



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-sixth Session

Bali, Indonesia
24 – 28 November 2014

PROPOSED DRAFT NUTRIENT REFERENCE VALUE FOR POTASSIUM IN RELATION TO THE RISK OF NON-COMMUNICABLE DISEASE AT STEP 4

(Prepared by the EWG led by the United States of America with the assistance of Chile)¹

Governments and interested international organizations are invited to submit comments at Step 3 on **Recommendations in paragraphs 50 and 64** in writing by email to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, e-mail codex@fao.org with copy to the German Secretariat of the CCNFSDU, Federal Ministry of Food, Agriculture and Consumer Protection, e-mail: ccnfsdu@bmelv.bund.de by **31 October 2014**.

1. BACKGROUND

Main Aspects, Importance, and Timeline for this Work

1. In July 2014, the Codex Alimentarius Commission approved new work for CCNFSDU to:

Recommend a proposed draft Nutrient Reference Value (NRV) in relation to non-communicable disease (NCD) for potassium and consequent amendments to the listing of an NRV-NCD in Section 3.4.4.2 of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985).
2. This work is deemed an important contribution to implementing the WHO Global Strategy on Diet, Physical Activity and Health (WHA Resolution 57.17) in addressing the global burden of diet-related NCDs. It responds to a 2006 WHO and FAO draft action plan for implementing this Global Strategy that proposed that the CCNFSDU and the Codex Committee on Food Labelling (CCFL) consider the development of NRVs for nutrients that are associated with risk of NCDs (CL 2006/44-CAC).
3. As part of WHO's work to review the scientific evidence of sodium in relation to NCD risk, CCNFSDU asked WHO at its 2010 32nd Session to consider the establishment of daily potassium intake values for the general population on the basis of dietary adequacy and/or reduction of NCD risk (REP11/NFSDU paragraph 49, Appendix III). In 2012, the WHO issued guidelines that recommended that potassium intake from food be increased and sodium intake decreased to reduce blood pressure and risk of cardiovascular disease (CVD), stroke and coronary heart disease (CHD) in adults (http://www.who.int/nutrition/publications/guidelines/potassium_intake/en/ http://www.who.int/nutrition/publications/guidelines/sodium_intake/en/).
4. The establishment of an NRV-NCD for potassium will complement the sodium NRV-NCD (Section 3.4.4.2 of the *Guidelines on Nutrition Labelling*) in providing an additional means for Codex member governments to reduce the global burden of diet-related NCDs.
5. The project document approved by the Commission identified 2015 as the target year for the Commission's adoption of the NRV-NCD for potassium.

¹ Members of the EWG include Argentina, Australia, Brazil, Canada, Costa Rica, Ecuador, India, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Norway, Thailand, Tunisia, Uruguay, FoodDrinkEurope, International Dairy Federation, International Frozen Food Association, and International Council of Grocery Manufacturers Associations, and International Special Dietary Foods Industry

Conduct of the Electronic Working Group

6. At its last session, CCNFSDU agreed to establish an electronic working group (eWG), chaired by the United States of America and co-chaired by Chile and working in English and Spanish.

7. In February 2014, an invitation to participate in this eWG was extended to Codex member countries (CMCs) and observers (COs). In May, the Chair/Co-chair circulated a consultation paper to the eWG members. Seventeen CMCs and 5 COs responded to the consultation. All (22) participating eWG members are acknowledged above.

8. The United States of America and Chile would like to express their sincere gratitude to the eWG participants who submitted comments. These comments were considered in preparing this report and raised important issues for discussion by the Committee.

2. PROPOSED NRV-NCD FOR POTASSIUM

Application of the General Principles (GP) for Establishing NRVs for the General Population

3.1. Selection of Suitable Data Sources to Establish NRVs

GP 3.1.1

GP 3.1.1 states that *“Relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be taken into consideration as primary sources in establishing NRVs.”*

9. The eWG was asked whether there was joint FAO/WHO scientific advice on potassium in relation to NCDs in addition to that provided in the 2003 joint WHO/FAO expert consultation on *Diet, Nutrition and the Prevention of Chronic Diseases* which concluded that there is convincing evidence that adequate dietary intake of potassium decreases risk of CVD (WHO, 2003, pp. 81,88).²

10. No other joint FAO/WHO scientific advice on potassium in relation to NCDs was identified by the eWG. It was noted by two CMCs that “FAO/WHO” should not be considered to mean “joint” or “and” but rather as “and/or” in GPs 3.1.1, 3.1.2, 3.2.2.3 and 3.3. Such interpretation enables consideration of the most recent FAO and WHO reports issued separately or jointly and thereby excludes the two international organizations from “RASBs other than FAO/WHO” in GP 3.1.2.

GP 3.1.2

11. GP 3.1.2 states that *“Relevant daily intake reference values that reflect recent independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review.”*

12. For the purposes of establishing an NRV-NCD, the working definition for a Recognized Authoritative Scientific Body (RASB) other than FAO and/or WHO is an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent*, authoritative and scientific advice on daily intake reference values through primary evaluation of the scientific evidence upon request and for which such advice is recognised through its use in the development of policies in one or more countries. (REP14/NFSDU, para 31).

* In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.

13. The eWG was asked whether there were RASBs, in addition to those listed in **Attachment 1**, that meet all of the components of the RASB definition and have conducted a primary evaluation of the science on the relationship between potassium intake and NCD risk.

14. Two CMCs identified the 2012 Nordic Nutrition Recommendation (NNR) to meet the RASB definition. One CMC identified the National Institute of Health and Nutrition (NIHN) of Japan as meeting the criteria for an RASB. Information about these two organizations is provided in **Attachment 2**.

GP 3.2.2 Selection of Nutrients and Appropriate Basis for NRVs-NCD

GP 3.2.2.1

15. GP 3.2.2.1 states that the following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD:

² <http://www.who.int/dietphysicalactivity/publications/trs916/download/en/>

⁹ Relevant convincing /generally accepted¹⁰ scientific evidence or the comparable level of evidence under the GRADE classification¹¹ for the relationship between a nutrient and non-communicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g., adults).

Public health importance of the nutrient non-communicable disease risk relationship(s) among Codex member countries.

⁹ At the time these guiding principles were drafted, the definition and criteria for “convincing evidence” from the following FAO/WHO report were used. *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 96. WHO, 2003.

¹⁰ For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

¹¹ WHO’s Guidelines Review Committee. *WHO Handbook for Guideline Development*. Geneva. World Health Organization (WHO). 2012 (http://apps.who.int/irs/bitstream/10665/75146/1/9789241548441_eng.pdf)

16. The eWG was asked if the first criterion in GP 3.2.2.1 was met for potassium, and if not, to provide a rationale.

17. Most (20) of the eWG members agreed that the first criterion in GP 3.2.2.1 had been met for potassium for the following reasons:

- The 2012 WHO *Guideline: Potassium Intake for Adults and Children*³ deemed the relationship between potassium and blood pressure to be of *high quality* (while there was no effect on total cholesterol, plasma noradrenaline and serum creatinine) (pages 11 and 20). (**Attachment 3**)
- The 2012 WHO potassium guideline was viewed to be the most systematic and up-to-date review of the literature.
- The 2012 Nordic Nutrition Recommendation (**Attachment 2**) and RASBs identified in the eWG consultation (**Attachment 1**) are supportive of the 2012 WHO potassium guideline.
- Blood pressure is a reliable biomarker for estimating CVD risk.
- An updated meta-analysis has been published (D’Elia et al., 2014) since the 2012 WHO potassium guideline, reaffirming the favorable effect of higher potassium intake on risk of stroke.
- A *convincing* level of evidence was demonstrated in the 2003 joint WHO/FAO expert consultation on *Diet, Nutrition, and Prevention of Chronic Diseases*.⁴

18. Two CMCs disagreed with or questioned whether the first criterion of 3.2.2.1 had been met. It was noted that only three studies (n=757) were conducted in normotensives for which increased potassium intake resulted in a non-significant increase (95% confidence interval (CI): - 0.95;0.77) in systolic blood pressure (2012 WHO potassium guideline, page 15).⁵ The WHO systematic review only supported a relationship of increased potassium intake and reduced blood pressure in hypertensive adults. While not defined, one CMC interprets “major segment” to mean a group described by age range or sex and not by the presence of a health condition. It was also noted that the GRADE classification in the 2012 WHO potassium guideline (page 20) had not been met because it did not take into account sample size or the heterogeneity in the countries (e.g., meta-analysis of 21 studies only represented 1,892 subjects). With respect to heterogeneity, it was questioned whether the studies used in the meta-analysis included tropical countries or countries where the etiology may be different from western countries.

19. To address the second criterion for GP 3.2.2.1, the eWG was asked if they agree that potassium is of sufficient health importance to warrant the establishment of an NRV-NCD.

20. Most (21) of the eWG members agreed that there was sufficient health importance to warrant the establishment of an NRV-NCD for potassium for the following reasons:

- The 2012 WHO potassium guideline issued a *strong* recommendation to increase potassium intake from food to reduce blood pressure and risk of CVD, stroke and CHD in adults (page 2).

³ http://www.who.int/nutrition/publications/guidelines/potassium_intake/en/

⁴ <http://www.who.int/dietphysicalactivity/publications/trs916/download/en/>

⁵ “In the three studies conducted exclusively in individuals with normal blood pressure, increased potassium intake resulted in a non-significant increase in systolic blood pressure of 0.09 mmHg (95%CI:-0.09,0.77) (quality of evidence moderate).”

- The 2012 WHO potassium guideline (page 5) states that the burden or morbidity and mortality from hypertension and related NCDs is currently one of the most urgent public health problems globally.
- The 2012 WHO potassium guideline (page 5) states that suboptimal systolic blood pressure is estimated to contribute to 49% of all coronary heart disease and 62% of all strokes.
- There are relatively low intake levels of potassium in many populations.

21. One CMC disagreed that there was sufficient health importance because the evidence from the 2012 WHO potassium guideline (page 15) only pointed towards its benefit in hypertensive people.

22. The below issues, including interpretation of the GRADE system, were raised for discussion by the committee:

- The ability of significant findings for only hypertensive people to meet the first element for 3.2.2.1 “..... for at least one major segment of the population (e.g., adults).”
- GP 3.2.2.1 provides no guidance as to what a comparable level of evidence of the GRADE system (e.g., quality) is to the 2003 WHO/FAO joint consultation (i.e., *convincing* evidence⁶). Thus further discussion among the committee is needed on interpretation of GP 3.2.2.1 in determining equivalency under the new WHO GRADE classification system⁷:

23. The current wording of GP 3.2.2.1 relates only to the level of evidence which could be interpreted as relevant only to the first component of the GRADE process (i.e., quality of the evidence). Does interpretation of the GRADE system relate solely to quality of the evidence or also the strength of the recommendation?

24. Does comparable level of evidence relate solely to the evidence of a nutrient-NCD relationship? and/or

25. Does comparable level of evidence relate to the level of evidence to establish an NRV-NCD?

26. **Attachment 3** summarizes the WHO GRADE reviews and strength of the recommendations for sodium and potassium for adults.

27. One CMC noted that an RASB should provide advice on a DIRV through “*primary evaluation of the scientific evidence upon request and for which such advice is recognised through its use in the development of policies in one or more countries.*” Based on this information, the CMC supported discussion on whether the strength of the evidence criterion in GP 3.2.2.1 can be met by RASB opinions on the validity of health claims in addition to DIRVs.

GP 3.2.2.2

28. General Principle 3.2.2.2 states that “*Relevant and peer-reviewed scientific evidence for quantitative values for daily intake should be available in order to determine an NRV-NCD that is applicable to the general population.*”

29. The eWG was asked if they agreed that there is relevant peer-reviewed scientific evidence for DIRVs for potassium available from WHO and nominated RASBs that is applicable to establishing a potassium NRV-NCD for the general population.

30. Most (20) eWG members agreed that scientific evidence from the WHO and RASBs is available for setting a quantitative values for daily intake. One CMC noted that while a *conditional* recommendation was set for adults, the quality of the evidence for potassium intakes of at least 3510 mg/day and systolic blood pressure was *high* (2012 WHO potassium guideline, pages, 17, 21).⁸ In comparison, the 2012 WHO Guidelines for sodium rated the evidence for the relationship between sodium and blood pressure as *high* quality, as well as for the < 2g/day value. The relationship between sodium and CVD endpoints (e.g. CVD, stroke, CHD) was rated *very low to moderate quality*. The WHO issued a *strong* recommendation to reduce sodium in order to reduce CVD endpoints and a *strong* recommendation to reduce sodium to < 2g/day. This was adopted by CCNFSDU. (See **Attachment 3** for details on the sodium and potassium quality ratings and strength of recommendation).

⁶ Evidence based on epidemiological studies showing consistent associations between exposure and disease, with little or no evidence to the contrary. The available evidence is based on a substantial number of studies including prospective observational studies and where relevant, randomized controlled trials of sufficient size, duration and quality showing consistent effects. The association should be biologically plausible.

⁷ http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf

⁸ “The recommended level of intake of ≥ 90 mmol/day is a *conditional* recommendation for adults because there is limited evidence regarding the precise level that will result in maximum health benefits. The recommendation is informed by moderate [children] and *high* [adults] quality evidence that consuming potassium at ≥90 mmol/day will provide a health benefit.”

31. One CMC noted that GP 3.1.3 refers to NRV-NCDs that reflect intake recommendations for the general population, and questioned whether the evidence for potassium on reduction of blood pressure that was supported only in people with hypertension (40% of the population)⁹ is sufficient qualification to establish a potassium NRV-NCD as a labelling value for the general population. It was noted, however, that the 2012 WHO potassium guideline (page 16) directed its *strong* recommendation to adults, with or without hypertension, and concluded that increasing potassium intake would likely broadly benefit the general population by noting the high global prevalence of hypertension, the relatively low potassium intakes in most populations and the clear benefit of increased potassium intake for hypertensive individuals. The definition for an NRV-NCD is silent on whether the risk reduction should be demonstrated in healthy populations as well. Setting an NRV-R for potassium was suggested to be considered instead.

32. One CMC disagreed that scientific evidence is available because DIRVs from tropical countries are not available where the etiologies may be very different.

GP 3.2.2.3

33. GP 3.2.2.3 states that “*Daily intake reference values from FAO/WHO or other recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake.*”

34. The eWG was asked whether the NRV-NCD should be expressed in mg, mmol or both in the *Guidelines on Nutrition Labelling* (Section 3.4.4.2).

35. All (22) eWG members supported expressing the NRV-NCD in mg. Several CMCs noted that the NRV-NCD could be expressed in both mg and mmol.

GPs 3.2.2.4 and 3.2.2.5

36. GP 3.2.2.4 states that “*For practical application in nutrition labelling, a single NRV-NCD for the general population should be established for each nutrient that meets the principles and criteria in this Annex.*”

37. GP 3.2.2.5 states that “*An NRV-NCD for the general population should be determined from the daily intake reference value for the general population or adults, or if given by sex, the mean of adult males and adult females.*”

38. The eWG was asked whether the NRV-NCD for potassium should be based only on an adult DIRV or also consider children, and if so how should it be considered with the adult DIRV.

39. Most (18) eWG members supported DIRVs based on adult values for the following reasons:

- Consistent with GP 3.2.1.2, 3.2.2.4 and 3.2.2.5
- Consistent with how sodium and saturated fat NRV-NCDs were established which have been based on the widest applicable age range for adult males and females.
- Increased potassium intake reduced systolic blood pressure by a small, nonsignificant amount and 2012 WHO potassium guideline issued a *conditional* recommendation that potassium intake from food to be increased to control blood pressure in children. The 2012 WHO potassium guideline recommendation for potassium intake is at least 90 mmol/day (3510 mg/day) for adults.
- CCNFSDU will work on values for children in the near future.

40. A few CMCs suggested that consideration should be given to children and adolescents on the basis of the AIs established by the IOM. One CO noted that the WHO *conditional* recommendation for adults (≥ 16 years) should be adjusted downward for children (2-15 years) and that it should be verified whether the adult DIRV is appropriate for children by using such adjustment.

GP 3.3 Consideration of Daily Intake Reference Values for Upper Levels

GP 3.3

41. General Principle 3.3 states that “*The establishment of general population NRVs should also take into account daily intake reference values for upper levels established by FAO/WHO or other recognized authoritative scientific bodies where applicable (e.g., Upper Level of Intake, Acceptable Macronutrient Distribution Range).*”

⁹ In 2010, WHO reported the overall prevalence of raised blood pressure in adults aged 25 and over, to be around 40% (35-46% in regions). WHO (2010) Global Health Observatory. Raise blood pressure, Situation and trends. http://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/

42. The eWG was asked if they agreed that the risk of adverse effects from potential increases in potassium intake in the general population is very low.

43. Most (21) eWG members agreed or did not object to the view that the risk of adverse effects from potential increases in potassium intake in the general population is very low based on information provided by the WHO, IOM and EFSA and the lack of ULs set by the IOM and EFSA. Some of these eWG members, however, noted 1) that formulated products should take into account the potassium/sodium ratio, 2) the need to continue monitoring new evidence so that a UL can be set if needed, and 3) the potential risk of adverse effects with potassium in supplement form, increased risk individuals with severe or moderate renal failure, CHD, hemodialysis, diabetes, and drugs affecting potassium balance.

44. One CMC disagreed that the risk of adverse effects are very low because the results of the meta-analysis on potassium intake and systolic blood pressure in individuals with normal blood pressure resulted in a wide 95% CI (-0.95,0.77) (2012 WHO potassium guideline, page 15).

Proposed NRV-NCD for Potassium

45. The eWG was asked if they agree with a proposed NRV-NCD of 3 500 mg for potassium based on the 2012 WHO guideline for potassium.

46. Most (21) of eWG members supported or did not object to an NRV-NCD of 3 500 mg (90 mmol) for potassium for the following reasons:

- Based on the most current evidence using a systematic review
- Based on *high* quality evidence
- Supported by nominated RASBs

47. It was noted by two COs who supported the NRV-NCD of 3 500 mg, that it should be considered to wait on the EFSA opinion for confirmation.

48. One CMC agreed with 3 500 mg in principle but noted that the NRV-NCD should be considered carefully based on ethnic and body weight of population groups in various parts of the world. This CMC also suggested consideration of the Japanese DIRV of 3 000 mg which was established for prevention of hypertension.

49. One CMC did not offer a view on the proposed NRV-NCD of 3500 mg because the WHO recommendation of at least 3510 mg/day is *conditional*. It was suggested that if the committee wishes to proceed with an NRV-NCD, then a footnote cautioning its use in the Codex Nutrition Labelling Guidelines could be included until more definitive data are available.

50. **Recommendation**

Based on the comments received from the eWG consultation, it is recommended that CCFSDU adopt 3500 mg as the NRV-NCD for potassium

3. PROPOSED AMENDMENTS TO THE GUIDELINES ON NUTRITION LABELLING (CAC/GL2-1985) TO INCLUDE A POTASSIUM NRV-NCD

Listing of NRVs-NCD

51. The *Guidelines on Nutrition Labelling* currently provide NRVs-NCD for saturated fatty acids and sodium. These NRVs-NCD are intake levels not to exceed. An NRV-NCD for potassium, however, would be an intake level to achieve.

52. The eWG was provided two options to consider. Under Option 1, the listing of the proposed NRV-NCD for **potassium** would simply be listed after the NRV-NCD for sodium, as shown below.

Option 1

3.4.4.2 NRVs-NCD

Saturated fatty acids	20 g ^{2,3}
Sodium	2000 mg ³
Potassium	3500 mg (proposed)

² This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories.

³ The selection of these nutrients for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003. The updated WHO guideline on sodium intake for adults and children (WHO 2012) further supports the selection of sodium.

53. As an alternative, the differences in the meaning of the NRVs-NCD for saturated fatty acids and sodium *versus* potassium could be clarified by inserting subheadings as indicated below (Option 2).

Option 2

3.4.4.2 NRVs-NCD

Intake levels not to exceed

Saturated fatty acids	20 g ^{2,3}
Sodium	2000 mg ³

Intake levels to achieve

Potassium	3500 mg (proposed)
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² This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories

³ The selection of these nutrients for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003. The updated WHO guideline on sodium intake for adults and children (WHO 2012) further supports the selection of sodium.

54. **The** eWG was asked which option they preferred and to recommend an alternative format, if needed.

55. Most (17) eWG members were supportive of Option 2 because this format would help reduce confusion about whether recommendations are minimal or maximal levels and would constitute guidance to governments. Two COs in support of Option 2 also proposed the following format:

Saturated fatty acids ≤ 20 g

Potassium ≥ 3500 mg

Sodium ≤ 2000 mg

56. **One** CMC supported a format that is able to differentiate between positive and negative nutrients; however, it was recommended to defer this issue to CCFL to consider how best these different concepts can be communicated.

57. **Two** CMCs were not in support option 2, but rather option 1, because such differentiation as provided in option 2 is not conveyed on the food label and is more complex.

Provision of a Footnote to the NRV-NCD for Potassium

58. As shown in the above options, footnotes are provided for saturated fatty acids and sodium. While footnote 2 does not apply to potassium, footnote 3 provides the source for the strength of the evidence and the DIRV for saturated fatty acids and sodium. To be consistent with footnote 3, the eWG was asked whether they supported the proposed footnote below:

Potassium 3500 mg (proposed)³

³The selection of sodium and potassium for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003. The updated 2012 WHO guidelines on sodium and potassium intake for adults and children further support the selection of sodium and potassium.

59. **While** most of the eWG members agreed or did not object to the proposed footnote, several eWG members suggested edits or alternative footnotes (below). One CMC raised the need to discuss whether the older 2003 WHO *Diet, Nutrition and the Prevention of Chronic Diseases* report is still needed.

60. One CMC did not support the footnote because there is no *convincing* evidence for potassium.

61. Suggestion 1 – Reflects the current reference to saturated fatty acids:

³The selection of ~~sodium and potassium~~ **these nutrients** for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003. The updated 2012 WHO guidelines on sodium and potassium intake for adults and children further support the selection of sodium and potassium.

62. Suggestion 2 – Reflects the use of the more recent and updated WHO guidelines for sodium and potassium, including **the** grading of the quality. This would require a new footnote (4) because footnote 3 currently includes saturated fatty acids. Also one CMC suggested that “defined” be replaced with “reported” to indicate that the footnote relates to the evidence cited for the relationship, as well as the definition of the strength of the evidence.

Saturated fatty acids only:

³The selection of **this nutrient** ~~sodium and potassium~~ for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as **reported** defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003. ~~The updated 2012 WHO guidelines on sodium and potassium intake for adults and children further support the selection of sodium and potassium.~~

Sodium and potassium:

⁴³The selection of ~~sodium and potassium~~ **these nutrients** for the establishment of an NRV was based on “**high quality**” ~~convincing evidence~~ for a relationship with NCD risk **as reported** ~~as defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003. The updated in the 2012 WHO guidelines on sodium and potassium intake for adults and children further support the selection of sodium and potassium.~~

63. Suggestion 3 – One **CMC** suggested a footnote that indicates that the NRV-NCD should be applied with caution as it is based on a *conditional* recommendation for adults in the 2012 WHO potassium guideline.

Potassium only:

⁵**This NRV should be applied with caution as it is based on a conditional recommendation for adults in the 2012 WHO guideline on potassium intake.**

Recommendation

64. Based on **the** comments received from the eWG consultation, it is recommended that CCNFSDU adopt the proposed amendments to the Guidelines on Nutrition Labelling (CAC/GL2-1985) to include a potassium NRV-NCD:

Tracked changes

3.4.4. 2 NRVs-NCD

Intake levels not to exceed

Saturated fatty acids 20 g^{2,3}

Sodium 2000 mg³⁴

Intake levels to achieve

Potassium 3500 mg^{4,5}

² This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories

³ The selection of ~~thisese~~ **these nutrients** for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as ~~defined~~ **reported** in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003. ~~The updated WHO guideline on sodium intake for adults and children (WHO 2012) further supports the selection of sodium.~~

⁴ **The selection of these nutrients for the establishment of an NRV was based on “high quality” evidence for a relationship with NCD risk as reported in the 2012 WHO guidelines on sodium and potassium intake for adults and children.**

⁵**This NRV should be applied with caution as it is based on a conditional recommendation for adults in the 2012 WHO guideline on potassium intake for adults and children.**

Clean

3.4.4.2

NRVs-NCD

Intake levels not to exceedSaturated fatty acids 20 g^{2,3}Sodium 2000 mg⁴Intake levels to achievePotassium 3500 mg^{4,5}

² This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories

³ The selection of this nutrient for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as reported in the report Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 916. WHO, 2003.

⁴ The selection of these nutrients for the establishment of an NRV was based on “high quality” evidence for a relationship with NCD risk as reported in the 2012 WHO guidelines on sodium and potassium intake for adults and children.

⁵ This NRV should be applied with caution as it is based on a conditional recommendation for adults in the 2012 WHO guideline on potassium intake for adults and children.

4. ADDITIONAL ISSUES FOR THE COMMITTEE’S CONSIDERATION

65. It was noted by a few COs that there was no discussion in the eWG consultation about a sodium/potassium ratio. The COs recognized that there is currently not sufficient evidence to establish a recommendation for the ratio, **however**, it was suggested to briefly address the ratio as the WHO did in its 2012 potassium guidelines. One CMC commented that the intake of potassium should be such that the sodium/potassium ratio remains at around 1.0 (2003 WHO/FAO, page 90).

5. ATTACHMENTS

Attachment 1 provides a listed of nominated RASBs and DIRVs on potassium

Attachment 2 provides a table of potential RASBs nominated by the eWG

Attachment 3 provides information on the 2012 WHO Guideline recommendations and GRADE reviews for sodium and potassium for comparison

6. ADDITIONAL REFERENCES USED AND CITED BY THE eWG

Appraisal of Guidelines for Research and Evaluation (AGREE) . <http://www.agreetrust.org/>

WHO (2013). A global brief on hypertension: silent killer, global public health crisis. http://www.who.int/cardiovascular_diseases/publications/global_brief_hypertension/en/

WHO Potassium Meta-Analyses

D’Elia, Iannotta C, Sabino O, Ippolito R. Potassium-rich diet and risk of stroke. Updated meta-analysis. Nutrition, Metabolism and Cardiovascular Diseases. 2014;24:585-587. <http://dx.doi.org/10.1016/j.numecd.2014.03.001>

D’Elia L, Barba G, Cappuccio FP, Strazzullo P. Potassium intake, stroke, and cardiovascular disease: A meta-analysis of prospective studies. J Am Coll Cardiol. 2011;57(10):1210-1219. Accessed 30 May 2014.

Aburto NJ, Hanson S, Gutierrez H, et al. Effect of increased potassium intake on cardiovascular risk factors and disease: Systematic review and meta-analyses. BMJ (Online). 2013;346(7903). Accessed 30 May 2014.

Country Intake Recommendations for Potassium

Héctor Bourges R.-Esther Casanueva-Jorge L. Rosado. Recomendaciones de Ingestión de Nutrientes para la Población Mexicana. Tomo I. Editorial Médica Panamericana, 2005.

Inadequate Intakes of Potassium in Countries

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Attachment 1

Potassium DIRVs provided by WHO and nominated RASBs

RASB	RASB Description and Process Evidence Informed Recommendations	Potassium DIRVs for adults
World Health Organization (WHO)/Nutrition Guidance Expert Advisory Group (NUGAG)	http://www.who.int/nutrition/publications/micronutrients/guidelines/en/ http://www.who.int/elena/about/guidelines_process/en/	At least 90 mmol/day (3510 mg/day) for adults
(Canada/United States) Institute of Medicine of the National Academy of sciences (IOM)	www.iom.edu/About-IOM.aspx www.iom.edu/About-IOM/Study-Process.aspx	Adequate Intake based on reduced risk of blood pressure, salt sensitivity and kidney stones 4700 mg/day (females and males)
European Food Safety Authority (EFSA)	www.efsa.europa.eu/en/aboutefsa.htm http://www.efsa.europa.eu/en/aboutefsa/efsahow.htm	
(Australia/New Zealand) National Health and Medical Research Council (NHMRC)	www.nhmrc.gov.au/about/organisation-overview/nhmrcs-role	Adequate Intake based on highest median intake for various age categories of adult males and females 2800 mg/day (females) 3800 mg/day (males)

Attachment 2

Potential RASBs nominated by eWG

Nominated RASB	National Institute of Health and Nutrition - Japan	Nordic Council of Ministers
1) Supported by one or more government(s) or competent national or regional authorities.	Thailand	Norway, Denmark, Finland, Iceland, and Sweden
2) Provides independent and transparent authoritative scientific advice on DIRVs through primary evaluation of the scientific evidence upon request.	Uenishi K, Ishimi Y, Nakamura K, Kodama H, Esashi T. Dietary Reference Intakes for Japanese. 2010: macrominerals. J Nutr Sci 2013; 59: S83-S90. (see the attached document or view at https://www.jstage.jst.go.jp/article/jnsv/59/Supplement/59_S83/pdf)	The 5th edition of the Nordic Nutrition Recommendations, NNR 2012, has been produced by a working group nominated by the Working Group on Food, Diet and Toxicology (NKMT) under the auspices of the Nordic Committee of Senior Officials for Food Issues (ÄK-FJLS Livsmedel). Systematic reviews (SR) were conducted by the experts, with assistance from librarians, for the nutrients and topics for which new data of specific importance for setting the recommendations has been made available since the 4th edition. The SRs are published in the Food & Nutrition Research journal and the other background papers can be found on the Nordic Council of Ministers (NCM) website http://www.norden.org/en/theme/nordic-nutrition-recommendation/what-is-the-nnr Guidelines developed for carrying out a systematic literature review: http://www.norden.org/en/publications/publikationer/2014-914 Public consultation process for NNR 2012: http://www.slv.se/en-gb/Startpage-NNR/
3) Is one whose advice on DIRVs is recognized through use in policy development in one or more countries?	The document of the nominated organization has been considered and used by the authority of Japan.	Dietary recommendations given by the authorities in Norway, Denmark, Finland, Iceland, and Sweden are based on the Nordic Nutrition Recommendations
RASB publication(s)	Dietary Reference Intakes for Japanese. 2010: macrominerals. J Nutr Sci 2013; 59: S83-S90 (see the attached document or view at http://www0.nih.go.jp/eiken/english/research/project_driv.html)	Nordic Nutrition Recommendations 2012 published by the Nordic Council of Ministers http://www.norden.org/en/publications/publikationer/2014-002
Basis for potassium DIRV	Maintain <i>in vivo</i> potassium balance AI – 2500 mg/day Prevention of hypertension UL-2700-3000 mg/day	Primarily blood pressure Recommended Intake (RI) 3500 mg/day (men) 3100 mg/day (women)

Attachment 3

2012 WHO Guidelines for adults (≥ 16 years of age)

	Quality of evidence (GRADE) for relationship with blood pressure (BP)	Quality of the evidence for the DIRV based on BP	Quality of evidence for CVD, CHD, stroke	Strength of the recommendation* for the relationship (BP, and risk of CVD, stroke and CHD)	Strength of the recommendation for a DIRV (BP and risk of CVD, stroke and CHD)
Sodium ¹	High (overall) High (hypertensive) Moderate (normal BP)	High < 2000 mg	Very low to moderate	Strong**	Strong 2000 mg
Potassium ²	High (overall) High (hypertensive) Moderate (normal BP)	Moderate ≥ 3510 mg	Very low to low	Strong	Conditional *** 3510 mg****

¹http://www.who.int/nutrition/publications/guidelines/sodium_intake/en/

²http://www.who.int/nutrition/publications/guidelines/potassium_intake/en/

*Strength of the recommendation considers quality of evidence, balance of benefits versus harms and burdens, values and preferences and resource use.

** Strong recommendations communicate the message that the desirable effects of adherence to the recommendation outweigh the undesirable effects. This means that in most situations the recommendation can be adopted as policy.

***Conditional recommendation is made when there is greater uncertainty about the four factors above or if local adaptation has to account for a greater variety in values and preferences, or when resource use makes the intervention suitable for some, but not for other locations. This means that there is a need for substantial debate and involvement of stakeholders before this recommendation can be adopted as policy.

****Conditional recommendation because there is limited evidence regarding the precise level that will result in **maximum** health benefits. The recommendation is informed by moderate and high quality evidence that consuming potassium at ≥ 90 mmol/day will provide a health benefit. However, the recommendation recognizes that the value may change if there are additional high-quality trials that determine the precise level of potassium intake that achieves the **most** favourable reduction in blood pressure and risk of cardiovascular disease, stroke, and coronary heart disease, without negative effect on other health outcomes such as blood lipids and catecholamine levels.