# CODEX ALIMENTARIUS COMMISSION







Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item No 7

CX/NFSDU 14/36/8-Add.1

# 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 NRV FOR POTASSIUM IN RELATION TO THE RISK OF NCD

Comments of Brazil, Canada, El Salvador, Ghana, Mexico, Philippines, African Union, FoodDrinkEurope and ICBA

#### **BRAZIL**

#### **SPECIFIC COMMENTS**

#### 50. Recommendation

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

# Clean

3.4.4.2 NRVs-NCD

Intake levels not to exceed
Saturated fatty acids 20 g<sup>2,3</sup>
Sodium 2000 mg<sup>4</sup>
Intake levels to achieve
Potassium 3500 mg<sup>4,5</sup>

# Response:

Brazil considers that the NRV-NCD of 3500 mg could be adopted for potassium considering that the 2012 WHO potassium guideline recommends an increase in potassium intake from food for reduction of blood pressure and risk of cardiovascular disease, stroke and coronary heart disease in adults (strong recommendation). WHO suggests a potassium intake of at least 90 mmol/day (3510 mg/day) for adults.

However, since this value is based on a "conditional recommendation", we think that the Committee may wish to consider the suggestion made by on CMC to set an NRV-R for potassium.

With regard to the footnote 5, we consider that it could be misinterpreted and difficult to apply in some countries.

#### **CANADA**

#### **General Comments**

Canada would like to thank the U.S. chair and Chilean co-chair for preparing this report. Canada does not object to CCNFSDU adopting 3500 mg as the NRV-NCD for potassium. We would also like to offer the following specific comments.

<sup>&</sup>lt;sup>2</sup> This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories

<sup>&</sup>lt;sup>3</sup> 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.

<sup>&</sup>lt;sup>4</sup> 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.

<sup>&</sup>lt;sup>5</sup>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.

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#### **Specific Comments**

With regard to the criteria of General Principle (GP) 3.2.2.1, Canada would like to reiterate that diagnosed and undiagnosed hypertensive individuals represent a major segment of the population, thus Canada believes that the first criterion for this GP is met for potassium.

Canada continues to support the establishment of a potassium NRV-NCD for the general population because of the reasons stated in the 2012 WHO guideline, such as the burden of morbidity and mortality from hypertension and related NCDs, suboptimal systolic blood pressure levels observed in most populations around the word and low intake levels of potassium in most populations.

With regard to the proposed amendments to the guidelines on nutrition labelling (CAC/GL2-1985) to include a potassium NRV-NCD, Canada supports the listing of NRVs-NCD for potassium as recommended in the draft report. With regard to the footnotes, Canada proposes the following edits for consideration:

- On page 12 of the draft report, replace the word "reported" with "described".
- Delete the wording "should be applied with caution" in footnote 5, because this wording may create confusion as to the application of the NRV-NCD for potassium in nutrition labelling by Codex member countries.

Suggested changes are shown below:

- <sup>2</sup> This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories
- <sup>3</sup> The selection of this nutrient for the establishment of an NRV was based on "convincing evidence" for a relationship with NCD risk as reported **described** in the report *Diet, Nutrition and the Prevention of Chronic Diseases.* WHO Technical Report Series 916. WHO, 2003.
- <sup>4</sup> 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 **described** in the 2012 WHO guidelines on sodium and potassium intake for adults and children.
- <sup>5</sup>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.

Suggested clean version:

- <sup>2</sup> This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories
- <sup>3</sup> The selection of this nutrient for the establishment of an NRV was based on "convincing evidence" for a relationship with NCD risk as described in the report *Diet, Nutrition and the Prevention of Chronic Diseases.* WHO Technical Report Series 916. WHO, 2003.
- <sup>4</sup> The selection of these nutrients for the establishment of an NRV was based on "high quality" evidence for a relationship with NCD risk as described in the 2012 WHO guidelines on sodium and potassium intake for adults and children.
- <sup>5</sup>This NRV is based on a conditional recommendation for adults in the 2012 WHO guideline on potassium intake for adults and children.

# **EL SALVADOR**

El Salvador supports the following proposed amendments to the Guidelines on Nutrition Labelling (CAC/GL 2-1985):

- 1. The recommendation to adopt 3500 mg as the NRV-NCD for potassium, as the daily intake.
- 2. Clarification of the various significances of the NRV-NCD for fatty acids and sodium and the NRV-NCD for potassium, by introducing subtitles (option 2) such as: "Intake levels that must not be exceeded" and "Intake levels that must be achieved", as the case may be, because this contributes towards reducing confusion in the recommendation when dealing with the maximum or minimum level at the same time as it may serve as governmental guidance. Nevertheless, CCNFSDU is asked to explain how this distinction will be communicated to consumers on the label.
- 3. Use of footnotes as follows:
  - <sup>2</sup> This value is based on the **daily** reference energy intake of 8370 kilojoules or 2000 kilocalories.
  - <sup>3</sup> The choice of this nutrient for the establishment of an NRV was based on "convincing evidence" that there is a relationship with the risk of NCD, as detailed in the report entitled Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series (TRS) 916. WHO, 2003.
  - <sup>4</sup> The choice of these nutrients for the establishment of an NRV was based on evidence "of a high quality" that there is a relationship with the risk of NCD, as detailed in the WHO's 2012 guidelines on the intake of potassium and sodium in adults and children.
  - <sup>5</sup> This NRV must be applied with caution because it is based on a conditional recommendation for adults of the WHO's 2012 guidelines on the intake of potassium in adults and children.

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# **GHANA**

Ghana agrees with the recommendation that, NRV-NCD for potassium be set at 3500mg. We also support **Option 2** as proposed amendment to the guidelines on nutrition labelling (CAC/GL2-1985) to include a potassium NRV-NCD.

# **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)

#### **RATIONALE**

This brings more clarity in the nutrition labelling.

For clarity, we propose that footnote 3 reads;

<sup>3</sup>The selection of this nutrient for the establishment of an NRV was based on "convincing evidence" for a relationship with NCD risk as [indicated] in the report, *Diet, Nutrition and the Prevention of Chronic Diseases.* WHO Technical Report Series 916. WHO, 2003.

# Rationale:

The use of the word "indicated" instead of reported is for clarity.

Title of report when presented in italics allows for consistency in the document.

# **MEXICO**

PROPOSED DRAFT NRV FOR POTASSIUM IN RELATION TO THE RISK OF NCD	COMMENTS BY MEXICO OCTOBER, 2014.
RECOMMENDATION 1:	
In light of the observations made during the eWG consultation, it recommends that the CCNFSDU accept the establishment of 3,500 mg as the NRV-NCD for potassium.	Mexico is in agreement with the value of <b>3,500 mg</b> as the <b>NRV-NCD for potassium</b> .
RECOMMENDATION 2	
PROPOSED AMENDMENTS TO THE GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985) TO INCLUDE AN NRV-NCD FOR POTASSIUM.	Mexico agrees with the separation of the NRV-NCD.
In light of the observations made during the eWG consultation, it recommends that the CCNFSDU adopt the proposed amendment to the guidelines on nutrition labelling (CAC/GL 2-1985) to include the establishment of an NRV-NCD for potassium:	
Excerpt with track changes	
3.4.4.2 NRV-NCD	
Intake levels that should not be exceeded Saturated fatty acids 20 g <sup>2, 3</sup> Sodium 2,000 mg <sup>3 4</sup>	
, ,	
Intake levels that should be reached Potassium 3,500 mg <sup>4, 5</sup>	
2 This value is based on the reference energy intake of 8,370 kilojoules or 2,000 kilocalories.	Foot of page 3: Mexico agrees with the support for the changes to the text.
3 The choice of thisese nutrients for the establishment of an NRV was based on "convincing evidence" that there is a relationship with the risk of NCD, as detailed presented in the report entitled Diet, Nutrition and the Prevention of Chronic	Foot of page 4: Mexico suggests deleting the phrase "on evidence 'of a high quality' that there is a relationship with the risk of NCD, as presented", as it refers to the WHO's 2012 guidelines on the intake of potassium and sodium in adults and children, in which

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Diseases. WHO Technical Report Series (TRS) 916. WHO, 2003. The updated WHO guideline on sodium intake for adults and children (2012) further supports the selection of sodium

- 4 The choice of these nutrients for the establishment of an NRV was based on evidence of a high quality that there is a relationship with the risk of NCD, as presented in the WHO's 2012 guidelines on the intake of potassium and sodium in adults and children.
- 5 This NRV must be applied with caution because it is based on a conditional recommendation for adults of the WHO's 2012 guidelines on the intake of potassium in adults and children.

the evidence used to establish both NRVs as well as the classification of these is detailed.

**Foot of page 5:** Mexico suggests deleting this note, as it refers to the *WHO's 2012 guidelines on the intake of potassium and sodium in adults and children*, as well as the footnote on the page before, and we think it could cause confusion when applied.

#### **PHILIPPINES**

#### **POSITION**

The Philippines expresses affirmation of support for the recommended level of 3500 mg as NRV-NCD for potassium considering the available scientific evidence on its beneficial effects on reduction of high blood pressure in adults, which in turn influences the risk of stroke and coronary heart disease. Establishing NRV-NCD for Potassium is a relevant and important task towards the implementation of the Global Strategy on Diet, Physical Activity and Health, in addressing the global burden of diet-related NCD. This proposed level is based on the most recent systematic review of the entire body of available scientific evidence, supported by nominated recogized authoritative scientific body (RASBs).

# **RATIONALE**

Currently, the major NCDs account for about 60% of all deaths and 43% of disease burden globally. These statistics are expected to increase (Strong *et al.*, 2005, WHO, 2005).

Moderate and high quality evidence support the 2012 WHO Potassium Intake Guideline recommendation to increase potassium intake and decrease sodium intake to reduce blood pressure and risk of cardiovascular disease, stroke and coronary heart disease in adults (WHO, 2012). High quality evidence shows that increased potassium intake reduces blood pressure in people with hypertension and has no adverse effect on blood lipid concentrations, catecholamine concentrations, or renal function in adults. This proposed potassium level as recently recommended by the World Health Organization would complement the established NRV-NCD for sodium. The health benefits of potassium include relief from stroke, blood pressure, heart and kidney disorders, anxiety and stress, as well as enhanced muscle strength, metabolism, water balance, electrolytic functions, and nervous system.

Accumulating body of evidence showed the positive effects of high potassium intakes. Increased consumption of potassium is perceived to counteract the negative effects of sodium consumption on blood pressure (WHO, 2012). Two interventional studies have varied dietary sodium and potassium in humans and found remarkable beneficial effects of increasing the potassium: sodium ratio on blood pressure (BP) and cardiovascular disease endpoints (McDonough and Nguyen, 2012). Higher potassium intake was associated with a 24% lower risk of stroke. The biggest reduction in blood pressure of 7.16 mm Hg occurred when the potassium intake increased at 90-120mmol/day with no minor side effects (Aburto et al., 2013). Several studies have shown that potassium intake is associated with a reduced risk of stroke incidence (Bazzano et al., 2001)) and mortality (Khaw and Connor 1987). Similarly, the meta-analysis by D'Elia et al. (2011) revealed that an average potassium intake of 1.64g (42mmol)/day had been associated with 21% stroke reduction, and a trend toward an inverse association between potassium intake and CVD risk in 3 cohorts. These findings could be attributed to the lowering of blood pressure in hypertensives & those with high sodium intake. The conclusion of a large prospective study of Japanese men and women showed that a high dietary potassium intake is inversely associated with the risk of mortality from total cardiovascular disease (Umesawa et al. 2008). Dietary strategies to increase potassium intake to the recommended level of 90 mmol/day may have the potentital to reduce the incidence of hypertension (Kieneker et al., 2014). The study of Papandreou et al. (2007) also demonstrated that systolic BP was significantly positively associated with age ( $\beta$ : 0.283, 95% CI: 1.440–2.484, p < 0.001), BMI ( $\beta$ : 0.267, 95% CI: 0.830–1.489, p < 0.001) and potassium.

We are of the opinion that the amount of potassium should be achieved through diets and not through supplements to minimize risk of very high intakes. It is important that any potassium NRV- NCD is achievable through diet (Sacks, 2011) (Appel, 1997) (Norris, 2004). WHO strongly recommends a reduction to <2g/day in sodium intake and an increase in potassium intake of 3510 mg/day from foods particularly vegetables and fruits to reduce blood pressure and risk of CVD, stroke and CHD in adults (WHO, 2012; RENI, 2014).

The Philippines does not support inclusion of footnote number 5 in the proposed amendment to Nutrition Labeling since it introduces some confusion, and is not aligned with the fact that the eWG considers that the proposed

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value meets the General Principles for establishing NRVs for the General Population. It would be misleading to propose a value for NRV-NCD, and, at the same time, call for caution. This is also in contradiction with what is said in the footnote 4 (high quality evidence). We recommend that this footnote be elaborated further for clarity and logic.

We also suggest that the following additional joint FAO/WHO and RASB scientific advice on potassium in relation to NCDs be considered in establishing an NRV-NCD for potassium:

- WHO Guideline on Sodium Consumption, the WHO Guideline on Potassium intake for adults and children (Geneva, WHO, 2012).
- The Panel on Dietary Reference Intakes for Electrolytes and Water, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes from IOM should also be reviewed

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# AFRICAN UNION

SECTION	AU POSITION	RATIONALE
Recommendation  Based on the comments received from the eWG consultation, it is recommended that CCNFSDU adopt 3500 mg as the NRV-NCD for potassium	AU supports the adoption of the recommendation.	<ul> <li>Based on the most current evidence using a systematic review</li> <li>Based on high quality evidence</li> <li>Supported by nominated RASBs</li> </ul>

# FOODDRINKEUROPE

FoodDrinkEurope wishes to express its appreciation to the delegation of the United States for leading the work of the electronic Working Group in preparation of this year's session of CCNFSDU.

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FoodDrinkEurope supports the proposed NRV-NCD for potassium for the general population of 3500 mg/day at this stage, as it is based on the most recent high quality available evidence using systematic review and supported by nominated RASBs. The proposed value is also aligned with the lower value of the recommended intake from WHO, and with the US FDA labelling value. This said, we would recommend to wait for the publication of the EFSA scientific opinion on reference intake for potassium (expected for end of this year) for confirmation.

We agree 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. However, in line with WHO, which has set their recommendation as conditional, we agree that further high quality trials are needed to determine the precise level of potassium that achieves the most favorable reduction in blood pressure and risk of CVD, stroke, and CHD without negative effects on other health outcomes (e.g. blood lipids and catecholamine levels).

We support the proposed modification of the Guidelines on Nutrition labelling, with footnotes 1, 2, 3 and 4. However, we think that the footnote number 5 introduces some confusion, and is not aligned with the fact that the eWG considers that the proposed value meets the General Principles for establishing NRVs for the General Population. Whilst recognizing the need for further studies, particularly in more tropical countries where it has been acknowledged that evidence is limited, it could be considered as misleading to propose a value for NRV-NCD, and, at the same time, call for caution. In that regard, we note that footnote 5 could be considered to be in contradiction to footnote 4, which refers to "high quality evidence". Therefore, we believe that the justification for footnote should be better explained to be able to decide whether it should be included, or how it could be rephrased.

We also like to reiterate our view that, in the future, research and reviews of the available evidence regarding the relevant nutrients should be considered altogether rather than in isolation (in line with the comments of some delegations during the 36<sup>th</sup> Codex Alimentarius Commission meeting regarding the NRV for saturated fat and labeling NRV for calcium).

An additional point for consideration is that, with regard to potassium, the optimal sodium/potassium ratio would be very relevant to look at, but also the interaction with other nutrients that may play a role in blood pressure regulation. As re-emphasized by the recent (2012) guideline on potassium intake in adults and children: "if an individual consumes sodium at the levels recommended in the WHO guideline on sodium intake, and potassium as recommended in the current guideline, the ratio of sodium to potassium would be approximately one to one, which is considered beneficial for health". Although the scientific evidence supporting this one-to-one ratio is only indirect, we could support this proposal, as it is derived from the two proposed NRV-NCD values for sodium and potassium. Moreover, it should be made clear that the ratio is a molar ratio.

Finally, with regard to the listing of NRV-NCDs, we support the view to defer this issue to CCFL, but we would like to express our preference for the alternative option that was suggested by two COs:

- Saturated fatty acids ≤ 20 g
- Potassium ≥ 3500 mg
- Sodium ≤ 2000 mg

# INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS - ICBA

ICBA has the following comments with respect to the *Proposed Draft Nutrient Reference Value for Potassium in Relation to the Risk of Non-communicable Diseases*, currently at Step 4.

#### **General Comments**

ICBA supports setting an NRV-NCD for potassium.

- There is strong scientific precedent for establishing such an NRV, including validation from authoritative scientific bodies such as FAO/WHO, the United States (U.S.) Institutes of Medicine and the U.S. Food and Drug Administration, the European Food Safety Authority, the Australian National Health and Medical Research Council, and Health Canada.
- The proposal meets the conditions established in the Codex General Principles for Establishing NRVs.
- The risk of adverse effects of increasing potassium intake in the general population is very low, with populations in many countries around the world consuming less than recommended levels.

# Specific Comments to paras 50 - 64 (CX/NFSDU 14/36/8)

eWG Recommendation	ICBA Position
Adopt 3500 mg as the NRV/NCD for potassium	ICBA agrees with the recommendation to adopt 3500 mg as the NRV/NCD for potassium.
Text for incorporation into the Guidelines on	In line with the views of most members of the eWG,

<sup>&</sup>lt;sup>1</sup> WHO. Diet, Nutrition and the Prevention of Chronic Disease. Report of a Joint WHO/FAO Expert Consultation. Geneva, World Health Organisation (WHO), 2003

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# Nutrition Labeling (CAC/GL2-1985)

# 3.4.4.2 NRVs-NCD

Intake levels not to exceed

Saturated fatty acids 20 g 2,3

Sodium 2000 mg 4

Intake level to achieve

Potassium 3500 mg 4,5

ICBA supports option 2 as expressed in para 53. Option 2 provides greater clarity on the meaning of the intake targets for the nutrients for which NRVs-NCD have been set

ICBA agrees with footnote 4.

ICBA questions the inclusion of footnote 5, which could create confusion as to whether or not governments should establish an NRV-NCD for potassium. ICBA suggests that footnote 5 be deleted.

<sup>&</sup>lt;sup>2</sup> This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories

<sup>&</sup>lt;sup>3</sup> The selection of this nutrient for the establishment ....WHO, 2003.

<sup>&</sup>lt;sup>4</sup> 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 guidelines on sodium and potassium intake for adults and children.

<sup>&</sup>lt;sup>5</sup> 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.