



THE TOMATO FOUNDATION

Vitamin E & Potassium

Tomato products and existing health claims in multiple territories

A Practical Guide to Usage & Labelling

The doctor of the future will give no medicines, but will interest his patients in the care of the human frame, in diet, and in the causes and prevention of disease.

(Thomas Edison)

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INTERNAL USE ONLY

Prologue

This short guide lays out some of the usage possibilities for health claims accessible through Potassium and Vitamin E content across the range of tomato products and in selected territories.

Disclaimer

The information supplied is not to be considered exhaustive and is to be referenced solely as a start point for more specific investigation. It comprises the views of the Tomato Foundation and does not constitute legal or other professional advice. The Tomato Foundation is not liable for any damages arising from its use.

Health claim basics

A health claim is any statement about a relationship between food and health.

Claims must be based on the current relevant scientific data and be sufficient to substantiate the claimed effect and the relationship to health.

As per *Codex*, health claim refers to any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Stated types of such claims include:

Nutrient function claims: A nutrition claim that describes the physiological role of the nutrient in the growth, development and normal functions of the body.

For example, 'Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A.'

Other function claims: These claims concern specific beneficial effects of the consumption of foods or their constituents in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health, improvement of a function, modifying or preserving health.

For example, 'Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A.'

Reduction of disease risk claims: Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

For example, 'A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A' or 'A healthful diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A'.

Governance and nomenclature of actual health claim types vary by territory.

Vitamin E

Vitamin E is a fat-soluble antioxidant found in many foods.

Although naturally occurring in 8 chemical forms, alpha- (or α -) tocopherol is the only form that is recognised to meet human requirements.

It helps to protect cells from the damage caused by free radicals. Free radicals are compounds formed when our bodies convert the food we eat into energy. People are also exposed to free radicals in the environment from cigarette smoke, air pollution, and ultraviolet light from the sun.

Scientists are investigating whether, by limiting free radical production and possibly through other mechanisms, vitamin E might help prevent or delay the chronic diseases associated with free radicals.

The body also needs vitamin E to boost its immune system so that it can fight off invading bacteria and viruses. It helps to widen blood vessels and keep blood from clotting within them. In addition, cells use vitamin E to interact with each other and to carry out many important functions.

Potassium

Potassium is an essential nutrient found in many foods. It is present in all body tissues and is required for normal cell function. The body needs potassium for almost everything it does, including proper kidney and heart function, muscle contraction, and nerve transmission.

Potassium has a strong relationship with sodium.

Territories

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The European Union (inc. UK)

Regulatory body: European Food Safety Authority (EFSA)

Types of health claim:

- 13.1 'General function' health claim
- 13.5 'New function' health claim
- 14.1a 'Risk reduction' health claim
- 14.1b 'Child development' health claim
- Nutrition claim

Recommended daily amounts:

- RDA (Recommended Daily Allowance)
- DRV (Dietary Reference Value)
- PRI (Population Reference Intake)
- AI (Adequate Intake)

<https://efsa.gitlab.io/multimedia/drvs/index.htm>

Standardised serving sizes:

Not defined.

Used in place - 100g, 100ml, single serving pack.

Vitamin E health claim

13.1 - Protection of DNA, proteins and lipids from oxidative damage (2010;8(10):1816)

Permitted wording

‘Vitamin E contributes to the protection of cells from oxidative stress’

Conditions of use

Claim may be used by foods (solids and liquids) containing more than 15% of the RDA (12mg)

> 1.8mg per 100g/100ml/single serving pack.

Claim may be used on beverages (excluding single serving packs) containing more than 7.5% of the RDA

> 0.9mg per 100ml.

Regulations

The claim may be used only for food which is at least a source of vitamin E as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1924-20121129&from=EN>

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<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0496:20081211:EN:PDF>

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<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32011R1169&from=EN#d1e32-61-1>

(Annex XIII)

Potassium Health Claims

13.1 - Muscular and neurological function (nervous system)
(2010;8(2):1469)

13.1 - Muscular and neurological function (muscle function)
(2010;8(2):1469)

13.1 - Blood pressure (2010;8(2):1469)

Permitted wording

‘Potassium contributes to normal functioning of the nervous system’

‘Potassium contributes to normal muscle function’

‘Potassium contributes to the maintenance of normal blood pressure’

Conditions of use

Claim may be used by foods (solids and liquids) containing more than 15% of the RDA (2000mg*) > 300mg per 100g/100ml/single serving pack.

Claim may be used on beverages (excluding single serving packs) containing more than 7.5% of the RDA > 150mg per 100ml.

*Amount proposed to rise to 3500mg/day. Timeframe unknown.

Regulations

As above, with addition of

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2017.e15121>

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United States of America

Regulatory body: Food and Drug Administration (FDA)

Types of health claim:

Authorized health claim

Health Claim based on Authoritative Statement

Nutrient content claim

Qualified health claim

Structure/Function claim

Recommended daily amounts:

RDA (Recommended Dietary Allowance)

DV (Daily Value)

EAR (Estimated Average Requirement)

<https://www.fda.gov/food/new-nutrition-facts-label/daily-value-new-nutrition-and-supplement-facts-labels>

Standardised serving sizes:

RACC (Reference Amounts Customarily Consumed).

Varies according to product type - <https://www.fda.gov/media/102587/download>

Vitamin E health claim

Nutrient content claim (*not a health claim*)

Permitted wording

‘Good source of Vitamin E’

‘Excellent source of Vitamin E’

Conditions of use

‘Good source of...’ wording may be used by foods containing more than 10% of the DV (15mg)

> 1.5mg per RACC.

‘Excellent source of...’ wording may be used by foods containing more than 20% of the DV (15mg)

> 3mg per RACC.

Regulations

The term ‘good source’ may be used on the label provided that the food contains 10-19 percent or more of the RDI or the DRV per reference amount customarily consumed.

The terms ‘high’ or ‘excellent source of...’ may be used on the label provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

<https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements#:~:text=Nutrient%20content%20claims%20describe%20he.more%2C%20reduced%2C%20and%20lite.>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.54>

(Section 101.54)

Potassium Health Claim

Health Claim based on Authoritative Statement

Permitted wording

‘Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke’

Conditions of use

**Claim may be used by foods containing more than 10% of the DV (4700mg*) AND ‘low in sodium’
>470mg potassium AND <140mg** sodium per RACC**

*DV amount increased from 3500mg in 2020

**If the RACC < 30g, sodium levels should measure 140mg or less per 50g serving

Regulations

Foods qualifying for the proposed claim must be a "good source of potassium" (contain 10 percent or more of the Daily Value for potassium) and be "low in sodium." Therefore, qualifying foods must have at least 470 mg of potassium per reference amount customarily consumed (RACC), and 140 mg or less of sodium per RACC.

In addition, qualifying foods also must be "low in fat," "low in saturated fat," and "low in cholesterol." Therefore, qualifying foods must contain 3 g or less of total fat per RACC, 1 g or less of saturated fatty acids per RACC, and not more than 15 percent of calories from saturated fatty acids. They also must contain 20 mg or less of cholesterol per RACC.

[https://www.fda.gov/food/food-labeling-nutrition/health-claim-notification-potassium-containing-foods#:~:text=The%20notification%2C%20as%20amended%2C%20states,reference%20amount%20customarily%20consumed%20\(RACC\)](https://www.fda.gov/food/food-labeling-nutrition/health-claim-notification-potassium-containing-foods#:~:text=The%20notification%2C%20as%20amended%2C%20states,reference%20amount%20customarily%20consumed%20(RACC))

Canada

Regulatory body: Food Directorate of Health Canada

Types of health claim:

- Disease risk reduction health claim
- Function health claim
- General health claim
- Nutrition (nutrient content) claim

Recommended daily amounts:

DV (Daily Value)

<https://www.canada.ca/en/health-canada/services/technical-documents-labelling-requirements/table-daily-values/nutrition-labelling.html#p1>

Standardised serving sizes:

RA (Reference Amount).

Varies according to product type - <https://www.canada.ca/en/health-canada/services/technical-documents-labelling-requirements/table-reference-amounts-food/nutrition-labelling.html#v>

Vitamin E health claim

Function claim

Permitted wording

‘A source of / good source of / excellent source of Vitamin E, a dietary antioxidant’

‘A source of / good source of / excellent source of Vitamin E, a dietary antioxidant that protects the fat in body tissues from oxidation’

Conditions of use

Claim with ‘Source of...’ wording may be used by foods containing more than 5% of the DV (15mg)

> 0.75mg per RA.

Claim with ‘Good source of...’ wording may be used by foods containing more than 15% of the DV (15mg)

> 2.25mg per RA.

Claim with ‘Excellent source of...’ wording may be used by foods containing more than 25% of the DV (15mg)

> 3.75mg per RA.

Regulations

On the label or advertisement for a food, it is not permissible to make a statement or claim that characterizes the vitamin or mineral content of a food unless:

- *a Daily value (DV) for the vitamin or mineral has been established [D.01.004(1)(a), D.02.002(1)(a), FDR]*

- a minimum of 5% of the DV per serving of stated size is present for the vitamin or mineral that is the subject of the claim [D.01.004(1)(b), D.02.002(1)(b), FDR]
- the vitamin or mineral content is declared as a percentage of the daily value per serving of stated size [D.01.004(1)(c), D.02.002(1)(c), FDR]
- the claim is one of the specific permitted exceptions

Nutrition Facts table must include a declaration of the content of the claimed vitamin or mineral nutrient per serving of stated size, both in terms of absolute amount and % Daily value (% DV).

<https://inspection.canada.ca/food-label-requirements/labelling/industry/nutrient-content/specific-claim-requirements/eng/1389907770176/1389907817577?chap=13>

<https://inspection.canada.ca/food-label-requirements/labelling/industry/health-claims-on-food-labels/eng/1392834838383/1392834887794?chap=9#s16c9>

Potassium Health Claim

Disease risk reduction health claim

Permitted wording

'A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is a good source of / high in potassium and is low in sodium.'

Conditions of use

Claim may be used by foods containing more than 10% of the DV (4700mg*) AND 'low in sodium' >470mg potassium AND <140mg sodium per RA

*If the RA < 30g, sodium levels should measure 140mg or less per 50g serving

Regulations

The food

- (a) other than a vegetable or fruit, does not meet the conditions set out in column 2 of the subject "low in energy" set out in item (b) of the Summary Table of Energy and Calorie Claims.*
- (b) contains at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient (see Weighted Recommended Nutrient Intake Table),*
 - (i) per reference amount and per serving of stated size, or*
 - (ii) per serving of stated size, if the food is a prepackaged meal;*
- (c) meets the conditions set out in column 2 of the subject "low in saturated fatty acids" set out in item (b) of the Summary Table of Saturated Fatty Acid Claims;*
- (d) contains 0.5% or less alcohol;*
- (e) meets the conditions set out in column 2 of the subject "free of sodium or salt" set out in item a) of the Summary Table for Sodium (Salt) Claims, if the label of or advertisement for the food carries statement or claim (1), (3), or (5) set out in column 1 of this item;*

(f) meets the conditions set out in column 2 of the subject "low in sodium or salt" set out in item b) of the Summary Table for Sodium (Salt) Claims, if the label of or advertisement of the food carries statement or claim (2), (4), or (6) set out in column 1 of this item; and

(g) contains 470 mg or more of potassium, if the label of or advertisement for the food carries statement or claims (3), (4), (5), or (6) set out in column 1 of this item,

(i) per reference amount and per serving of stated size, or

(ii) per serving of stated size, if the food is a prepackaged meal.

<https://inspection.canada.ca/food-label-requirements/labelling/industry/health-claims-on-food-labels/eng/1392834838383/1392834887794?chap=7#s8c7>

Australia and New Zealand

Regulatory body: Food Standards Australia New Zealand (FSANZ)

Types of health claim:

High level health claim
General level health claim
Nutrient content claim

Recommended daily amounts:

NRV (Nutrient Reference Value)
RDI (Recommended Daily Intake)
<https://www.nrv.gov.au/node/3>

Standardised serving sizes:

Not defined.
Used in place - 100g, 100ml.

Vitamin E health claim

General level health claim

Permitted wording

‘Vitamin E contributes to cell protection from free radical damage’

‘Good source of Vitamin E, which contributes to cell protection from free radical damage’

Conditions of use

Claim may be used by foods containing more than 10% of the RDI (10mg) > 1 mg per 100g/100ml.

Claim with ‘Good source of...’ wording may be used by foods containing more than 25% of the RDI (10mg) > 2.5 mg per 100g/100ml.

Regulations

- a) The vitamin or mineral is mentioned in Column 1 of the table to section S1–2 or S1–3; and
- b) a serving of the food contains at least 10% *RDI or *ESADDI for that vitamin or mineral; and
- c) a claim is not for more of the particular vitamin or mineral than the amount permitted by section 1.3.2–4 or 1.3.2–5; and
- d) the food is not any of the following:
 - (i) a formulated caffeinated beverage;
 - (ii) food for infants;
 - (iii) a formulated meal replacement;
 - (iv) a formulated supplementary food;
 - (v) a formulated supplementary sports food.

Paragraph (b) does not apply where:

- (i) a maximum claimable amount applies in relation to the mineral or vitamin; and*
- (ii) the serving size is less than the reference quantity; and*
- (iii) the reference quantity contains at least 10% *RDI or *ESADDI for the vitamin or mineral; and*
- (iv) the maximum claimable amount is less than 10% *RDI or *ESADDI per serving.*

<https://www.foodstandards.gov.au/code/Documents/Sched%204%20Nutrition%20and%20health%20claims%20v159.pdf>

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Potassium Health Claim

None.

Content indicated on the nutrition information panel.

Regulations

The nutrition information panel indicates the sodium and potassium content.

<https://www.foodstandards.gov.au/industry/labelling/Pages/Potassium-and-blood-pressure.aspx>

<https://www.legislation.gov.au/Details/F2017C00711>

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Japan

Regulatory body: Consumer Affairs Agency

Types of health claim:

Foods with Nutrient Function Claims (FNFC)

Foods with Function Claims (FFC)

Foods for Specified Health Uses (FOSHU)

(4 FOSHU types - Regular, Qualified, Standardized, Reduction of disease risk)

Food for Special Dietary Uses (FOSDU)

Recommended daily amounts:

RDA (Recommended Dietary Allowance)

EAR (Estimated Average Requirement)

AI (Adequate Intake)

<https://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/Overview.pdf>

Standardised serving sizes:

Used in place - 100g, 100ml, serving, package.

Vitamin E health claim

Food with Nutrient Function Claim

Permitted wording

'Vitamin E helps to protect fat in the body from being oxidized and to maintain the cell health'

Conditions of use

Claim may be used by foods (solids) containing nutrient between a range of upper and lower limits.

> 2.4* mg per 100g, serving, package.

Claim may be used by foods (liquids) containing nutrient between a range of upper and lower limits.

> 1.2 mg per 100ml, serving, package.

Upper range is 150mg. Labels must also carry a 'Warning indication' message.

*Lower range possibly redefined as 1.89mg

<https://www.sciencedirect.com/science/article/pii/S0924224416303806>

(Table 1)

Regulations

Amount of nutritional ingredient in the recommended daily intake of the product must be within the specified range.

Not only the nutrient function claims but also the warning indications must be displayed.

<https://www.mhlw.go.jp/english/topics/foodsafety/fhc/01.html>

<https://www.mhlw.go.jp/english/topics/foodsafety/fhc/04.html>

Potassium Health Claim

Food with Nutrient Function Claim

Permitted wording

'Necessary for maintenance of normal blood pressure'

Conditions of use

Claim may be used by foods (solids) containing nutrient between a range of upper and lower limits.

> 840mg per 100g, serving, package.

Claim may be used by foods (liquids) containing nutrient between a range of upper and lower limits.

> 420mg per 100ml, serving, package.

Upper range is 2800mg. Labels must also carry a 'Warning indication' message.

Regulations

Amount of nutritional ingredient in the recommended daily intake of the product must be within the specified range.

Not only the nutrient function claims but also the warning indications must be displayed.

<https://www.sciencedirect.com/science/article/pii/S0924224416303806>

(Table 1)

India

Regulatory body: Food Safety and Standards Authority of India (FSSAI)

Types of health claim:

Nutrient Function claim

Other Function claim

Reduction of disease risk claim

Recommended daily amounts:

RDA (Recommended Dietary Allowance)

[https://www.fssai.gov.in/upload/advisories/](https://www.fssai.gov.in/upload/advisories/2020/01/5e159e0a809bbLetter_RDA_08_01_2020.pdf)

[2020/01/5e159e0a809bbLetter_RDA_08_01_2020.pdf](https://www.fssai.gov.in/upload/advisories/2020/01/5e159e0a809bbLetter_RDA_08_01_2020.pdf)

Standardised serving sizes:

Used in place - 100g, 100ml.

Vitamin E health claim

Nutrient content claim (*not a health claim*)

Permitted wording

‘Source of / Provides / Contains Vitamin E’

‘High in / Higher / Increased / More / Rich in / Vitamin E’

Conditions of use

‘Source of...’ wording may be used by foods (solids) containing more than 15% of the RDA (10mg)

> 1.5mg per 100g.

‘Source of...’ wording may be used by foods (liquids) containing more than 7.5% of the RDA (10mg)

> 0.75mg per 100ml.

‘High in...’ wording may be used by foods (solids) containing more than 30% of the RDA (10mg)

> 3mg per 100g.

‘High in...’ wording may be used by foods (liquids) containing more than 15% of the RDA (10mg)

> 1.5mg per 100ml.

Regulations

A claim that a food containing the nutrient mentioned in column (2) is likely to have the benefits as mentioned in column (3) or has the same meaning for the consumer may be made subject to the conditions as mentioned in column (4).

<https://fssai.gov.in/upload/uploadfiles/files/>

[Compendium Advertising Claims Regulations 04_03_2021.pdf](#)

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Potassium Health Claim

Nutrient function claim

Permitted wording

Diets containing good sources of potassium and low in sodium, fat and saturated fat may help reduce the risk of high blood pressure.

Conditions of use

Claim may be used by foods (solids) containing more than 15% of the *RDA (3750mg)* and less than 0.12 g of sodium, 3g of fat and 1.5g of saturated fat per 100g > 562.5mg and < 0.12g of sodium, < 3g of fat, < 1.5g of saturated fat per 100g

Claim may be used by foods (liquids) containing more than 7.5% of the *RDA (3750mg)* and less than 0.12g of sodium, 1.5g of fat and 0.75g of saturated fat per 100ml > 281.25mg and < 0.12g of sodium, < 1.5g of fat, < 0.75g of saturated fat per 100ml.

Regulations

'...the food is a good source of potassium and is low in sodium and low in total fat and saturated fat.'

<https://fssai.gov.in/upload/uploadfiles/files/>

[Compendium Advertising Claims Regulations 04_03_2021.pdf](#)

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