another noted that this is consistent with the draft NHMRC New Food Guidance System for Australia – Foundation and total diets and considered that the % values for protein, total fat, carbohydrate and saturated/trans fat should be consistent with that document. It was also suggested that the various options should be modelled from a public health perspective and that the figures selected should be in line with public health messages.

Several submitters considered it was inappropriate to recommend the lower level of 20% energy from fat as this is insufficient to meet essential fatty acid requirements and insufficient for achieving the intakes of unsaturated fat recommended for chronic disease risk reduction. It was recommended that FSANZ review this lower level and that the emphasis be on saturated fat reduction rather than reducing all fats (to be able to achieve a ratio of polyunsaturated fatty acid (PUFA) to saturated fatty acid (SFA) of greater than 1). It was noted that the Heart Foundation PUFA recommendation could not be achieved with a total fat intake of less than 27% energy (in an 8,000 kJ/day diet). Therefore it was recommended that the lower end of the recommended range of total fat be reviewed and proposed that it should be 27% of energy, not 20%. There was some support for saturated-and-trans fat at less than 8% to align with National Heart Foundation advice, while other submitters supported the 8-10% of energy.

Some submitters considered the upper end of CHO range should be around 58% - 60% of energy to allow for the suggested change to the total fat level of 27%, which would enable a sufficient intake of unsaturated fats.

It was also noted that any revision of macronutrient rNRVs should consider the impact on %DI labelling.

4.3.7 Selection of 2006 NRV for sodium

Sodium differs from most other nutrients in that it has both an adequacy measure (i.e. AI) and an SDT; there is also an upper limit (UL) for sodium.

The values are:

- 2006 NRV adult AI: 460-920 mg
- SDT: 1600 mg
- adult UL: 2300 mg.

The current rNRV for sodium (2,300 mg) in the Code is based on the upper bound of the adult 1991 RDI. However this value has become the adult UL in the 2006 NRVs. FSANZ believes that, on principle, the UL should not form the basis of a future rNRV. Also, the population intake generally exceeds the SDT.

Possible approaches

- 1 *Base rNRV for sodium on SDT (1600mg)*
- 2 *Base rNRV for sodium on AI (460-920mg)*

FSANZ's preferred approach at Consultation

At consultation, FSANZ considered that the value of the rNRV for sodium must be revised downwards as the current rNRV (2,300mg) now represents the UL for sodium. Population sodium intakes are above the UL but efforts by public health bodies and some manufacturers are encouraging its reduction. Of the 2006 options available, an rNRV based on the SDT (1600mg) was preferred rather than the AI (460-920mg) because it provides a more practical target given current intakes, while also conferring a preventative health benefit.

Issues raised by submitters

Although there were diverse views on the basis for the rNRV for sodium, overall the majority of submitters supported a reduction. A small number of submitters supported the preferred option of the SDT (1600mg) whereas maintaining the status quo (2300mg) or selecting the AI (460-920mg) were fairly equally supported. In addition, several supported an unspecified reduction regardless of the level.

Generally jurisdictions and health professionals tended to support a reduction in the current rNRV with several preferring use of the AI, whereas many industry submitters tended to support retaining the status quo.

The rationale for selecting the rNRV was diametrically opposed. One view held that the AI is not appropriate as it is unrealistically low compared with the mean daily adult sodium intake in Australia and New Zealand (2670 mg and 2890 mg respectively). In contrast, the other view was that the sodium rNRV should reflect actual estimated requirement, the AI, and not what might be reachable based on current consumption.

Submitters who supported maintaining the status quo noted that an rNRV based on a SDT set for chronic disease prevention may not be appropriate for all segments of the general population. Others considered any revision of the rNRV should be based on actual intake and a realistic approach taken for people to achieve a healthy diet. Also, this should be supported by a commitment from industry to reduce sodium in foods in a stepwise approach along with education activities.

In support of the preferred option i.e. the SDT (1600 mg), it was acknowledged that using the SDT is not consistent with basing rNRVs on nutrient adequacy, but is justified due to the adverse health effects of an excessive sodium intake.

In support of selecting the rNRV based on the AI, it was noted that rNRVs based on measures of adequacy would ensure consistency across the Code which was considered an important principle. Also, this group generally agreed that health benefits are more likely to occur if the AI is used for the rNRV as it could assist with achieving the population recommendation to reduce sodium intake. Selecting the AI is also in line with a chronic disease risk reduction approach, whereas using the SDT is inconsistent with the approach taken with other nutrients i.e. although the SDT represents a more 'reachable' target for population intakes, it is less likely to decrease the risk of chronic disease than the lower AI for sodium.

Also, the AI would better inform consumers of the true estimated requirement when products choose to list the % Daily Intake of sodium. It was recognised that using the AI for sodium may present challenges for industry, although this could encourage a reduction of sodium in processed food and create strong incentives for industry.

The safety of children was noted as a concern if an rNRV is selected that is above the sodium UL for children. The SDT of 1600 exceeds the UL for sodium for children 4 - 8 years. In addition, if further age categories are added, there are no age-specific SDTs for sodium which is of concern for children who require a limited sodium intake due to their immature kidneys. However, there are age-specific AIs for sodium. Also, an AI based rNRV would provide more meaningful labelling information for children aged 4 – 8 and 9 – 13 years.

Also, it was noted that basing the sodium rNRV on the amount that is required for good health and not on the UL as it is currently, has the potential for the UL to mislead consumers that they need to eat that amount each day. It was suggested that in this case a new wording on labels may be required, as the RDI or DI based on a UL would have a different meaning to one based on an AI.

Food industry submitters expressed concern that the preferred option of lowering the rNRV for sodium to 1600 mg/day may lead to consequences on taste, safety, physical parameters and the preservative role of salt in processed food if a food is reformulated. It was also noted that there are already a number of industry initiatives in place to reduce the salt content of processed foods and industry are committed to these programs which involve reformulation and innovation.

Several submitters commented on the issue of consumer confusion if the rNRV for sodium changes to a lower value. A lower rNRV would increase the % Daily Intake on the label and consumers may not understand the formulation has not changed. In addition, it was noted that consumer research has shown that gradual salt reductions in food products over time are better accepted by consumers than one significant reduction.

It was recognised that any approach must be practical for the food industry and be accompanied by a consumer education campaign to reduce sodium intake.

4.3.8 Units for niacin

The 2006 NRVs for niacin are expressed as niacin equivalents (NE) to account for a contribution from dietary protein of the essential amino acid tryptophan⁴. If tryptophan data are not available, NE can be calculated from total protein content on the assumption that the protein content contains tryptophan. Hence the NE of a food is greater than its pre-formed niacin content when a food contains tryptophan or protein. This is the case for most foods.

The current Codex revision has selected NEs as the unit of measurement for niacin for labelling purposes and notes that it is consistent with the units used in the FAO/WHO publication on human requirements (2004).

In the Code the rNRV for niacin is only a proportion of its 1991 RDI (mg NE) and is expressed as mg niacin rather than mg NE. The niacin rNRV is derived from the 1991 RDI (average 16 mg NE, men and women) but adjusted to account for the proportion of Australian dietary NE intake contributed by pre-formed niacin i.e. 10 mg pre-formed niacin. In the absence of official ULs, basing the rNRV on a proportionate value had the effect of restricting the amount of niacin that could be added to foods.

Possible approaches

- 1 *Maintain current approach of niacin based on pre-formed niacin*
- 2 *Base rNRV on niacin equivalents from pre-formed niacin and tryptophan or protein*

FSANZ preferred approach at Consultation

At consultation Approach 2 was preferred because it would provide consumers with information about the contribution of foods to their NE requirements while still ensuring that niacin-fortified foods would not pose a risk from excessive niacin intakes.

Issues raised by submitters

All submitters responding on the units for niacin, with one exception, supported the FSANZ preferred approach to update the rNRV to mg NE.

Submitters suggested that dietary modelling is necessary to ensure safe levels as a change to NE could potentially mean some foods are fortified with higher levels of added niacin. Another submitter noted that the labelling criteria guidelines will need to be revised to align with any change to NE which could impact on fortification.

One submitter advised that options for testing foods for NE are complex and FSANZ should discuss these with food testing laboratories prior to any change.

4.3.9 Units for folate

The 2006 NRVs for folate are expressed as Dietary Folate Equivalents (DFEs) in recognition of the increased bioavailability⁵ of folic acid relative to natural folates in food. The highest 2006 EAR or RDI is 400 µg DFE (range 300 – 400µg DFE).

⁴ NE (mg) = pre-formed niacin (mg) + [tryptophan (mg)/60 or protein (g)/6]

⁵ Bioavailability means the proportion of the ingested nutrient that is absorbed and utilised through normal metabolic pathways. It is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparations, and host-related intestinal and systemic factors.

The rNRV for folate in the Code was derived from the 1991 RDI for total folate (μg) which assumed no difference in bioavailability of natural folates and folic acid. The Code requires folate to be declared as μg folate with the current rNRV set at 200 μg total folates. Internationally, Codex proposes the use of Dietary Folate Equivalents (DFEs⁶) for labelling purposes.

Possible approaches

- 1 *Maintain current approach of micrograms of total folates*
- 2 *Update units to micrograms of dietary folate equivalents*

FSANZ'S preferred approach at Consultation

Approach 2 was preferred because it is consistent with official recommendations and international trends. However, FSANZ noted that any increase in risk of excess intake for younger age categories from increased fortification levels would need to be carefully managed.

Issues raised by submitters

Most submitters commenting on the units for folate supported the FSANZ's preferred approach to update the rNRV to DFEs.

With a growing number of products being fortified with folic acid, and the difference in bioavailability compared with folate, it was considered appropriate to ensure consistency and provide a single unit to give consumers a better indication of the total folate available in a food. The change to dietary folate equivalents would give a better indication of the total amount of folate in the food.

Caution was expressed that the rNRV for folate should not be increased to 400 micrograms of DFE without a better understanding of all possible long term effects.

It was suggested that changing the rNRV for folate may mean that the limits for voluntary and mandatory folic acid fortification may need to be revised. In addition, any increase in risk of an excess intake for younger age categories from increased voluntary fortification levels would need to be carefully managed.

Some submitters expressed concern that a change from micrograms of total folates to DFE might encourage manufacturers to add more folic acid to foods and folic acid fortified foods could be seen as more advantageous than foods with natural sources of folate due to their higher levels of folate equivalents. This could potentially lead to risk of excess intake of folic acid and of foods fortified with folic acid, possibly displacing nutrient rich unfortified foods. It was noted that the folate units selected should not disadvantage nutrient rich products that are high in natural folate but low in added folic acid, when compared to products that are nutrient poor but fortified with folic acid.

Support for maintaining the status quo of micrograms of total folate included consistency with current Codex recommendations.

The need to develop an approved test method was noted as one is not currently available. Also, sufficient time needs to be allowed to develop proficiency testing prior to the changes being gazetted.

⁶ DFEs = μg natural folates in food + 1.67 μg folic acid

4.3.10 Dietary fibre

There are some differences in the definition of dietary fibre between the 2006 NRVs and the Code which may need to be considered when revising the rNRV for fibre.

The 2006 NRVs establish an AI for dietary fibre derived from median intakes from national Australian and New Zealand surveys. However, the dietary fibre values in the supporting food composition databases were analysed by AOAC International methods (Australia) or the Englyst method (New Zealand), neither of which fully measure resistant starch. The 2006 NRV's regard resistant starch as a type of dietary fibre, therefore the median intakes of dietary fibre of each age-sex group were adjusted upwards by 2 – 4 grams to take account of estimated resistant starch intake.

The Code contains a definition of dietary fibre and also lists several AOAC International methods of analysis that can be used for analysis of dietary fibre content of foods for the purposes of label declaration. These methods also underpin the existing Daily Intake value and [draft] criteria for dietary fibre content claims in Proposal P293 – Review of Health and Related Claims. Some of the listed methods partially measure resistant starch although no method is listed that measures resistant starch only.

The reference value given in the Code for calculating the percentage of daily intake of dietary fibre is 30g.

Possible approaches

1 *Adjust downwards the 2006 NRV for dietary fibre to maintain consistency with dietary fibre as measured by existing methods of analysis in the Code*

2 *Adopt 2006 NRV for dietary fibre and update Code to add a method of analysis for total resistant starch to the list of approved methods of analysis for dietary fibre*

FSANZ's preferred approach at Consultation

Approach 2 was preferred to maintain consistency with the basis of the 2006 NRVs for dietary fibre. It could also provide more opportunities for industry and consumers to meet their dietary fibre needs.

Issues raised by submitters

Most submitters commenting on fibre supported a review of the current rNRV although there were differing views on how best to do this. Many submitters suggested that additional approaches to the two options provided in the Consultation Report should be considered in a wider review of dietary fibre in the Code.

Submissions included a range of views on the definition of dietary fibre, the level that should be adopted, the health benefits of various dietary fibre components, and test methodology.

There were differing views on the appropriate definition of dietary fibre for use in the Code. These included the Codex (2009) definition and the European Food Safety Authority (EFSA 2010) scientific opinion on Dietary Reference Values for carbohydrates and dietary fibre. The rationale for updating the definition of dietary fibre included the need to better distinguish between fibre and other carbohydrates.

There were also several views on the level of dietary fibre that should be adopted. Concern was expressed that the preferred approach of selecting the 2006 NRV average of the fibre AI for men and women, and therefore an rNRV of 27.5g, is a decrease of 2.5g compared to the current rNRV in the Code. There was concern from a public health perspective when even higher fibre intakes are known to be protective and many people do not reach the current rNRV of 30g. Therefore there was support for maintaining levels of at least 30g and possibly 33g per day i.e. the midpoint between the SDT for both genders (28g and 38g) in the 2006 NRVs. Maintaining the current level would also reduce unnecessary impact while aligning with the 2006 NRVs of 27.5g which is close to the current rNRV of 30g.

Another suggestion was the adoption of a dietary fibre rNRV that is mid-way between the current rNRV (30g) and the highest SDT (38g) i.e. 34g. This would acknowledge dietary fibre's capacity to improve health via its impact on obesity, heart disease, diabetes and certain cancers.

There were various views on the selection of a suitable test method. It was recommended that approved method(s) of analysis for resistant starch should be determined separately from any proposal to revise the rNRVs. Several relevant methods were suggested (AACC, AOAC 2005 and McCleary 2010). Development of a direct, adequately validated analytical procedure which gives an accurate measure of the resistant starch level in foods as eaten was also suggested.

The alignment of food composition data for dietary fibre with the test method was raised in submissions. If the preferred approach is adopted, there will be a requirement to update the food composition database for fibre to provide accurate information.

Submitters were concerned about the benefit of adding certain types of dietary fibre to food. Concern was expressed about the use of inulin or resistant starch to add dietary fibre and to then carry a content claim (e.g. inulin to yoghurt). It was suggested this could be misleading for consumers as it would conflict with the dietary guidelines which recommend fruit, vegetables and wholegrain cereals as a source of dietary fibre.

There were differing views on the benefits of resistant starch and some submitters were concerned that the preferred approach could increase the opportunities for industry to add extrinsic fibre ingredients such as resistant starch, to otherwise nutrient poor foods. Others saw an opportunity for industry to increase the dietary fibre value of foods and to be able to provide consumers and health professionals with accurate information on the dietary fibre content of foods.

Implementing a change to the rNRV for dietary fibre would require a review of the current fibre levels in all products and label updates. It was noted that sufficient time should be provided to allow for testing and label updates once a method of analysis is established. This would be a costly process due to the requirement for analytical testing.

4.3.11 *New nutrients not currently in the Code*

A number of nutrients were assigned NRVs for the first time in 2006, i.e. linoleic acid, alpha-linolenic acid, long chain omega-3 fatty acids, total water, choline, fluoride and potassium. Although a RDI for potassium was set in the 1991 RDIs, it is the only nutrient that does not have an rNRV listed in the Code.

Although none of these 'new' nutrients have rNRVs in Standard 1.1.1 of the Code at present, some are referenced in other ways. Therefore there is potential to have rNRVs for these nutrients in the Code as part of a revision of the rNRVs.

4.3.11.1 Possible approaches

1 Do not include rNRVs for 'new' nutrients in the Code

2 Include rNRVs for 'new' nutrients in the Code

FSANZ's preferred approach at Consultation

FSANZ's preferred Approach was to include rNRVs for all 'new' nutrients in the Code unless stakeholder comment (e.g. from consumers and industry) indicated no support for a particular nutrient such as total water.

Based on the precedents discussed in subsection 6.3 of the Consultation Paper, FSANZ proposed that the rNRVs for the 'new' nutrients (refer to Table 8.1 of the Consultation Paper) be based on AIs where no other option exists. Where more than one 2006 NRV exists per nutrient, basing the rNRV on the AI is consistent with the proposed approaches for protein (which also has an AMDR) and certain vitamins (that also have SDTs). FSANZ notes that the 2006 NRVs do not treat total fat and fatty acids consistently i.e. fat, saturated-and-trans fat, linoleic acid and linolenic acid have AMDRs but long chain omega-3 fatty acids have a SDT. All these constituents except saturated-and-trans fat are assigned AIs and for all age categories with the exception of total fat which is assigned an AI only for infants.

The 2006 NRV publication reports that potassium can blunt the effect of sodium chloride on blood pressure and it could be argued that for the general population, the rNRV for potassium should not be based on the AI but rather on the SDT to be consistent with the SDT for sodium. FSANZ will give further consideration to this particular issue.

Where rNRVs for new nutrients are included in the Code, both existing and new nutrition claim criteria should be considered.

Currently, nutrition claims⁷ in relation to the omega fatty acid content of a food can be made however these claims are not related to, or expressed as, a proportion of the rNRV. For example, under clause 13 of Standard 1.2.8, claims for 'source' of omega-3 fatty acids are based on absolute values i.e. 200 mg alpha-linolenic acid (ALA) per serve or 30 mg total eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) per serve. It may be appropriate to consider whether the criteria for these types of claims should be based on, and expressed as, a percentage of the rNRV. Consideration may also be given to the development of content claim criteria for other new nutrients such as potassium, choline.

FSANZ also asked the specific question: *"Should rNRVs for new nutrients in the Code be used as the basis for developing content claim criteria? If so, which nutrients should be considered?"*

Issues raised by submitters

Nearly all submitter comments were in favour of including rNRVs for new nutrients in the Code. However, water was excluded by most submitters, and some commented only on essential fatty acids.

Some submitters also supported the use of rNRV for the new nutrients as the basis for developing content claim criteria to be consistent with other nutrients in the Code. Additional rNRVs would enable claims and therefore improve consumer communication on the benefits of these new nutrients.

⁷ Note: the term nutrition claim is currently used in the Code whereas the term nutrition content claim has been recommended in Proposal P293 - Nutrition, Health and Related Claims.

Submitters suggested that new claims criteria should be developed for those nutrients that do not already have established criteria, and that existing claim criteria (e.g. omega-3 fatty acids) should also be reviewed. It was also suggested that the methodology used to determine minimum content levels could be reviewed.

In general there was agreement for basing the rNRV for new nutrients on the AI, except for linoleic acid and ALA where some submitters suggested the AMDR could be used. However, a few submitters stated that content claims should not be made for those nutrients which have an AI, as there is potential to overestimate requirements.

Additional issues were raised for consideration when developing rNRVs or claims for new nutrients:

- To safeguard from excess intakes, existing fortification permissions or claim criteria such as for omega-3 fatty acids, should be reviewed taking into account the new rNRV together with current consumption patterns.
- Restrict the foods that qualify for permission to add nutrients and make content claims, so as not to encourage increased intake of less healthy foods. The development of nutrient content claims should be aligned with the nutritional value of the food.
- Consumers may be confused by content claims for a nutrient that is important for body functioning (e.g. choline, fluoride and potassium), but is not relevant to current population health issues.
- FSANZ should consider how rNRVs based on AI would be declared in the nutrition information panel, given that the acronym 'AI' is unfamiliar to consumers.

Comments on specific new nutrients were also provided as follows:

Essential fatty acids

The health benefits of the omega-3 fatty acids DHA, EPA and in some cases Docosapentaenoic acid (DPA), and ALA were advocated including specific rNRV recommendations for age and life stages. However, some submitters were more cautionary with regards to DPA recommending a comprehensive assessment of the evidence base and the implications of including DPA in nutrient content claims. However, it was noted that red meat contains EPA, DHA as well as DPA and is the second largest contributor of omega-3 fatty acids in the Australian diet. Consideration of DPA could improve red meat's ability to make a claim. Consumer research indicates that few consumers are aware of the omega-3 fatty acid content of red meat.

Strong reservations were expressed with supporting references by one submitter on promoting new rNRVs for linoleic acid and ALA which could have unintended negative consequences.

The role of fatty acids in foetal and infant neurological and retinal development was raised. The suggestion was made that dietary fats such as linoleic acid, ALA and long chain omega-3 fatty acids be specifically regulated in Standard 2.9.3, in addition to Standard 1.2.8, to address the specific nutritional requirements of older infants and young children. At present, the current content claims for dietary fats are regulated under Standard 1.2.8 and are based on the average dietary requirements for adults.

There were also several recommendations to differentiate between long chain and shorter chain omega-3 fatty acids.

Provision of a separate rNRV for omega-3 and omega-6 fatty acids was recommended so that foods making content claims could also include a % DI value on the NIP.

Selection of the SDT for long chain omega-3 fatty acids was recommended in preference to the AI. It was noted that SDTs are more in line with international recommendations and the AI is based on actual median intakes and not on physiological need. SDTs are available for adults and children over 14 years of age and it was suggested that energy-adjusted SDTs could be developed for other age categories.

Fluoride

It was noted that fluoride needs particular consideration as many water supplies to homes in Australia and New Zealand are fluoridated and the consumer is unlikely to be conscious of this when they consume tap water. So providing an rNRV for labelling purposes on a food or beverage could potentially be misleading.

Wholegrain

Several submitters supported the inclusion in the Code of an rNRV for wholegrain. While FSANZ acknowledges this suggestion, the term 'wholegrain' is used to describe ingredients or foods derived from the whole grain rather than a nutrient. In addition, the 2006 NRVs did not include a reference value for wholegrain.

4.3.12 Potential new age and new life stage categories for labelling purposes

The 2006 NRVs for micronutrients, protein, dietary fibre and some fatty acids are reported in 10 age categories, divided by gender beginning at nine years of age, as well as for three age categories for pregnancy and lactation (see Table 8.3 of the Consultation Paper). The 2006 NRVs for carbohydrate, total fat and sodium (as SDT) are reported for one age category aged 14 years and older and these nutrients are not reported separately for pregnancy and lactation.

The Code currently refers to three age categories (without reference to gender) in relation to rNRVs:

- 4 - 12 months (Standard 2.9.2)
- 1 - 3 years (Standard 1.1.1)
- Unspecified (general population) (Standard 1.1.1)

Possible approaches

- 1 Do not include rNRVs for more age categories and life stages
- 2 Consider including additional age categories and/or life stages

FSANZ's preferred approach at Consultation

FSANZ did not have a view on whether rNRVs should be established for new age categories or life stages. Setting new age categories or life stages would allow for nutrient declaration to be expressed in terms of nutrient requirements for these new categories.

New categories could either replace the general population rNRVs as reference values for current % DI and %RDI in the NIP or provide an additional source of rNRVs for declaration of nutrient content in relation to these new categories.

FSANZ asked submitters whether *FSANZ should consider introducing these new categories into the Code, and if so, to perform which functions?*

Issues raised by submitters

The majority of responses on this issue were in favour of specific new categories, such as children, with fewer supporting other categories such as pregnancy and lactation. There was considerable support for FSANZ to further consider introducing additional age categories and/or life stages that would enable the provision of information particularly on products that target different population groups such as children or the older population e.g. over 70 years of age. Some submitters qualified their support by stating the use of new categories should be voluntary. Separate categories for males and females, and groups with specific dietary requirements outside of age and gender were also suggested. In contrast, several submitters recommended that consumer research on the use of NRV information by consumers is undertaken in the first instance. Most industry submitters supported the inclusion of new ages on a voluntary basis particularly a children's age category. Although some health professionals and jurisdictions supported this view, they considered more research on this issue was needed.

Overall, there was strong support for the inclusion of additional rNRV categories for children e.g. for foods such as breakfast cereals and snacks. Some submitters emphasised that when foods are marketed to a specific age group such as children, a claim stating the % DI for a nutrient should be accurate for the target market. One submitter supported the use of a mandatory statement to indicate which age range the reference values represent. Others thought that the target population group should be specified in the NIP and the NIP columns restricted to only those groups, as it might be confusing to consumers to have several columns in the NIP. It was suggested it might also be necessary for the Code to define or determine what a child's product is. It was noted that this approach would be more appropriate for consumers, and potentially aid in preventing overconsumption, and would also enable industry to ensure a more appropriate nutrient profile.

Some submitters suggested that nutrients where the NRV is distinctly different across the age and life stage categories, such as protein and calcium, should be considered. It was also suggested that rNRVs for the new age categories could be used in conjunction with a claim. This could require an extra NIP column on a voluntary basis.

An alternate view was to retain one key set of rNRVs for use on NIPs (Standard 1.2.8), for the criteria for vitamin and mineral claims and for setting maximum content levels (Standard 1.3.2). The potential to make use of other rNRVs on products targeting specific population subgroups and foods regulated under Part 2.9 (Special Purpose Foods) of the Code could be further developed. For example, one submitter suggested there was potential for content claims specific to various stages such as older infants and young children for dietary fats such as ALA, linoleic acid, long chain polyunsaturated fatty acids (such as DHA and EPA) and dietary fibre, to address the different nutritional requirements. Associated with this, the development of an industry *User Guide or Code of Practice* for the appropriate use of these NRVs was recommended.

Submitters provided specific comments in support of rNRVs for children included:

- There is potential for excessive intakes of micronutrients when the %DI on products predominantly aimed for children are based on adult requirements.
- A %DI based on adult requirements could potentially contribute to the significant issue of childhood obesity and encouragement of overconsumption.
- A lower sodium intake is needed for young children when kidneys are still maturing and when salt appetites are being established.

Several submissions discussed the possible age categories for children. Some suggested only one additional age group may be necessary i.e. an average of values for boys and girls aged 4-13 years, as many food products aimed at children would likely apply to this age range. Others suggested the different age categories for children as identified in the NHMRC document, child and teenage groups, and a single new age group of 4-8 years. It was suggested that the additional rNRVs for children should be for energy, the macronutrients, vitamins and minerals including sodium. This would enable new labelling information to better inform the nutritional needs of children.

Some submitters did not support any new categories; others were unsure of the benefit of having new age and life stages and recommended more research was needed to determine the use of the label information.

Three major issues were raised by this group; firstly differentiating foods for different age categories and life stages on a label could confuse consumers, be misleading if not clear, require numerous columns in the NIP, and take up limited label space. It was considered that food labels should be simpler and more informative, and not become more complex. Secondly, the potential to encourage the production and marketing of unnecessarily fortified foods which could undermine the development of lifelong healthy dietary habits was noted. The view was expressed that this may be beneficial to food industry but may result in increased food costs for the consumer. The third issue was strong caution regarding the introduction of rNRVs for pregnancy and lactation as this could encourage development of foods specifically for these life stages. It was noted that this might undermine public health messages to pregnant and breastfeeding women about the need for a diet from a wide variety of foods. As few foods are currently targeted specifically to pregnant and lactating women, rNRVs for these life stages were not considered to have many label applications at present.

4.4 Additional issues raised

A number of additional issues in relation to revising the rNRVs were identified including:

- The need for a common extensive transition time for changes to be made to minimise costs and reduce consumer confusion. Transition periods of 12 months to 4 years were suggested. It was also suggested that old or new NRVs on labels should be made clear to consumers in a uniform way during the transition period.
- That changes to rNRVs be harmonised with Codex standards wherever possible to reduce the regulatory burden on industry particularly importers and exporters. It was also suggested that a final determination of rNRVs may not be desirable until key international recommendations on rNRVs are available and until the proposed Australian National Health Survey 2011 is assessed.
- That a definition of an rNRV is considered and consultation on this was suggested.
- That any change to rNRVs and the ability to make nutrient claims should not disadvantage nutrient rich core foods so that they can communicate that they are a 'good source' of key nutrients in line with dietary guidance e.g. calcium in dairy products.

Some further comments were also provided for FSANZ's consideration for example, standardisation of serving sizes, alignment of values for fortification of dairy and dairy alternatives, review of the maximum claimable amounts in relation to the absolute permitted levels of vitamins and minerals (e.g. in some cases industry may not be able to claim the permitted amount as this may be higher than the maximum claimable amount), consideration of a rNRV for sugars (total or added), development of rNRVs for specific dietary requirements other than those based on age and gender and changes to Standard 2.9.1 - Infant Formula Products. It was noted that NRV changes to infant formula products should be considered during the review of Standard 2.9.1.

4.5 Potential impacts of a revision of the rNRVs

Identification of the potential impacts of changes to the rNRVs is an important outcome of the consultation. Some impacts were noted in relation to the specific issues as discussed above in this report. Further impacts identified include:

- Impacts on consumers

Many submitters considered that consumers would be confused by changes to nutrient labelling and nutrient claims as a result of changing the rNRVs. Related to this, it was noted that rNRVs can be used as tools for targeted public health and nutrition education activities.

Changes to vitamin and mineral claim requirements and label declarations are likely to cause confusion despite the fact that there is no formulation change e.g. consumers may believe the product has changed as opposed to the reference value changing. A comprehensive education strategy targeting both consumers and health professionals was recommended.

This was considered particularly challenging for products that are formulated and marketed as supplementary foods, such as Standard 2.9.3 – Formulated Supplementary Foods for Young Children, where nutrients are added for specific purposes e.g. if a company chooses not to reformulate so can no longer make a claim the company may need to provide information to the consumer to explain these changes.

Submitters also considered that most consumers would not understand the difference between an AI, SDT or UL; hence any change to the rNRV should include either an educational element or a disclosure below the NIP. The new labels must provide the most relevant information to an individual consumer in a form that is clear and unambiguous.

Another submitter considered the impact of changing rNRVs on labels would not necessarily translate into changes in consumer eating habits. It was suggested that rNRVs are used as a guideline to help inform rather than drive dietary choices.

- Impacts on the food industry

The costs to industry and the transition period were common themes in many of the submissions from the food industry.

The costs to industry would arise from:

- food reformulation costs to meet claims criteria if the rNRV increases
- designing and printing of new labels, including NIPs, front-of-pack labelling, and nutrition content claims
- changes to some consumer communication tools such as websites, brochures, information datasheets and advertisements
- communication campaigns to targeted consumers to minimise confusion with changing nutrition content claims or nutrient levels in products
- education programs for key internal (e.g. employees) and external stakeholders (e.g. retailers, health care professionals) to inform of the changes
- new food composition laboratory analysis
- providing substantiating evidence, application fees, post implementation monitoring compliance costs

- internal company administrative system changes, such as product specifications and internal database updating.

It was noted that a more accurate cost assessment cannot be determined until the type and values of NRV changes to be adopted are known. More detailed costing would be provided if FSANZ raises a proposal.

Industry submitters noted that it is vital that costs and product packaging and reformulations are minimised. It was considered important to consider the actual numerical changes that would result from the revision of the rNRVs and whether there is an overall net benefit i.e. a benefit to public health versus the cost to industry. Industry submitters requested that changes to the rNRVs are limited to those that are deemed absolutely necessary to maintain the accuracy and intent of the Code.

Also, many submitters emphasised the need to provide an adequate transition time to make the changes, and the importance of co-ordination with other likely labelling changes to reduce the impact. The recent completion of a major update to packaging due to the addition of folic acid and iodine under the mandatory fortification requirements was noted.

- Impacts on government and enforcement agencies of Australia and New Zealand

Several submitters expected government resources would be needed in a number of areas.

These include carrying out dietary modelling to ensure the upper level of nutrients is not exceeded for child population groups and the funding of awareness campaigns to educate consumers about changes. Monitoring, particularly of portion sizes with a change to the rNRV for sodium may also be needed.

In addition, it was noted that it is too early to determine all the likely impacts on stakeholders as FSANZ has not decided as yet whether or how to review the Code. Also, various other non-government organisations have an interest in particular nutrients targeted in this review and would have specific impacts to consider e.g. Osteoporosis Australia, World Action on Salt and Health (AWASH) and the National Heart Foundation of Australia (NHFA).

4.6 Overall Conclusion from consultation

Overall there was general support for a revision of the rNRVs to reflect the 2006 NRVs and contemporary science. However, there was a range of issues identified that submitters considered should be taken into account when considering any revision of the Code (see Section 2.3.2.).

Submitters also generally supported the underlying Principles that FSANZ put forward to guide a revision of the rNRVs in the Code noting that an additional Principle to reflect FSANZ's objective to protect public health was needed.

For many, although not all of the technical issues raised in the Consultation Paper the preferred approach was generally supported by most of those submitters who commented on a particular issue. However, various points were raised for FSANZ's consideration (Section 4.3). More divergent views were expressed for four particular issues i.e. the most appropriate NRV to use for sodium, dietary fibre, the selection of rNRVs and calculation methods for carbohydrates and fats, and the selection of new age and life stage categories.

In addition, the cost to industry, the benefits to public health, alignment with the timeframes and transition periods for other related work, the need for consumer education and research, and consistency with international approaches were all identified as matters that need to be considered in a revision of the rNRVs in the Code.

5. Next Steps

FSANZ is now considering the next steps for undertaking a revision of the rNRVs in the Code. Stakeholder views will help inform FSANZ's approach to any future action.

FSANZ is also aware of the impacts of other related matters, which may have implications for labelling changes, such as the Labelling Review. The Final Report, *Labelling Logic - Review of Food Labelling Law and Policy (2011)* was released by the Australian Government on 28 January 2011. The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) is responsible for developing a whole-of-government response to the recommendations of the Final Report.

The whole-of-government response to the recommendations in the Labelling Review is currently being developed and is expected to be released by the Ministerial Council by the end of 2011.

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ATTACHMENTS

Attachments to the Consultation Paper:

- 1 Definitions of 2006 Nutrient Reference Values
- 2 List of Abbreviations

DEFINITIONS OF 2006 NUTRIENT REFERENCE VALUES

- EAR*** ***Estimated Average Requirement***
 A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.
- RDI** **Recommended Dietary Intake**
 The average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97–98 per cent) healthy individuals in a particular life stage and gender group.
- AI**** ***Adequate Intake (used when an RDI cannot be determined)***
 The average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.
- EER** **Estimated Energy Requirement**
 The average dietary energy intake that is predicted to maintain energy balance in a healthy adult of defined age, gender, weight, height and level of physical activity, consistent with good health. In childhood, pregnancy and lactation the EER is taken to include the needs associated with the deposition of tissues or the secretion of milk at rates consistent with good health.
- UL**** ***Upper Level of Intake***
 The highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse affects increases.
- AMDR**** ***Acceptable Macronutrient Distribution Range***
 An estimate of the range intake for each macronutrient for individuals (expressed as per cent contribution to energy), which would allow for an adequate intake of all the other nutrients whilst maximising general health outcome.
- SDT**** ***Suggested Dietary Target***
 A daily average intake from food and beverages for certain nutrients that may help in prevention of chronic disease.
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* Reference value types in *italics* are new, i.e. they were not part of the 1991 RDIs

List of Abbreviations

<u>Abbreviation</u>	<u>Full Name</u>
ACCC	Australian Competition And Consumer Commission
AI	Adequate intake
ALA	Alpha-linolenic acid
AMDR	Acceptable macronutrient distribution range
BMI	Body mass index
EPA	Eicosapentanoic acid
DFE	Dietary folate equivalent
DHA	Docosahaexaenoic acid
DI	Daily intake
DoHA	Department of Health and Ageing
DPA	Decosapentanoic acid
DTI	Daily target intake
EAR	Estimated average requirement
EER	Estimated energy requirement
EPA	Eicosapentaenoic acid
ESADDI	Estimated safe and adequate daily dietary intake
LC n-3 PUFA	Long chain omega-3 polyunsaturated fatty acids
NE	Niacin equivalents
NHMRC	National Health and Research Council
NHS	National health survey
NIP	Nutrition information panel
NRVs	Nutrient reference values
NZ MoH	New Zealand Ministry of Health
PAL	Physical activity level
PUFA	Polyunsaturated fatty acid
RDI	Recommended dietary intake
rNRVs	Regulatory nutrient reference values
RS	Resistant starch
SDT	Suggested dietary target
SFA	Saturated fatty acid
UL	Upper level of intake
WHO	World health organization