

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to potassium and maintenance of normal muscular and neurological function (ID 320, 386) and maintenance of normal blood pressure (ID 321) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to potassium and maintenance of normal muscular and neurological function and maintenance of normal blood pressure. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is potassium, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that potassium is sufficiently characterised.

Muscular and neurological function (ID 320, 386)

The claimed effects are “signal transduction and muscle contraction” and “nerve function”. The target population is assumed to be the general population. The Panel considers that maintenance of normal muscular and neurological function is a beneficial physiological effect.

1 On request from the European Commission, Question No EFSA-Q-2008-1107, EFSA-Q-2008-1108, EFSA-Q-2008-1173, adopted on 21 December 2009.

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On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the dietary intake of potassium and normal muscular and neurological function.

Blood pressure (ID 321)

The claimed effect is “blood pressure”. The target population is assumed to be the general population. The Panel considers that maintenance of normal blood pressure is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that, even if one meta-analysis of RCTs did not observe an effect on BP following potassium supplementation, most observational and most of the RCTs reviewed in three meta-analyses, two of them including well controlled trials and adjustment for confounders, report a significant association/effect between potassium intake and lower BP. Although not all authoritative bodies agree on this association, European and American professional associations recommend to increase dietary potassium intakes for the prevention and management of human hypertension and biologically plausible mechanisms for these effects have been proposed.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the dietary intake of potassium and the maintenance of a normal blood pressure.

The Panel considers that, in order to bear the claims, a food should be at least a source of potassium as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

KEY WORDS

Potassium, electrolyte balance, muscle, nerves, blood pressure, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is potassium, which is a well recognised nutrient and can be measured by established methods. Potassium occurs naturally in foods in several forms, mainly as organic salts.

Different forms of potassium are authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006⁵ and Annex I of Directive 2002/46/EC⁶). This evaluation applies to potassium naturally present in foods and those forms authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006 and Annex I of Directive 2002/46/EC).

Potassium is naturally present in unprocessed foods mainly in association with bicarbonate-generating precursors such as citrate, and to lesser extent phosphate. Potassium is authorised for addition to foods for technological purposes (Regulation (EC) No 1333/2008⁷) and for addition to foods for nutritional purposes (Annex I of the Regulation (EC) No 1925/2006). Potassium is also authorised for use in food supplements (Annex II of the Directive 2002/46/EC). This evaluation applies to potassium naturally present in foods and those forms authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006).

The Panel considers that the food constituent, potassium, which is the subject of the health claims is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal muscular and neurological function (ID 320, 386)

The claimed effects are “signal transduction and muscle contraction” and “nerve function”. The Panel assumes that the target population is the general population.

The Panel considers that maintenance of normal muscular and neurological function is a beneficial physiological effect.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

⁵ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.

⁶ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

2.2. Maintenance of normal blood pressure (ID 321)

The claimed effect is “blood pressure”. The Panel assumes the target population is the general population.

In the context of the proposed wording, the Panel notes that the claimed effect relates to the maintenance of a normal blood pressure.

Blood pressure (BP) is the pressure (force per unit area) exerted by circulating blood on the walls of blood vessels. Elevated BP, by convention above 140 mmHg (systolic) and/or 90 mmHg (diastolic), may compromise the normal arterial and cardiac function.

The Panel considers that maintenance of normal blood pressure is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

Potassium is the major intracellular cation and plays a significant role in several physiological processes. Potassium has a crucial role in energy metabolism and membrane transport. A major function of potassium is membrane polarisation, which depends on the extra- and intra-cellular concentrations of potassium (gradient trans-membrane). Relatively small changes in the concentration of extracellular potassium greatly affect the gradient trans-membrane and thereby neural transmission, muscle contraction, and vascular tone (IoM, 2005; Preuss, 2006).

3.1. Maintenance of normal muscular and neurological function (ID 320, 386)

Approximately 98% of the total body potassium is located within the cell, where its concentration can be 30 times that of the extracellular fluid. Nevertheless, the concentration of potassium in the extracellular fluid is a critical determinant of neuromuscular excitability (EVM, 2002). Potassium deficiency or hypokalaemia is defined as low (below 137 mg/L or 3.5 mmol/L) plasma potassium concentrations. Hypokalaemia can be the result of either an intracellular shift of potassium, potassium depletion, or both (JHCI, 2003). Signs and symptoms of hypokalaemia owing to changes in the polarisation of cell membranes include muscle weakness, arrhythmia, cardiac arrest, and intestinal ileus. Mental depression and confusion can also develop (SCF, 1992).

The Panel notes that hypokalaemia rarely results from dietary inadequacy, but rather from crash diets, diarrhoea, diabetic acidosis, vomiting, intense or prolonged sweating, body burns and heavy urine losses owing to the use of diuretics (EVM, 2002).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of potassium and maintenance of normal muscular and neurological function.

3.2. Maintenance of normal blood pressure (ID 321)

Twenty three references have been provided, all pertinent for the assessment of the claimed effect, including statements from authoritative bodies (IoM, 2005; Lichtenstein et al., 2006, FDA, 2000; Appel et al., 2006), meta-analysis of randomised controlled trials (Capuccio and MacGregor, 1991; Whelton et al., 1997; Geleijnse et al., 2003), large observational studies (Dyer et al., 1994), as well as single studies on the effects of different potassium salts (He et al., 2005; Braschi and Naismith, 2008) or low doses of potassium (Naismith and Braschi, 2003) on BP.

The American Heart Association recommends increasing dietary potassium intakes to 4.7 g/d as a diet-related modification that effectively lowers BP (Appel et al., 2006; Lichtenstein et al., 2006) preferably by increasing consumption of potassium-rich foods (e.g. fruits and vegetables) instead of

supplements. This recommendation is in line with the recommendations from the US Food and Nutrition Board, which has set an intake of 4.7 g potassium per day from food as an adequate intake, mainly based on its blood pressure-lowering effects (IoM, 2005). In this report, data from a large number of observational studies reporting potassium intake (or urinary excretion of potassium as a proxy of intake) from foods were reviewed. Whereas potassium intake generally showed an inverse (and sodium intake a direct) association with BP values and/or the risk of hypertension, the sodium/potassium ratio was a stronger predictor than the intake of either electrolyte alone. Owing to the high colinearity between sodium and potassium intakes, the effects of either one on BP were difficult to estimate.

Most of the intervention studies on the effects of potassium on BP have been conducted with supplements of potassium chloride and have been reviewed in four meta-analysis of randomised controlled trials (RCTs) (Capuccio and MacGregor, 1991; Whelton et al., 1997; Geleijnse et al., 2003; Dickinson et al., 2006), three of them included in the US Food and Nutrition Board report (Capuccio and MacGregor, 1991; Whelton et al., 1997; Geleijnse et al., 2003). Three of the meta-analysis included exclusively trials where the only difference between the intervention and control groups was potassium intake (Whelton et al., 1997; Geleijnse et al., 2003; Dickinson et al., 2006).

The meta-analysis by Whelton et al. (1997) included 33 RCTs (2,609 subjects 18-79 years old), from which 12 trials were on normotensives (1,005 subjects) and 21 in hypertensives (1,560 subjects). Only in four trials subjects received concurrent antihypertensive medications. All but six trials provided potassium chloride as supplements. Systolic and diastolic BP significantly decreased with potassium supplementation as compared to placebo after adjustment for confounders, i.e., the effect size estimates were higher when only trials in non-pharmacologically treated subjects were considered (n=29). The effects were also more pronounced at higher urinary sodium excretions.

In the meta-analysis by Geleijnse et al. (2003), 27 RCTs with a mean duration of six weeks (range 2 to 114 weeks) were included. A significant reduction in systolic and diastolic BP was observed after adjustment for confounders with potassium supplementation as compared to placebo. Age, gender, and initial sodium and potassium excretion did not change the effect size estimates, but the effects were higher in hypertensive subjects.

The meta-analysis by Dickinson et al. (2006) included six RCTs (483 subjects older than 18 years) and observed large (but not significant) reductions in BP following potassium supplementation (8-16 weeks follow-up). The authors concluded that the evidence on the effects of potassium supplementation on BP is inconclusive owing to the large heterogeneity between trials.

The BP-lowering effect of potassium could be mediated by direct vasodilatation, by suppression of the sympathetic nervous system and the renin-angiotensin-aldosterone axis (COMA, 1991), and/or by its natriuretic effects (i.e. it increases urinary excretion of sodium chloride), which is independent of the accompanying ion (EFSA, 2005). This is supported by the observation that moderate potassium deficiency (without hypokalaemia) is characterised by increased BP and salt sensitivity, and that potassium lowers BP more in subjects with high sodium intakes. Potassium intake can also attenuate and even revert the hypertensive effects of sodium chloride in salt-sensitive individuals in a dose-dependent manner (IoM, 2005). Since data from observational studies has been obtained with potassium intakes from foods (as organic acids such as citrate) whereas intervention studies have been mostly conducted with potassium chloride, the effects on BP can likely be attributed to potassium itself independent on the accompanying ion (IoM, 2005).

In weighing the evidence, the Panel took into account that, even if one meta-analysis of RCTs did not observe an effect on BP following potassium supplementation (Dickinson et al., 2006), most observational and most of the RCTs reviewed in three meta-analyses (Whelton et al., 1997; Geleijnse et al., 2003; Dickinson et al., 2006), two of them including well controlled trials and adjustment for confounders, reported a significant association between potassium intake and lower BP. Although not

all bodies agree on this association (JHCI, 2003), European and American professional associations recommend increasing dietary potassium intakes for the prevention and management of human hypertension (Appel et al., 2006; Lichtenstein et al., 2006; Mancia, 2007) and biologically plausible mechanisms for these effects have been proposed.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of potassium and the maintenance of a normal blood pressure.

4. Panel's comments on the proposed wording

4.1. Maintenance of normal muscular and neurological function

The Panel considers that the following wording reflects the scientific evidence: "Potassium contributes to normal muscular and neurological function."

4.2. Maintenance of normal blood pressure

The Panel considers that the following wording reflects the scientific evidence: "Potassium helps maintain normal blood pressure."

5. Conditions and possible restrictions of use

The Panel considers that in order to bear the claims a food should be at least a source of potassium as per Annex to Regulation 1924/2006. Tolerable Upper Intake Levels (UL) have not been established for potassium in children, adolescents and adults (EFSA, 2006).

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, potassium, which is the subject of the health claims is sufficiently characterised.

Maintenance of normal muscular and neurological function (ID 320, 386)

- The claimed effects are "signal transduction and muscle contraction" and "nerve function". The target population is assumed to be the general population. Maintenance of normal muscular and neurological function is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of potassium and the maintenance of normal muscular and neurological function.
- The following wording reflects the scientific evidence: "Potassium contributes to normal muscular and neurological function."

Maintenance of normal blood pressure (ID 321)

- The claimed effect is "blood pressure". The target population is assumed to be the general population. Maintenance of normal blood pressure is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of potassium and the maintenance of a normal blood pressure.

- The following wording reflects the scientific evidence: “Potassium helps maintain normal blood pressure.”.

Conditions and possible restrictions of use

- In order to bear the claims a food should be at least a source of potassium as per Annex to Regulation 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1107, EFSA-Q-2008-1108, EFSA-Q-2008-1173). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation (EC) No 1924/2006 on nutrition and health claims made on foods⁸ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁹

Foods are commonly involved in many different functions¹⁰ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁸ OJ L12, 18/01/2007

⁹ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

¹⁰ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to potassium including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food component	Health Relationship	Proposed wording
320	Potassium	Signal transduction and muscle contraction	Potassium is needed for muscle function
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Erwachsene, 100 – 500 mg, upper limit 1000 mg - Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungsverordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten. - Kalium in Verbindung mit Magnesium ist essentiell für eine rhythmische Herzarbeit und ordnungsgemäße Kontraktion von Herzmuskelzellen. - MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 		
321	Food or Food constituent	Health Relationship	Proposed wording
	Potassium	Blood pressure	<p>Increasing Potassium intake helps maintain healthy blood pressure;</p> <p>Potassium helps promote healthy blood pressure;</p> <p>Potassium is important for keeping blood pressure healthy</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - Erwachsene, 30ml for 4-6 Wochen - MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG - muss den relevanten Bestimmungen der ClaimsVO entsprechen - Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungsverordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten. - 100 mg Nahrungsergänzung - Daily amount to be consumed to produce claimed effect: 3100 miligram(s), No factors that could interfere with bioavailability, Habitual intake. Provided that renal function is normal, it is almost impossible to induce potassium overload by dietary means alone. Excessive use of supplemental forms of potassium can cause acute hyperkalaemia. Intakes above 450mmol (17.6g) may induce symptomatic hyperkalaemia in some individuals and would represent a threshold for acute toxicity. 			
386	Food or Food component	Health Relationship	Proposed wording
	<p>Name of Food product: Potassium</p> <p>Description of food in terms of food legislation</p>	<p>Health benefits of food: Potassium plays an important role in nerve function</p>	<p>Exact wording of claim as it appears on product:</p> <p>Potassium benefits nerve function</p> <p>Examples of any alternative wording</p>

	<p>categories: food not covered by specific food legislation</p> <p>Was food on Irish market before 1st July 2007: Yes</p>	<p>Do benefits relate to a disease risk factor: No</p> <p>Target group: All of the general population including children and adults</p>	<p>that may be used in relation to claim: Potassium plays an important role in nerve function</p> <p>Is claim a picture: No</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - Daily amount to be consumed to produce claimed effect: 3100 miligram(s). Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: Habitual intake. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know. Provided that renal function is normal, it is almost impossible to induce potassium overload by dietary means alone. Excessive use of supplemental forms of potassium can cause acute hyperkalaemia. Intakes above 450mmol (17.6g) may induce symptomatic hyperkalaemia in some individuals and would represent a threshold for acute toxicity. 			