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Assessment of dietary intake of potassium in relation to upper guidance level

Opinion of the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of the Norwegian Scientific Committee for Food Safety

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Assessment of dietary intake of potassium in relation to upper guidance level

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Assessed and approved

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Competence of VKM experts

Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third party interests. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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Summary

The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) has, at the request of the Norwegian Food Safety Authority (Mattilsynet; NFSA), evaluated the intake of potassium in the Norwegian population. VKM has also evaluated the consequences of amending the existing maximum limit for potassium at 1000 mg/day to 300, 2000 or 3000 mg/day in food supplements.

Potassium is an essential mineral to humans and is important as the osmotically active element inside the cells, whereas sodium and chloride are the main elements outside the cells. The enzyme Na^+/K^+-ATPase pumps potassium ions into the cells and sodium ions out of the cells and helps keep the intracellular potassium concentration about 30 times higher than that of plasma and interstitial fluids.

The plasma potassium concentration is maintained within narrow limits (3.5 to 5.0 mmol/L) by multiple mechanisms making up the potassium homeostasis. The strict regulation is essential for a broad array of important physiological processes, like the resting cellular membrane potential and the transmission action in neuronal, muscular and cardiac tissue. Potassium is also important for hormone secretion, vascular tone, systemic blood pressure control, gastrointestinal motility, acid-base balance, glucose and insulin metabolism, mineralocorticoid action, renal concentration ability and fluid and electrolyte balance. Both hypo- and hyperkalaemia result in increased mortality.

The EFSA recommendations (2016) for adequate intake (AI) of potassium is 3500 mg/day for adults, both sexes, whereas the recommended intake (RI) in the Nordic Nutrition recommendations (2012) is 3500 mg/day for men and 3100 mg/day for women.

Tolerable upper intake levels have not been established for potassium from food, because intake from food has not caused adverse health effects in the healthy population. In children the renal function rapidly reaches the normal adult level in early childhood and no concern about high intake of potassium from food has been put forward.

Potassium chloride supplement has, however, resulted in hyperkalaemia and case reports have described heart failure and cardiac arrest at plasma concentrations above 5.5 mmol/L and doses over 6.5 - 6.8 g supplementary potassium per day.

VKM proposes to use 3000 mg/day of potassium as an upper guidance level for daily dose of supplemental potassium in adults since this dose has not been shown to cause hyperkalaemia or heart failure, and has not resulted in gastrointestinal lesions.

The proposed upper guidance level for adults extrapolated for body weights corresponds to 2630 mg/day for adolescents 14 to <18 years, 1860 mg/day for children 10 to < 14 years and 990 mg/day for children 3 to 10 years.

For vulnerable groups all doses of potassium supplementation could lead to hyperkalaemia. Vulnerable groups such as persons with impaired kidney function and elderly have been estimated to comprise 15-20% of the population of Norway. However, most of the vulnerable individuals will be aware of the condition and be under medical supervision.

Accordingly, all the evaluated doses from NFSA (300, 1000, 2000 and 3000 mg/day of potassium in food supplements are at or below the suggested upper guidance level for supplemental potassium for adults (>18 years). In adolescents 14 to <18 years, the supplemental doses of 300, 1000 and 2000 mg/day are below the suggested upper guidance level. For the younger age groups, only 300 mg/day is below the suggested upper guidance level for supplemental potassium.

Key words: VKM, risk assessment, Norwegian Scientific Committee for Food Safety, potassium, food supplement, upper level, exposure.

Sammendrag på norsk

På oppdrag fra Mattilsynet har Vitenskapskomiteen for mattrygghet vurdert inntaket av kalium i den norske befolkningen i relasjon til øvre tolerable inntaksnivåer (UL). VKM har også vurdert konsekvenser av å endre den eksisterende maksimumsgrensen for kalium i kosttilskudd på 1000 mg/dag til 300, 2000 eller 3000 mg/dag.

Kalium er et essensielt mineral for mennesker, og er sentralt som osmotisk element inne i cellene, mens natrium og klorid er de sentrale elementene på utsiden av cellene. Enzymet Na^+/K^+-ATPase pumper kaliumioner inn i cellene og natriumioner ut av cellene og sørger for å opprettholde en kaliumkonsentrasjon inne i cellene som er omlag 30 ganger høyere enn i plasma og mellom cellene.

Kaliumkonsentrasjonen i plasma er godt regulert gjennom flere mekanismer som utgjør kaliumhomeostasen. Kaliumkonsentrasjonen varierer lite (3,5 til 5,0 mmol/L). Regulering av kaliumkonsentrasjon er essensiell for et bredt spekter av viktige fysiologiske prosesser, som cellemembranens hvilepotesial og overføring av signaler i nerveceller og muskel- og hjertevev. Kalium er også viktig for hormonutskillelse, vaskulær plastisitet, regulering av systemisk blodtrykk, gastrointestinal motilitet, syre- og basebalansen, glukose- og insulinmetabolismen, mineralkortikoid aktivitet, nyrenes evne til å konsentrere urin og væske- og elektrolyttbalansen. Både for lite og for mye kalium (hypokalemi og hyperkalemi) i blodet er forbundet med økt dødelighet.

EFSAs anbefalinger (fra 2016) for adekvat inntak (AI) av kalium er 3500 mg/dag for voksne kvinner og menn, mens anbefalt inntak (RI) i de nordiske landene (fra 2012) er 3500 mg/dag for menn og 3100 mg/dag for kvinner.

Det er ikke fastsatt tolerable øvre inntaksnivåer for kalium fra mat, fordi det er ikke vist at inntak av kalium fra mat og drikke kan gi negative helseeffekter i den friske befolkningen. Nyrefunksjonen hos barn når raskt samme nivå som voksne, og heller ikke hos barn har høyt inntak av kalium fra mat gitt grunn til bekymring.

Tilskudd med kaliumklorid har imidlertid ført til hyperkalemi, og både hjertesvikt og hjertestans er beskrevet i case-studier ved plasmakonsentrasjoner over 5,5 mmol/L.

VKM foreslår å benytte 3000 mg kalium per dag som et øvre veiledende nivå for daglig dose i tilskudd ettersom det ikke er vist hyperkalemi, hjertesvikt eller sårdannelse i mave/tarmkanalen gastrointestinale lesjoner ved dette inntaksnivået fra kaliumtilskudd.

Med utgangspunkt i kroppsvekt for voksne, blir de ekstrapolerte øvre veiledende nivåene 2630 mg/dag for ungdom 14 til <18 år, 1860 mg/dag for barn 10 til < 14 år og 990 mg/dag for barn 3 til 10 år.

For sårbare grupper vil alle de foreslåtte dosene kaliumtilskudd kunne medføre hyperkalemi. Sårbare grupper som eldre og de med nyresvikt vært estimert til å utgjøre 15-20% av den norske befolkningen. På individnivå vil imidlertid de mest utsatte personene være kjent med sin egen tilstand, og være under medisinsk tilsyn.

Alle de spesifiserte dosene fra Mattilsynet (300, 1000, 2000 og 3000 mg/dag) kalium i kosttilskudd er på eller under det foreslåtte øvre veiledende nivået for kaliumtilskudd hos voksne (>18 år). For ungdom 14 til <18 år vil dosene 300, 1000 og 2000 mg/dag være på eller under det foreslåtte øvre veiledende nivået. I de yngre aldersgruppen er det bare 300 mg/dag som er under det foreslåtte øvre veiledende nivået for kaliumtilskudd.

Abbreviations and/or glossary

Abbreviations

ACE – angiotensin converting enzyme
AI – adequate intake
AR – average requirement
ARB – angiotensin receptor blockers
bw – body weight
CI – confidence interval
DRI – dietary reference intake
DRV – dietary reference value
EKG – electrocardiogram
EAR – estimated average requirement (IOM).
EFSA – European Food Safety Authority
EVM – Expert group on vitamins and minerals of the Food Standard Agency, UK
IOM – Institute of Medicine, USA
IU – international unit
LOAEL – lowest observed adverse effect level
NFSA – Norwegian Food Safety Authority [*Norw.*: Mattilsynet]
NNR – Nordic Nutrition Recommendations
NOAEL – no observed adverse effect level
PRI – population reference intakes
RDA – recommended dietary allowances
RI – recommended intake
SCF – Scientific Committee for Food
SUL – safe upper intake level
UF – uncertainty factor
UL – tolerable upper intake level
VKM – Norwegian Scientific Committee for Food Safety [*Norw.*: Vitenskapskomiteen for Mattrygghet]

Glossary

P5, P25, P50, P75 or P95-exposure is the calculated exposure at the 5, 25, 50, 75 or 95-percentile.

Percentile is a statistical measure indicating the value below which a given percentage of the observations fall. E.g. the 95-percentile is the value (or score) below which 95 percent of the observations are found.

EFSA – Dietary Reference Values (DRVs) (EFSA, 2010)

Average Requirement (AR) is the level of intake of a defined group of individuals estimated to satisfy the physiological requirement of metabolic demand, as defined by a the specific criterion for adequacy for the nutrient, in half of the healthy individuals in a life stage or sex group, on the assumption that the supply of other nutrients and energy is adequate.

If an AR cannot be determined than an Adequate Intake is used.

Adequate Intake (AI) is defined as the average (median) daily level of intake based on observed, or experimentally determined approximations or estimates of a nutrient intake, by a group (or groups) of apparently healthy people, and therefore assumed to be adequate. The practical implication of an AI is similar to that of a population reference intake, i.e. to describe the level of intake that is considered adequate for health reasons. The terminological distinction relates to the different ways in which these values are derived and to the resultant difference in the "firmness" of the value.

Population Reference Intake (PRI) is derived from AR of a defined group of individuals in an attempt to take into account the variation of requirements between individuals.

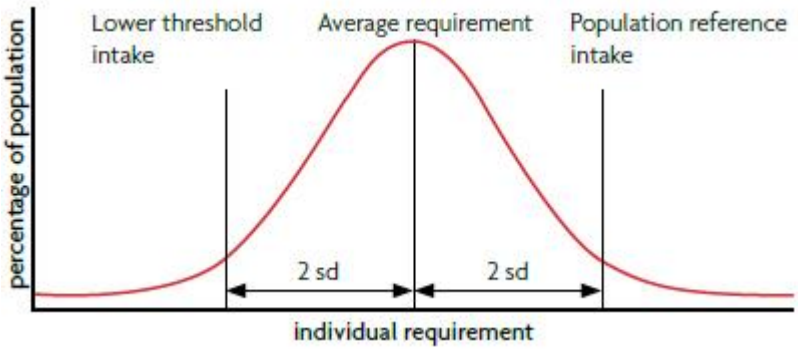

Figure 1 Population reference intake (PRI and average requirements (AR), if the requirement has a normal distribution and the inter-individual variation is known (EFSA, 2010).

Lower Threshold Intake (LTI) is the lowest estimate of requirement from the normal distribution curve, and is generally calculated on the basis of the AR minus twice its SD. This will meet the requirement of only 2.5% of the individuals in the population.

Tolerable Upper intake Level (UL) is the maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans.

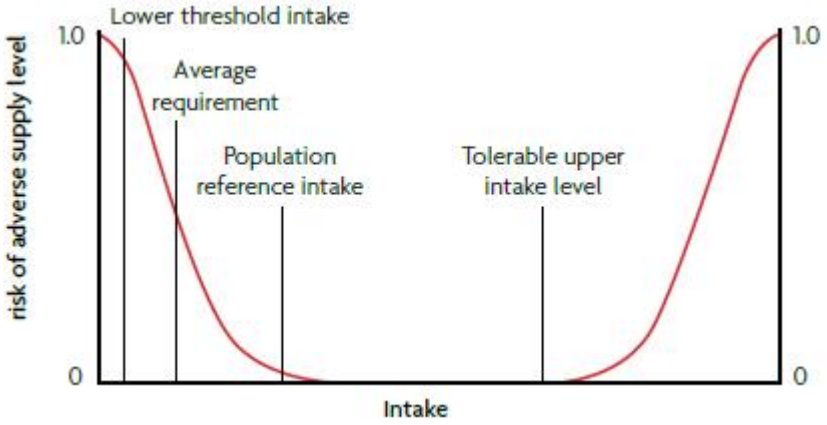

Figure 2 Relationship between individual intake and risk of adverse effects due to insufficient or excessive intake using EFSA terminology.

IOM - Dietary Reference Intakes (DRIs) (IOM, 2000)

Estimated Average Requirement (EAR) is a nutrient intake value that is estimated to meet the requirement of half the healthy individuals in a life stage and gender group.

Recommended Dietary Allowances (RDA) is the dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group. RDA = EAR + 2 SD_{EAR} or if insufficient data to calculate SD a factor of 1.2 is used to calculate RDA; RDA = 1.2*EAR

Adequate Intake (AI) is the recommended intake value based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of healthy people that are assumed to be adequate – used when an RDA cannot be determined

Tolerable Upper Intake Level (UL) is the highest level of nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in the general population.

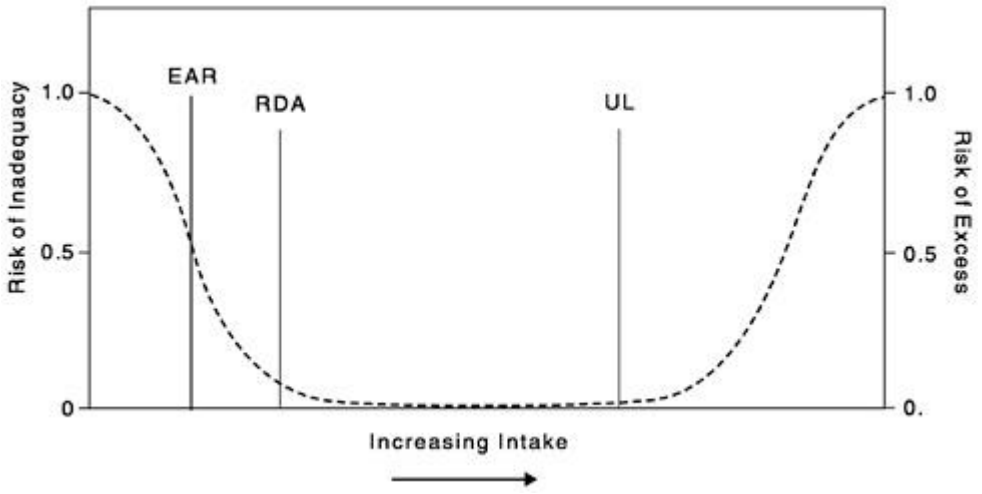

Figure 3 Dietary reference intakes using IOM terminology.

NNR -Recommended Intake (NNR Project Group, 2012)

Average Requirement (AR) is defined as the lowest long-term intake level of a nutrient that will maintain a defined level of nutritional status in an individual i.e. the level of a nutrient that is sufficient to cover the requirement for half of a defined group of individuals provided that there is a normal distribution of the requirement.

$AR_{NNR} = EAR_{IOM} = AR_{EFSA}$

Recommended Intake (RI) is defined as the amount of a nutrient that meets the known requirement and maintains good nutritional status among practically all healthy individuals in a particular life stage or gender group. $RI = AR + 2SD_{AR.}$

$RI_{NNR} = RDA_{IOM} = PRI_{EFSA}$

Upper Intake Level (UL) is defined as the maximum level of long-term (months or years) daily nutrient intake that is unlikely to pose a risk of adverse health effects in humans.

$UL_{NNR} = UL_{IOM} = UL_{EFSA}$

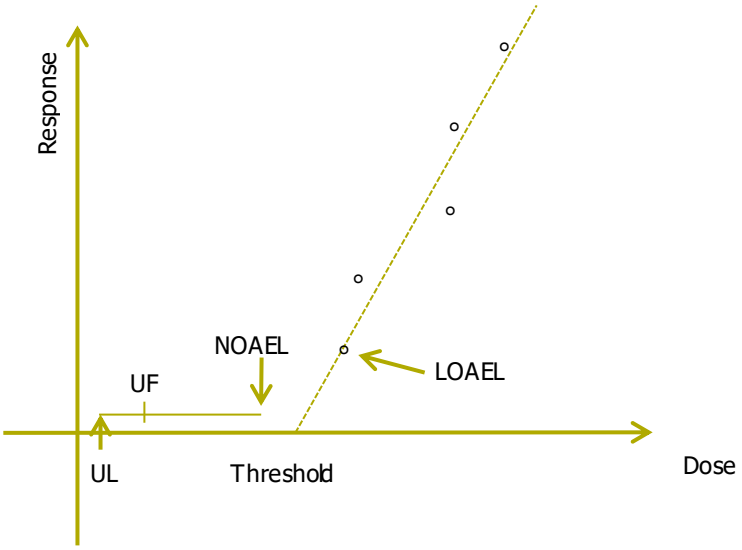

Figure 4 Derivation of Upper Intake Level (UL)

UF: Uncertainty factor

Expert group on vitamins and minerals (EVM), UK (EVM, 2003)

Safe Upper Intake Level (SUL): EVM (2003) used SUL instead of UL and defined SUL as the determination of doses of vitamins and minerals that potentially susceptible individuals could take daily on a life-long basis, without medical supervision in reasonable safety. The setting of these levels provided a framework within which the consumer could make an informed decision about intake, having confidence that harm should not ensue. The levels so set will therefore tend to be conservative.

Background as provided by the Norwegian Food Safety Authority

Directive 2002/46/EC on food supplements was implemented in Norwegian law in 2004 in Regulation 20 May 2004 No. 755 on food supplements. Pursuant to Directive 2002/46/EC, common maximum and minimum levels of vitamins and minerals in food supplements shall be set in the EU.

National maximum limits for vitamins and minerals were established in the former vitamin and mineral supplements regulation from 1986 and were continued in the 2004 regulation.

The European Commission started establishing common limits in 2006, but the work was temporarily put on standstill in 2009. The time frame for the further work is not known.

Maximum limits for levels of vitamins and minerals in food supplements shall be set on the basis of the following criteria, pursuant to article 5 in Directive 2002/46/EC:

- Upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups
- Intake of vitamins and minerals from other dietary sources

When the maximum levels are set, due account should also be taken of reference intakes of vitamins and minerals for the population.

Pending establishment of common maximums limits in the EU, the Norwegian Food Safety Authority is evaluating the national maximum limits for vitamins and minerals in food supplements.

Assessment of potassium

The Norwegian Food Safety Authority will evaluate the national maximum limits for potassium in the food supplement regulation. The minimum and maximum limits for the content of vitamins and minerals in food supplements are listed in Annex 1 to the food supplement regulation:

Background Table Minimum and maximum limits for potassium in the food supplement regulation (October 2015).

	Minimum amount per recommended daily dose	Maximum amount per recommended daily dose
Potassium, mg	200	1000

Permitted potassium substances which may be used in the manufacture of food supplements are listed in "Forskrift om kosttilskudd 2012", http://www.lovdata.no/cgi-wift/ldles?doc=/sf/sf/sf-20040520-0755.html.

Terms of reference as provided by the Norwegian Food Safety Authority

The Norwegian Food Safety Authority (NFSA, Mattilsynet) requests the Norwegian Scientific Committee for Food Safety (VKM) to assess the intake of potassium from the diet, including fortified products, in all age groups in the population above 1 year (mean intakes, median, P5, P95).

VKM is also requested to conduct scenario estimations to illustrate the consequences of amending maximum limits for potassium (to 300, 2000 or 3000 mg/day, as examples) in food supplements, and to evaluate these scenarios against already established tolerable upper intake levels.

Assessment potassium

1 Introduction

Potassium (K) is a reactive alkali metal, which is only found as a salt in nature. The atomic mass is 39.1 Da and potassium is only present in one oxidation state (+ 1). Potassium is an essential mineral to humans and is important as the osmotically active element inside the cells, whereas sodium and chloride are the main elements outside the cells. The enzyme Na^+/K^+-ATPase pumps potassium ions into the cells and sodium ions out of the cells and helps keep the intracellular potassium concentration about 30 times higher than that of plasma and interstitial fluids. This concentration gradient is important for the transmission of electrical activity in nerve fibres and muscle cells.

The plasma potassium concentration is maintained within narrow limits (3.5 to 5.0 mmol/L) by multiple mechanisms making up the potassium homeostasis. The strict regulation is essential for a broad array of important physiological processes, including the resting cellular membrane potential and the transmission action in neuronal, muscular and cardiac tissue. Potassium is also important for hormone secretion, vascular tone, systemic blood pressure control, gastrointestinal motility, acid-base balance, glucose and insulin metabolism, mineralocorticoid action, renal concentration ability and fluid and electrolyte balance (Gumz et al., 2015). The importance of potassium homeostasis is illustrated by findings that patients with both hypo- and hyperkalaemia have increased mortality (Goyal et al., 2012).

The tight regulation of extracellular levels of potassium can be illustrated by the fact that the dietary intake may contain more potassium (46-77 mmol per day in a mixed Western diet (Intersalt Cooperative Research Group, 1988) than the total plasma potassium content (20 to 25 mmol). To maintain potassium homeostasis two processes are involved - an internal and an external. External potassium balance is mainly through renal excretion, between 77% and 92% of total dietary intake. Internal potassium homeostasis regulation acts through asymmetric distribution of total body potassium, increasing intracellular total body potassium. Potassium transfer between extracellular and intracellular compartments is influenced by a variety of endogenous and exogenous factors (Gumz et al., 2015). Potassium uptake by the cells is promoted by increase in plasma potassium concentration, insulin, epinephrine and aldosterone, metabolic alkalosis, and by drug activating β-2 adrenergic receptors (EFSA, 2016). Transport from the cells is promoted through decreased plasma potassium concentration, metabolic acidosis, hyperosmolarity of the extracellular fluid, and α-antagonist drugs.

Due to the Na^+/K^+-ATPase pump, potassium and sodium metabolism are strongly interrelated. Although renal sodium regulation is closely related to that of potassium, sodium intake does not influence potassium excretion except at very high sodium intakes (Kirkendall et al., 1976). Potassium also interacts with calcium, enhancing urinary loss of calcium upon

potassium depletion and decreases calcium excretion upon potassium supplementation. In studies comparing supplements, the alkaline potassium bicarbonate and potassium citrate had a calcium sparing effect, whereas the effect of potassium chloride was much smaller (Lambert et al., 2015).

Important sources of potassium in the Nordic diets are potatoes, fruits and berries, vegetables, and milk and dairy products. Average potassium intake in nine countries in EU ranged between 2460 and 3990 mg per day among adults (EFSA, 2016).

2 Recommendations and tolerable upper intake levels

2.1 Recommendations

Institute of Medicine (IOM, 2004), USA

IOM (2004) did not set an Estimated Average Requirement (EAR) for potassium due to lack of dose-response trials demonstrating effects. Potassium serum concentration is tightly regulated, and serum potassium cannot be used as a sensitive indicator of potassium status. In the IOM report potassium impacts on blood pressure, cardiovascular disease, bone demineralisation, kidney stones formation, and acid-base balance were evaluated, and an Adequate Intake (AI) from food was set at 4.7 g (120 mmol)/day for adults (both genders). This intake level should maintain lower blood pressure, reduce the adverse effects of sodium chloride intake on blood pressure, reduce the risk of recurrent kidney stones, and possibly decrease bone loss. In the generally healthy population with normal kidney function, a potassium intake from foods above AI should not pose increased risk of adverse effects because excess potassium is readily excreted in the urine. Based on average energy intake levels for each age groups AIs for children and adolescents were derived by extrapolating from adult AI.

Table 2.1-1 IOM recommendations for average intake (AI) of potassium intakes, both sexes.

Age, both sexes	mg/day	
	Men	Women
6-11 mo.		
1-3 years	3000	3000
4-8 years	3800	3800
9-13 years	4500	4500
14-18 years	4700	4700
18- >75 years	4700	4700
Pregnant	-	4700
Lactating	-	5100

European Food Safety Authority (EFSA, 2016), EU

The EFSA (2016) report concluded that there are too few available potassium balance studies, and that the studies are too heterogeneous with regard to populations examined and duration to set dietary reference values (DRVs) for potassium. Several studies of the relationship between potassium intake and cardiovascular outcomes are referred to and one new study on blood pressure showing a beneficial effect of 3500 mg/day of potassium was given extra attention (Kieneker et al., 2014). In this study the risk of hypertension (defined

as blood pressure ≥140/90 mm Hg or initiation of blood pressure–lowering drugs) was prospectively studied in 5511 normotensive subjects aged 28 to 75 years not using blood pressure–lowering drugs at baseline. Potassium excretion was measured in two 24-hour urine specimens at baseline (1997-1998) and midway during follow-up (2001-2003). The lowest sex-specific tertile of potassium excretion (men: <68 mmol/24 h; women: <58 mmol/24 h) had an increased risk of hypertension after multivariable adjustment (hazard ratio, 1.20; 95% CI, 1.05-1.37), compared with the upper 2 tertiles. Thus low urinary potassium excretion was associated with an increased risk of developing hypertension.

Table 2.1-2 EFSA recommendations (2016) for adequate intake (AI) of potassium, both sexes.

Age, both sexes	**mg/day**	
	Men	Women
7-11 mo.	750	750
1-3 years	800	800
3-10 years	1100	1100
11-14 years	2700	2700
15-17 years	3500	3500
18- >75 years	3500	3500
Pregnant	-	3500
Lactating	-	4000

The reference values for children and adolescents are extrapolated from adult values using isometric scaling and body weights of the age group and application of growth factor.

Norwegian Scientific Committee for Food Safety (VKM, 2014), Norway

In a report where benefit and risk of replacing sodium chloride with potassium chloride in industrial food production was evaluated, VKM performed a search for meta-analyses of positive health effects of potassium (VKM, 2014). Three meta-analyses were found on stroke, and six on blood pressure (of which two were included in the IOM report, (Cappuccio and MacGregor, 1991; Whelton et al., 1997). VKM concluded that an intake of at least 3500 mg potassium per day most probably would lead to decrease in the risk of stroke and a beneficial effect on blood pressure.

Nordic Nutrition Recommendations (NNR, 2012)

The recommendations (RI) from 2004 were upheld with the argument that these recommendations had been strengthened with concerns to blood pressure and reduced risk of stroke and other cardiovascular diseases (NNR Project Group, 2012).

Table 2.1-3 NNR recommendations for intake (RI) of potassium intakes, both sexes.

Age, both sexes	mg/day	
	Men	Women
6-11 mo.	-	-
1-2 years	-	-
2-5 years	1800	-
6-9 years	2000	-
10-13 years	3300	2900
14- >75 years	3500	3100
Pregnant	-	3100
Lactating	-	3100

The reference values for children and adolescents are extrapolated from adult values based on need for growth and adjusted for body weight.

2.2 Tolerable upper intake levels

Institute of Medicine (IOM, 2004), USA

IOM (2004) did not set a tolerable upper intake level (UL) for potassium from food based on the notion that in the generally healthy population with normal kidney function, a high potassium intake from food will be excreted through the kidneys. After adaptation to a high potassium intake the maximum excretion rate has been estimated to 31.3 g/day, a level that would be difficult to achieve from food alone (Berliner, 1961 cited in IOM, 2004).

Six studies conducted among normotensive individuals showed that a total intake from diet plus supplements of between 6-15.6 g potassium per day did not increase serum potassium or pose gastrointestinal discomfort as long as supplemental potassium was given in smaller quantities at a time. However, IOM acknowledged that in individuals with impaired urinary excretion even a potassium intake below 4.7 g (120 mmol)/day can have adverse cardiac effects (arrhythmias) from a resulting hyperkalaemia. Cardiac arrhythmias from hyperkalaemia are the most serious consequence of excessive potassium plasma concentration which might lead to death. The actual level at which hyperkalaemia increases the risk of serious arrhythmias is uncertain (Kallen et al., 1976). Case reports have described heart failure and cardiac arrest at plasma concentrations above 5.5 mmol/L, however, this condition has only been reported in individuals on medication with some type of renal or heart disease. Most individuals with reduced kidney or heart function are argued to be under medical supervision and as such aware of the condition. Common drugs that can substantially impair potassium excretion are angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), and potassium-sparing diuretics. Medical conditions associated with impaired urinary potassium excretion include diabetes, chronic renal insufficiency, end-stage renal disease, severe heart failure, and adrenal insufficiency. Elderly individuals are at increased risk of hyperkalaemia because they often have one or more of these conditions or are treated with one of these medications.

In infants the renal secreting capacity is initially lower than that in adults, but the renal function rapidly reaches the normal adult level in early childhood. Therefore there is little concern about high intake of potassium from food during childhood, but in infancy potassium should be limited in formula and complementary foods.

With regard to potassium supplementation IOM (2004) refers to the notion that it can lead to acute toxicity also in healthy individuals. Supplementation with potassium is therefore only recommended under medical supervision.

European Food Safety Authority (EFSA, 2005), EU

EFSA (2005) did not set a UL for potassium due to insufficient data. Risk of adverse effects from potassium intake from food sources up to 5-6 g/day was considered to be low for the general population. It was stated that long-term intake of about 3 g per day as supplemental potassium chloride had not caused elevated plasma potassium or gastrointestinal symptoms in healthy individuals. No information was given for children or adolescents.

In a study by Rabelink et al. (1990) the adaptation to early (72 hours) and late (20 days) potassium loading was studied. In four equal meals every 6th hour 15.6 g potassium was given per day in six healthy subjects and potassium balance was achieved after 48 hours. Upon discontinuation of potassium loading a negative potassium balance was seen which lasted for 24 hours, indicating that adaptation to both high and low potassium intakes seems to happen within days. However, in an earlier study with seven healthy subjects given single doses of potassium (6.5-5.8 g) in solution, two subjects had increased T-wave EKG and paraesthesia of hands and feet parallel with hyperkalaemia (Keith et al., 1941).

Long-term intake of potassium chloride supplements (more than 2 years) with 3.1 g potassium per day, divided in three daily intakes, did not cause hyperkalaemia in middle-aged, hypertensive men on a sodium restricted diet (Grimm et al., 1990).

Potassium supplementation may cause gastrointestinal symptoms like abdominal pain, nausea and vomiting, diarrhoea, and ulceration of the oesophagus, stomach and duodenum and ileum. This seems to be more dependent on the formulation than on the dose. Slow releasing tablets seem to induce more lesions than microencapsulated tablets (McMahon et al., 1982).

EFSA proposed that supplemental doses of up to 3000 mg potassium per day seems to be without overt adverse effects in healthy adults, but may be associated with gastrointestinal lesions depending on formulation.

Expert Group on Vitamins and Minerals (EVM, 2003), UK

EVM (2003) concluded that there are insufficient data to establish a Safe Upper Level (SUL) for potassium. In the evaluation three studies were referred to, two on formulation and mucosal erosions (McMahon et al., 1982; McMahon et al., 1984) and one on dose (Grimm et

al., 1990; Grimm et al., 1988). In the McMahon studies the microencapsulated tablets gave less mucosal erosions compared with the slow releasing wax coted tablets. EVM reported that in the study by Grimm et al. (1990), 3700 mg potassium was given to healthy subjects (148 subjects in the potassium group and 150 in the placebo group). Adverse effects (nausea, vomiting abdominal pain, diarrhoea and blood in stools) were reported in both groups.

EVM (2003) proposed that supplemental doses of up to 3700 mg potassium per day seem to be without overt adverse effects (equals 60 mg/kg bw in a 60 kg adult) to the general population, but may be associated with gastrointestinal lesions depending on formulation. Extrapolation of the guidance level to children on body weight basis was evaluated to be appropriate.

Nordic Nutrition Recommendations (NNR, 2012)

NNR Project Group (2012) suggested the value from EVM, i.e. 3.7 g/day from supplements, as an upper guidance level for adults. It was stated that supplemental intakes up to this level are generally not associated with adverse effects, but certain preparations might induce mild lesions of the gastrointestinal mucosa.

Norwegian Scientific Committee for Food Safety (VKM, 2008), Norway

In 2008, VKM was requested to determine a UL for potassium with the questions "what should be set as an upper safe limit, and based on which health risks with special conditions in Norway that should be taken into account"?

VKM (2008) used the reports from IOM (2004), SCF (1993) and NNR (2004) (cited in VKM, 2008). Elderly people were determined to comprise the largest vulnerable group, and it was concluded that a safe upper limit from supplements and fortification should not exceed 1 g/day.

Norwegian Scientific Committee for Food Safety (VKM, 2014), Norway

In the benefit risk report of replacing sodium salt with potassium salts, VKM (2014) used reports from WHO, 2006 and 2012, EFSA, 2005, 2010 and 2011 and EVM, 2003 (cited in VKM, 2014). In 2014, VKM concluded that an intake of 3.0 g potassium/day (energy adjusted for children) in addition to the mean intake of potassium from food is anticipated to be safe for the healthy population.

However, for vulnerable persons with impaired kidney function, hyperkalaemia may occur even with a modest increase in potassium intake and they are advised to keep their potassium intake below 1.5 g/day.

It was further stated that in Norway, 202 persons are waiting for a kidney graft, about 500 000 persons have diagnosed or undiagnosed chronic kidney disease, the prevalence of diagnosed diabetes (type I and II) was estimated to be 90-120 000 and undiagnosed diabetes to be equally high, the number of infants (below one year) was 60 530 in 2013, and the number of persons aged 85 years and older was 113 700 in 2013. Hence, a very large proportion of the Norwegian population would be at risk of hyperkalaemia with a replacement of potassium salt for sodium salt in industrial food production.

2.2.1 Summary tolerable upper intake levels

UL or SUL has not been established for potassium intake from food, because intake from food has not caused adverse health effects in the healthy population. Acute toxic effects of potassium chloride tables, however, has resulted in hyperkalaemia. Furthermore, case reports have described heart failure and cardiac arrest at plasma concentrations above 5.5 mmol/L in individuals on medication with some type of renal or heart diseases (IOM, 2004). Gastrointestinal symptoms have also been described after chronic ingestion of potassium chloride in case reports and supplemental studies. Symptoms are abdominal pain, nausea and vomiting, diarrhoea, and ulceration of the oesophagus, stomach and duodenum and ileum. There are limited data on carcinogenicity of potassium chloride and no data on genotoxicity or reproductive toxicity of potassium chloride.

In the table below suggested ULs for supplementation with potassium salts are shown.

Table 2.2.1-1 Overview of suggested upper guidance levels for potassium salts in supplements in adults set by various authorities.

	UL/SUL mg/day from food	Suggested upper guidance levels for supplements	Based on
IOM, 2004	Not established	Not established	
EFSA, 2005	Not established	Suggested 3000 mg/day	Based on hyperkalaemia and heart failure (Grimm 1990)
EVM, 2003	Not established	Suggested guidance level 3700 mg/day	Gastrointestinal lesions (Grimm 1990)
NNR, 2012	Not established	Suggested 3700 mg/day	EVM report 2003
VKM, 2008		1000 mg/day supplements + fortification	Kidney malfunction
VKM, 2014	Not established	Suggested 3000 mg/day	EFSA report 2005

VKM proposes to use 3000 mg/day as a suggested upper guidance level for daily dose of supplemental potassium since this dose did not cause hyperkalaemia or heart failure, and did not result in gastrointestinal lesions (Grimm et al., 1990).

In children the renal function rapidly reaches the normal adult level in early childhood and no concern about high intake of potassium from food has been put forward. Extrapolation of the

suggested upper guidance level for food supplements to children on body weight basis may be appropriate.

Default body weights suggested in EFSAs guidance are 70 kg for adults, 61.3 kg for adolescents 14 to <18 years, 43.4 kg for children 10 to < 14 years and 23.1 kg for children 3 to 10 years. The proposed suggested upper guidance level of 3000 mg/day supplemental potassium for adults adjusted for body weights corresponds to 2600 mg/day for adolescents 14 to <18 years, 1860 mg/day for children 10 to < 14 years and 990 mg/day for children 3 to 10 years.

For vulnerable groups, which according to VKM report 2014 amount to about 800 000 individuals in Norway, all doses of potassium supplementation could lead to hyperkalaemia. However, most of the vulnerable individuals will be aware of the condition and be under medical supervision.

3 Intakes and scenarios potassium

3.1 Short description of the Norwegian dietary surveys

The estimated intakes of potassium presented in this opinion are based on data from the national food consumption surveys in young children (2-year-olds), children and adolescents (9- and 13-year-olds) and adults (aged 18 to 70 years). The national food consumption surveys were conducted by the Department of Nutrition, University of Oslo in collaboration with the Directorate of Health, the Norwegian Food Safety Authority and the Norwegian Institute of Public Health. Different methodologies were used in the tree different surveys and thus direct comparisons between the age groups may be misleading.

A description of the food consumption surveys and the different methodologies used is given below.

Adults: "Norkost 3" is based on two 24-hour recalls by telephone at least one month apart. Food amounts were presented in household measures or estimated from photographs (Totland et al., 2012). The study was conducted in 2010/2011, and 1787 adults (925 women and 862 men) aged 18-70 participated.

9- and 13-year-old children/adolescents: "Ungkost 3" is based on a 4-day food intake registration with a webbased food diary. All food items in the diary were linked to photographs for portion estimation (Hansen et al., 2016). The study was conducted in 2015 and 636 9-year-old children and 687 13-year-old adolescents participated.

4-year-old children: "Ungkost 3" is based on a 4-day food intake registration with a webbased food diary. All food items in the diary were linked to photographs for portion estimation (Hansen et al., 2017). The study was conducted in 2016, and 399 4-year-olds participated.

2-year-old children: "Småbarnskost 2007" is based on a semi-quantitative food frequency questionnaire. In addition to predefined household units, food amounts were also estimated from photographs. The study was conducted in 2007, and a total of 1674 2-year-olds participated (Kristiansen et al., 2009).

3.2 Dietary intakes of potassium in the Norwegian population

Intake of potassium in the various age groups and in groups of users of potassium supplements are presented in tables in Appendix 1. The tables in Appendix 1 also include estimates for P25 and P75. Potassium intake from fortified products is not included in the calculations, but are evaluated to be very low.

Adults (n=1787)

The mean intake of potassium from the diet alone is 3797 mg/day (median 3634 mg/day) in adults (n=1787). The P5 intake is 2029 mg/day and the P95 intake is 5991 mg/day.

In Norkost 3, 24 participants (1%) reported use of potassium-containing supplements. Their mean total intake of potassium including that from food supplements is 3968 mg/day (median 3592 mg/day).

Mean intake of potassium from supplements alone in adults reporting use of potassium-containing supplements is 80 mg/day (median 35 mg/day).

In 13-year-olds (n=687)

The mean intake of potassium from the diet alone is 2465 mg/day (median 2360 mg/day) in 13-year-olds. The P5 intake is 1218 mg/day and the P95 intake is 4083 mg/day.

In Ungkost 3, no 13-year olds reported use of potassium-containing supplements.

In 9-year-olds (n=636)

The mean intake of potassium from the diet alone is 2356 mg/day (median 2302 mg/day) in 9-year-olds. The P5 intake is 1367 mg/day and the P95 intake is 3491 mg/day.

In Ungkost 3, no 9-year olds reported use of potassium-containing supplements.

In 4-year-olds (n=399)

The mean intake of potassium from the diet alone is 2121 mg/day (2090 mg/day) in 4-year-olds. The P5 intake is 1312 mg/day and the P95 intake is 3100 mg/day.

In Ungkost 3, only two 4-year olds reported use of potassium-containing supplements.

In 2-year-olds (1674)

The mean intake of potassium from the diet alone is 2338 mg/day (median 2250 mg/day) in 2-year-olds. The P5 intake is 1301 mg/day and the P95 intake is 3654 mg/day.

In Småbarnskost 2007, no 2-year olds reported use of potassium-containing supplements.

4 Assessment of the intakes of potassium

Dietary calculations have been performed for intake in P5, P25, mean, P50, P75 and P95 in children (2-, 4-, and 9-year-olds), adolescents (13-year-olds) and in adult men and women. Mean and median intake of potassium among adults, 2-, 4-, and 9-year-old children reaches the recommended intake by the NNR. Mean intake of potassium among adolescents (13-year-olds) did not reach the NNR recommended intake. Mean and median intakes of potassium among adults reached the NNR recommended intake. All age groups reached the recommended intake in P95 (Figure 4-1).

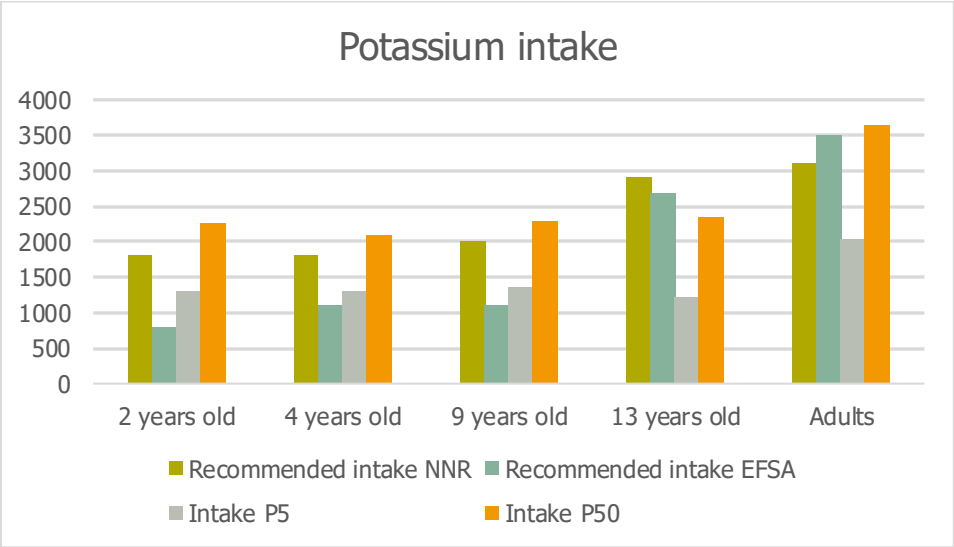

Figure 4-1 Recommended intake of potassium set by NNR 2012 and by EFSA 2016, and calculated intake of potassium from food at P5 and P50.

Use of supplements was low (24%) and only among adults. Mean intake of potassium from supplements alone among those reporting use of potassium-containing supplements was 80 mg/day (median 35 mg/day).

5 Uncertainties

For the determinations of the upper levels for potassium, IOM, EVM, NNR, VKM and EFSA have not reached the same conclusions, indicating uncertainty regarding establishment of these upper levels for adults, and have not mentioned upper levels for children and adolescents. Although some long-term RCTs are presented, and potassium supplementation in healthy subjects seems to be of low concern, the effects of freely sold potassium supplements on vulnerable groups are still unknown.

It should be noted that the intakes have been calculated based on various food consumption surveys for the different age categories and a comparison of calculations across age groups can be misleading. The calculated intakes in the higher and lower percentiles are always associated with a higher degree of uncertainty than mean or median intakes.

The percentile estimates of dietary intake are prone to random error due to the limited number of participants in the food consumption surveys. The largest degree of uncertainty is present in the estimated percentiles for 4-year-olds with a sample size of n=399, corresponding to about 20 observations below the 5-percentile and above the 95-percentile, respectively.

Another issue is the validity of the estimated exposure data. Low participation rates in the national food consumption surveys give rise to systematic errors and limit the representativeness of the participants compared with the background population in Norway. The participation rates among adults, 13-, 9-, 4- and 2-year-olds in the food consumption surveys were 37%, 53%, 55%, 20%, and 56%, respectively. In general, those participating had a considerably higher education level than the background population, and they are expected to represent a health-conscious subgroup of the population. Some population subgroups are not covered, e.g. ethnic minorities.

6 Answers to the terms of reference

The Norwegian Food Safety Authority (NFSA, Mattilsynet) has requested the Norwegian Scientific Committee for Food Safety (VKM) to assess the intake of potassium from the diet, including fortified products, in all age groups in the population above 1 year.

VKM was also requested to conduct scenario estimations to illustrate the consequences of amending maximum limits for potassium (to 300, 2000 or 3000 mg/day) in food supplements. The existing maximum limit for potassium in food supplements is 1000 mg/day, and is therefore included in the conclusion.

VKM proposes to use 3000 mg/day of potassium as an upper guidance level for daily dose of supplemental potassium in adults based on no reports on hyperkalaemia, heart failure or gastrointestinal lesions at that dose. Extrapolation of the suggested upper guidance level for food supplements to children based on body weight may be appropriate. The proposed 3000 mg/ day potassium suggested as upper guidance level for adults adjusted for body weights corresponds to 2600 mg/day for adolescents 14 to <18 years, 1860 mg/day for children 10 to < 14 years and 990 mg/day for children 3 to 10 years.

An overview of the conclusions is presented in Table 6-1.

Table 6-1: An overview of the conclusions for potassium according to doses in supplements.
Green: No exceedance of the suggested upper guidance level.
Red: Exceedance of the suggested upper guidance level.

Doses in supplements / Age group	300 mg/day	1000 mg/day	2000 mg/day	3000 mg/day
Adults > 18 years				
14 to <18 years				
10 to < 14 years				
3 to 10 years				

7 Data gaps

Because of lack of studies, no ULs could be set for potassium. More age groups should be included in dietary surveys in addition to subgroups like different ethnical groups.

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Appendix I

Summary tables of potassium intake for all age groups

Intakes of potassium in the various age groups are presented in the tables below. The tables summarise intakes from the diet alone, potassium-containing supplements alone (users only) and total intakes from both diet and supplements (Tables 1-2). Intakes are also given for both genders.

Table 1 Potassium intakes from diet alone in various age groups (mg/day).

	Adults (n=1787)	13 years (n= 687)	9 years (n=636)	4 years (n=399)	2 years (n=1674)
Potassium from diet alone, mean	3797	2465	2356	2121	2338
Potassium from diet alone, median	3634	2360	2302	2090	2250
Potassium from diet alone, P5	2029	1218	1367	1312	1301
Potassium from diet alone, P25	2947	1845	1873	1722	1839
Potassium from diet alone, P75	4534	2982	2780	2467	2740
Potassium from diet alone, P95	5991	4083	3491	3100	3654

Table 2 Potassium supplement users intake of total potassium from diet and supplements, and from supplements alone (users only), in adults (mg/day).

	Adults (n=24)
Total potassium from diet and supplements, mean	3968
Total potassium from diet and supplements, median	3592
Total potassium from diet and supplements, P5	-
Total potassium from diet and supplements, P25	-
Total potassium from diet and supplements, P75	-
Total potassium rom diet and supplements, P95	-
Potassium from supplements alone, mean	80
Potassium from supplements alone, median	35
Potassium from supplements alone, P5	-
Potassium from supplements alone, P25	-
Potassium from supplements alone, P75	-
Potassium from supplements alone, P95	-