

<b>Project Start Date</b>	<b>01/01/03</b>
<b>Project End Date</b>	<b>30/06/03</b>
<b>Project Code</b>	<b>ZQ0203</b>

# JHCI

Joint Health Claims Initiative

PO Box 43, Leatherhead

Surrey, KT22 7ZW

Ph: 01372 822 378

Fax: 01372 822 288

[www.jhci.co.uk](http://www.jhci.co.uk)

**JHCI Ref: JHCI/76/03**

## **FINAL TECHNICAL REPORT**

### **PART 1:**

**A Process to Define and Identify Well-Established Health Statements**

### **PART 2:**

**A list of Well-Established Nutrient Function Statements**

A report by the Joint Health Claims Initiative to the Food Standards Agency

Prepared by  
JHCI Executive Director

17<sup>th</sup> Dec 2003

# Table of Contents

Executive Summary.....	4
Introduction.....	8
Objectives and Aims.....	10
Scope of Work.....	12
Part 1: A Process to Define and Identify Well-Established Health Statements	13
Part 2: A List of Well-Established Nutrient Function Statements:	
• Adoption of the process developed in Part 1.....	14
• Overview of methodology.....	15
• Detailed methodology.....	16
• Discussion and recommendations.....	23
• General references.....	25
<b>Results:</b>	
Table 1a: Well-established nutrient function statements (common to all vitamins and minerals).....	26
Table 1b: Well-established nutrient function statements (specific to certain vitamins and minerals).....	27
Table 2: Rejected nutrient function statements.....	38
<b>Annexes:</b>	
Annex 1: The Joint Health Claims Initiative background information...	49
Annex 2: Evaluation Report of a pilot study.....	51
Annex 3: Nomenclature of nutrients.....	63
Annex 4: Index to quotes from source documents.....	66
Annex 5: Source document reference list.....	262

# EXECUTIVE SUMMARY

## Background

In recognition of the growing need to protect and promote public health, the European Commission has recently adopted a draft proposal for a Regulation on nutrition and health claims, which will require that all health claims for food be approved before they are released on the market. This includes the adoption of a list of health claims based on well-established science although at this stage the Commission has not yet defined a process for identifying well-established health claims, or addressed the issue of how to handle existing health claims on the European market.

The Commission welcomes contributions and suggestions from Member States, and as such, the Food Standards Agency commissioned the Joint Health Claims Initiative to develop a framework and produce an initial list of well-established health statements on which claims could be based.

In the absence of specific controls on health claims, the Food Standards Agency supports the work of the UK Joint Health Claims Initiative (JHCI), a democratic group that represents the concerned interests of the consumer movement, the food industry and food law enforcement officers. A Code of Practice for Health Claims for Food has been developed by JHCI and an Expert Committee of independent, respected scientists has been created to assess the scientific validity of claims (further details about the work of the JHCI can be found at [www.jhci.co.uk](http://www.jhci.co.uk)).

## Purpose

The objectives of this project were to deliver:

- (i) a process to define and identify well-established health statements, and
- (ii) a list of well-established nutrient-function statements for twenty-eight vitamins and minerals.

This work was undertaken primarily to help inform the UK position during negotiations with the European Commission on its proposed legislation for nutrition and health claims. In addition to presenting a ‘tried and tested’ process and real examples of well-established nutrient function statements during negotiations, it is also expected that the results of this report will form the UK’s contribution to a European-wide list “of permitted claims describing the role of a nutrient or other substance in growth, development and normal physiological functions of the body”, which are “based on long-established and non-controversial science” (Brussels, 16.7.2003, COM (2003) 424 final).

It is also envisaged that this report could:

- assist in the development of a mechanism for handling health claims that are already on the market when the health claims legislation comes into force. This will help ensure that suitable products carrying well-established statements are not withdrawn from the market unnecessarily;
- provide a framework for identifying well-established health statements that are based on generally accepted scientific data, which could, over time, be used as a tool to add well-established claims to the European-wide list described above;
- provide a transparent process for fast-track approvals of well-established health claims in the UK, until such time as the European legislation has been implemented; and
- provide a list of well-established nutrient function statements for 28 vitamins and minerals for regulators wishing to determine the scientific accuracy of related health claims on products being sold to consumers.

## **The process**

Before the list of well-established health statements could be produced it was necessary, firstly, to define 'well-established', given that this can mean different things to different people. For example, it could mean that a health claim is in common usage or has been on the market for many years. But it might also, more legitimately, mean that a health claim is well attested by a vast body of knowledge and is, for example, to be found in textbooks of nutrition. For the purposes of this project, well-established was defined as 'Consistent reporting in the majority of source documents of relevant functions'.

Secondly, it was necessary to set out a clear process for deciding whether or not statements were in fact 'well-established'. Therefore the process, developed in the first part of the project, explains how the list of well-established nutrient function statements was produced. Full details of this process have been documented in the Final Technical Report.

Essentially, the process involved selecting and reviewing reports of respected scientific committees to assess the consistency in reporting about nutrients and their functions. Information provided by the USA's Institute of Medicine's (IOM) publications on Dietary Reference Intakes was used as a starting point for drawing up a list of possible functions, as these documents are internationally recognised and based on objective studies in humans.

Reports by reputable expert groups from the UK and Europe were also reviewed, both to cross-check and demonstrate consistency in the functions reported by the IOM and to anglicise the health statements for the UK population.

## **The list**

The process was designed to define and identify well-established health statements for any dietary component, from vitamins to whole foods, and any type of health benefit, including those related to enhanced functions and functions that reduce the risk of developing disease.

However, the second part of the project was limited to identifying well-established statements for 28 vitamins and minerals listed in Annex 1 to the Food Supplements Directive (2002).

Statements were also limited to those linked to a health effect in the body that were based on normal physiological functions and were related to quantities of nutrients that can be obtained from a normal diet. To ensure that the statements were related to normal structures and functions only, they had to correspond with the following structured phraseology: 'x is necessary for / contributes to the normal structure / function of y'.

It must be noted that the statements included on the final list were not considered in terms of their legal acceptability or meaningfulness to consumers, nor were they considered in terms of their application to food products, and, as such, are not approved health claims for food.

These limitations were adopted to ensure the timely provision of information to the Food Standards Agency during its negotiations with the European Commission on the forthcoming nutrition and health claims legislation.

## **The method**

Monographs were prepared for each nutrient by reviewing the agreed source documents and quoting relevant functions that met specified inclusion criteria (see Final Technical Report for details). The monographs were presented to an independent committee of scientific experts (the JHCI Expert Committee), which made a recommendation about the inclusion of the statements to final list. A second independent party (the JHCI Council) ratified the experts' recommendations, ensuring a consistent and transparent approach has been applied throughout the process to generate the statements.

This project successfully developed a robust and transparent process to define and identify well-established health statements. The application of which has resulted in 82 well-established nutrient function statements, which were presented in two groups:

- a) Well-established nutrient function statements common to all vitamins and minerals.
- b) Well-established nutrient function statements specific to certain vitamins and minerals.

Statements that did not meet the criteria for inclusion on the final list were also noted, together with their reasons for rejection. This was usually, for example, because the function was already captured by, or the result of, functions encapsulated by another statement; they did not relate to a normal structure or function role in the body; the data was insufficient or inconsistent; or there was not a plausible mechanism to support the supposed function.

The statements have been limited to quantities of nutrients that can be obtained from a normal diet and therefore functions based on pharmacological levels of intake have not been considered. Although the remit of this project did not include quantification of the statements, it is recommended that such work be carried out in the future, so that consumers are aware of the quantities of nutrients required from their diet in order to maintain these normal physiological functions.

This research demonstrates that a model framework for adopting well-established health statements is workable and effective and, as such, could be adapted for use by other European Member States during the development of the Community-wide list of well-established health claims. By doing so, it is hoped that a smooth transition period will follow the implementation of the proposed nutrition and health claims Regulation and minimise the unnecessary withdrawal and subsequent return of legitimate, well-established health claims that have already been on the market for some time.

The Joint Health Claims Initiative, in due course, intends to publish an expanded list of approved generic health claims. This will include those well-established nutrient function statements, which, after consultation with members of the JHCI Council with expertise in current UK food law and the consumer perception of health claims, are considered to be legally acceptable and are likely to be meaningful and not misleading to consumers.

**Until such time however, the statements are not approved for use as health claims on food products.**

# INTRODUCTION

In recent years the European Community has seen rapid growth in consumer demand for healthier food choices. Together with the growing body of evidence for the beneficial effects of certain foods and nutrients on health, this has resulted in the increased use of health claims on food products. It is important that information on labels, in advertising or in other promotional contexts about the health benefits of the food is scientifically accurate, meaningful to consumers and honest.

Current UK legislation on claims includes the Food Safety Act 1990 and the Trade Descriptions Act 1968, which prohibit false and misleading claims. In addition, the Food Labelling Regulations 1996 (as amended) lay down the labelling requirements of foods generally and prohibits medicinal claims, that is, claims that a food will prevent, treat or cure a disease. In the absence of specific controls on health claims, the Food Standards Agency supports the work of the UK Joint Health Claims Initiative (JHCI), a democratic group that represents the concerned interests of the consumer movement, the food industry and food law enforcement officers. A Code of Practice has been developed by JHCI and an Expert Committee of independent, respected scientists has been created to assess the scientific validity of claims (further details about the work of the JHCI and the members of its Council and Expert Committee have been included as Annex 1).

The JHCI Code of Practice defines a health claim as: ‘A direct, indirect or implied claim in food labelling, advertising and promotion that consumption of a food carries a specific health benefit or avoids a specific health detriment’. The JHCI process for approving a health claim for food is rigorous, as it not only considers the validity of health statements, but also the legitimacy of their application to food products. Due to the reliance on submissions from interested parties, and the comprehensive nature of the validation process, expansion of the list of JHCI validated health claims has been slower than expected.

The European Commission has adopted a Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods. This proposal is likely to institute a pre-market approval system for health claims, which includes the development of a positive list, or ‘Register’, of health claims based on “generally accepted data”. However, the Commission has not yet proposed a definition of “generally accepted data”, nor has it addressed the issue of how to handle existing health claims on the European market.

There are few data available about the range of existing health claims in the UK market. The Food Standards Agency is addressing this information gap by commissioning a market audit of health claims, due for publication in late 2003. In the meantime, the JHCI operates to provide, to those who seek it, an opinion on the validity and application of health claims. To date the JHCI has considered six generic health claim applications, which then raises questions about the authenticity of health claims that do not appear on the list of JHCI approved claims, or have not been publicly vetted by independent experts.

Such claims may be considered to be well-established, because of their common usage or because they have been in use for many years, on the assumption that they are supported by “generally accepted data”. But in the absence of a positive list of validated well-established claims, the sometimes inconsistent and exaggerated use of the facts have led to consumer confusion and scepticism about the truthfulness of some health claims.

The Food Standards Agency is committed to help ensure that consumers are not misled as to the safety or nature of foodstuffs. As such, it commissioned the JHCI to develop a process to define and identify claims that are well-established because they are substantiated by scientific statements of fact that are found in a range of credible reference documents.

To demonstrate the workability of the process to identify well-established health statements, a list of ‘well-established nutrient function statements’ has been generated. The process is applicable to any type of health claim, or any dietary component. To begin with its application has been limited to the identification of well-established normal functions for the 28 vitamins and minerals, which may be found in food products, listed in Annex 1 to the Food Supplements Directive (2002/46/EC).

The process, together with the list of well-established nutrient function statements, has been developed primarily to assist the Food Standards Agency in negotiations with the European Commission on its forthcoming nutrition and health claims legislation.

The JHCI intends, in due course, to use the well-established nutrient function statements as a basis to expand its list of approved generic health claims by including statements that are deemed suitable for use on food products, in terms of legal and consumer acceptability.



# **OBJECTIVES AND AIMS**

## **OBJECTIVE 1:**

**To develop a process for defining and identifying well-established health statements**

### **Aim 1.1**

To help inform the UK position during negotiations with the European Commission on its forthcoming nutrition and health claims legislation.

### **Aim 1.2**

To assist in the development of a mechanism for handling existing health claims during the implementation of the forthcoming nutrition and health claims legislation.

### **Aim 1.3**

To provide a framework for identifying claims that are based on generally accepted scientific data, which can be added to a positive list of well-established health claims for use by European member states.

### **Aim 1.4**

To provide a transparent process for fast-track approvals of well-established health claims in the UK, in the absence of forthcoming nutrition and health claims legislation.

## **OBJECTIVE 2:**

**To use the process at objective 1 to produce a list of well-established nutrient-function statements**

### **Aim 2.1**

To demonstrate the workability and rigour of the process developed at objective 1.

### **Aim 2.2**

To help further inform the UK position during negotiations with the European Commission on its forthcoming nutrition and health claims legislation.

### **Aim 2.3**

To help form the UK's contribution to a European-wide positive list of well-established health statements.

**Aim 2.4**

To provide a list of well-established nutrient function statements for 28 vitamins and minerals listed in Annex 1 to the Food Supplements Directive (2002/46/EC) for regulators wishing to determine the scientific accuracy of related health claims.

**Aim 2.5**

To provide a basis for comparative analyses of health claims currently on the market in the UK.

# SCOPE OF WORK

## Scope of Work

Objective 2 (to produce a list of well-established nutrient-function statements) has been limited to the generation of statements that:

- i) are based on well-established scientific evidence - not emerging scientific evidence;
- ii) are linked to a health effect in the body which is based on a normal physiological function - not an enhanced function; function that reduces the risk of developing a disease; or, function that can be attributed to the prevention, treatment or cure of a disease;
- iii) are restricted to the vitamins and minerals listed in the Annex 1 to the Food Supplements Directive (2002/46/EC);
- iv) are related to quantities of nutrients that can be obtained from a normal diet - not pharmacological quantities which may be present in foods or supplements;
- v) have not been considered in terms of their legal acceptability or meaningfulness to consumers; and
- vi) have not been considered in terms of their application to food products and as such **are not approved health claims for food.**

These limitations were adopted to ensure the timely provision of information to the Food Standards Agency during its negotiations with the European Commission on the forthcoming nutrition and health claims legislation.

The Agency envisages that, in the future and by using the process presented in Part 1, the list of well-established health statements could be expanded to include statements that relate to all relevant dietary components, and to enhanced functions or functions that reduce the risk of developing disease.

# **PART 1**

## **A Process to Identify and Define Well-Established Health Statements**

This process has been designed to define and identify well-established health statements for any dietary component, from micronutrients to whole foods, and any type of health benefit, including those related to enhanced functions and functions that reduce the risk of developing disease.

This process does not involve consideration of the potential application of the statements to food products, in terms of their legal acceptability or meaningfulness to consumers, and therefore does not result in a list of approved health claims. It does however provide a sound scientific basis for generating health claims from well-established scientific statements of fact.

### **Steps to define and identify well-established health statements:**

- Step 1.** Clearly define 'well-established'.
- Step 2.** Determine priority order for groups of nutrients, dietary components and types of potential health claims to be considered.
- Step 3.** Establish working definitions as necessary.
- Step 4.** Agree credible source documents, to draw up a list of possible functions, effects or benefits for nutrients and dietary components, and to identify which of these functions are 'well established'.
- Step 5.** Develop phraseology as necessary to provide a guide for wording of statements.
- Step 6.** Draw up list of well-established health statements.

## **PART 2**

# **A list of Well-Established Nutrient Function Statements**

### **Adoption of the Process to Define and Identify Well-established Health Statements, developed in Part 1**

The Process to Define and Identify Well-Established Health Statements was adopted and approved for use following a pilot study using vitamin C to test the workability of Steps 1 – 6. An evaluation, including refinements to the process following the pilot study, has been included as Annex 2.

This process has been employed to produce a list of well-established nutrient function statements for the vitamins and minerals listed in Annex 1 to the Food Supplements Directive (2002/46/EC). For the purposes of this project, consideration has been given only to statements linked to health effects in the body which are based on normal physiological functions - not enhanced functions, functions that reduce the risk of developing a disease, or, functions that that can be attributed to the prevention, treatment or cure of a disease.

# METHODOLOGY

## Overview of methodology

The following is an overview of the methodology employed by the JHCI to develop a list of well-established nutrient function statements, using the process developed at Part 1 to produce the list resulting from Part 2. A detailed description of this methodology is presented in the next section.

I. Completion of Steps 1 – 5 of the Process to Define and Identify Well-established Health Statements:

*Step 1: Clearly define ‘well-established’.*

*Step 2: Determine priority order for groups of nutrients, dietary components and types of potential health claims to be considered.*

*Step 3: Establish working definitions as necessary.*

*Step 4: Agree credible source documents, to draw up a list of possible functions, effects or benefits for nutrients and dietary components, and to identify which of these functions are ‘well established’.*

*Step 5: Develop phraseology as necessary to provide a guide for wording of statements.*

II. Preparation of monographs for each nutrient, by reviewing the agreed source documents and quoting relevant functions that meet inclusion criteria.

III. Generation of statements using phraseology as a guide.

IV. Recommendation by independent experts (in this case, the JHCI Expert Committee), about the inclusion of statements to final list.

V. Revision of the list of well-established nutrient function statements, in accordance with recommendations by the independent experts.

VI. Ratification, by a second independent party (in this case, the JHCI Council), of the experts’ recommendations, ensuring a consistent and transparent approach has been applied throughout the process to generate the statements.

VII. Completion of Step 6 of the Process to Define and Identify Well-established Health Statements:

*Step 6: Draw up list of well-established health statements.*

## **Detailed methodology**

### **I. Completion of Steps 1 – 5 of the Process to Define and Identify Well-established Health Statements**

#### **Step 1:**

***Clearly define ‘well-established’.***

For the purposes of this process, ‘well-established’ has been defined as:

‘Consistent reporting in the majority of source documents of relevant functions’.

It was considered unrealistic for all source documents to be consistent in their reporting of relevant functions, due to variations in the date of publication and with emerging evidence contained in the more recent documents.

#### **Step 2:**

***Determine priority order for groups of nutrients, dietary components and types of potential health claims to be considered.***

For the purposes of this project the following list of nutrients, Annex 1 to the Food Supplements Directive (2002/46/EC), has been selected. It is considered likely that reference to these nutrients will be made in the forthcoming European nutrition and health claims legislation:

Vitamin A	Calcium
Vitamin D	Magnesium
Vitamin E	Iron
Vitamin K	Copper
Thiamin (B <sub>1</sub> )	Iodine
Riboflavin (B <sub>2</sub> )	Zinc
Niacin	Manganese
Pantothenic Acid	Sodium
Vitamin B <sub>6</sub>	Potassium
Folate	Selenium
Vitamin B <sub>12</sub>	Chromium
Biotin	Molybdenum
Vitamin C	Fluoride
	Chloride
	Phosphorus

Alternative nomenclature for these nutrients has been included as Annex 3, as listed in the British Journal of Nutrition’s ‘Directions to Contributors’.

In order to ensure the timely provision of information to the Food Standards Agency during its negotiations with the European Commission on the forthcoming nutrition and health claims legislation, consideration has been given only to nutrient function statements linked to health effects in the body which are based on a normal physiological functions.

**Step 3:**

***Establish working definitions as necessary.***

**i) Well-established**

‘Consistent reporting in the majority of source documents of relevant functions’  
(As agreed in Step 1)

**ii) Nutrient function**

‘A claim that describes the physiological role of the nutrient in growth, development and normal functions of the body’  
(Codex Guidelines for the Use of Nutrition Claims, CAC/GL 23-1997).

**iii) Health statement**

‘A statement related to a health benefit, or the avoidance of a health detriment’  
(adapted from JHCI Code of Practice, 2000)

**Step 4:**

***Agree credible source documents, to draw up a list of possible functions, effects or benefits for nutrients and dietary components and to identify which of these functions are ‘well-established’.***

Information provided by the USA’s Institute of Medicine’s (IOM) publications on Dietary Reference Intakes has been used as a starting point for drawing up a list of possible functions, as these documents are internationally recognised and based on systematic reviews of in vivo evidence.

Reports by reputable expert groups from the UK and Europe have also been reviewed, both to cross-check and demonstrate consistency in the functions reported by the IOM and to anglicise the health statements for the UK population. The UK Expert Group on Vitamins and Minerals (EVM) has recently published its findings on Safe Upper Levels for Vitamins and Minerals (May 2003). As this final report was not published at the time that JHCI undertook its reviews of vitamins and minerals, draft reports of the EVM on Safe Upper Levels for Vitamins and Minerals were used instead (see Source document Reference List, page 264, for details).

**Reference Groups**

The complete list of source documents is presented in Annex 5. References have been grouped according to the expert group that produced the report, to demonstrate consistency used in the range of source documents reviewed, as follows:



**Reference Group 1:**

US Institute of Medicine - Dietary reference intakes for vitamins and minerals (1997 – 2001).

**Reference Group 2:**

*'Encyclopedia of Human Nutrition 2E'*.

Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego: Academic Press, c1999.

**Reference Group 3:**

Reports of the European Scientific Committee on Food (1992 - 2003).

**Reference Group 4:**

Draft Reports of the UK Expert Group on Vitamins and Minerals (2002).

**Reference Group 5:**

*Handbook of Nutrition and Food*. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.

**Reference Group 6:**

Reports of the UK Committee on Medical Aspects of Food and Nutrition Policy (1991 – 2000).

**Reference Group 7:**

*Introduction to Human Nutrition*. Edited on behalf of The Nutrition Society by Michael J. Gibney, Hester H. Vorster and Frans J. Kok. Blackwell Science, September 2002.

**Reference Group 8:**

Reports of the British Nutrition Foundation Task Force (1989 – 1995).

**Reference Group 9:**

International Life Sciences Institute (Europe) Concise Monograph Series (1999).

**Step 5:**

***Develop phraseology as necessary to provide a guide for wording of statements***

To provide a framework to develop standardised health statements the nutrient function statements have been phrased according to the following structured phraseology:

a) 'x is necessary for / contributes to the normal structure / function of y'

or

b) 'x is necessary for / contributes to normal z'

Where:

- **x** is a vitamin or mineral listed in Annex 1 of the Food Supplements Directive (2002)
- **x** is 'necessary for' 'y' or 'z' if the structure / function cannot occur without them
- **y** is the whole body; a bodily system (e.g. cardiovascular system); organ (e.g. heart,); a tissue (e.g. blood); or a component of a tissue (e.g. red blood cells)
- **z** is a normal function of the body (e.g. metabolism) or a specific function (e.g. oxidative processes)

## **II. Preparation of a monograph for each nutrient, by reviewing the agreed source documents and quoting relevant functions**

### **Selection of source documents for each nutrient**

- Source documents from reference groups 1 – 4 have been reviewed for all nutrients, except for iron, sodium, potassium, fluoride and chloride, for which alternative source documents were used in the absence of reports from groups 1 – 4 (refer to Annexes 4.16, 4.21, 4.22, 4.26 and 4.27 respectively for detailed reference lists for these nutrients).
- Additional documents were reviewed for many nutrients following the advice of independent experts about reputable source documents for specific nutrients. This was necessary in cases where an expert group had not yet undertaken a review of a specific nutrient, or when additional clarity about the role of the nutrient was required.
- The actual source documents reviewed for each nutrient are listed together with quotes presented in Annex 4, in addition to the full Reference List found in Annex 5.

### **Criteria for the inclusion of quotes**

Quotes were selected for inclusion if they:

- i) stated the role of the nutrient in normal physiological functions in humans; and
- ii) related to quantities of nutrients that can be obtained from a normal diet; and
- iii) were supported by a corresponding quote in at least one other source document; and
- iv) illustrated the range of consistency in the reporting of the role of the nutrient in normal physiological functions; and
- v) represented the totality of evidence in relation to the functions cited in the source documents; and
- vi) provided supporting information about:
  - classical symptoms of clinical deficiency; and
  - plausible mechanisms of the role of the nutrient in normal physiological functions; and
  - possible influences of the role of the nutrient in normal physiological functions on disease endpoints.

### **Criteria for the exclusion of quotes**

Quotes were not selected for inclusion if they:

- i) related to enhanced functions, functions that reduce the risk of developing a disease, or, functions that that can be attributed to the prevention, treatment or cure of a disease; or
- ii) related to quantities of the nutrient over and above that which can be obtained from the normal diet; or
- iii) were not supported by a corresponding quote in at least one other source document.

### III. Generation of statements using phraseology as a guide

Statements were generated for well-established nutrient functions by categorising the information to reflect the phraseology described in Step 5, as follows:

Nutrient	Effect on	Necessary for	Contributes to	Normal structure	Normal function
Vitamin A	Vision	✓			✓

Resulting in the nutrient function statement:

Vitamin A is necessary for normal vision.
---

#### **Well-established nutrient function statements common to all vitamins and minerals**

All of the nutrients reviewed are essential and necessary for health and normal body functions including: reproduction; conception; development; growth and body maintenance. Such statements considered to be well-established have been presented in Table 1a and are phrased, for example, as follows: *'Zinc contributes to normal development'*, whereby the word 'contributes' indicates that all nutrients have an equally essential role in these general functions.

#### **Well-established nutrient function statements specific to certain vitamins and minerals**

Table 1b focuses on specific, notable functions for individual nutrients. Some nutrients have a particularly significant role in the general functions mentioned above and have therefore warranted an additional statement in Table 1b. Such statements have been phrased, for example, as follows, *'Zinc contributes to normal reproductive development'*, to indicate that the nutrient has an essential role over and above that which is listed in the table of statements common to all vitamins and minerals (Table 1a). The word 'necessary' has been used in Table 1b when the structure / function cannot occur without the relevant nutrient.

Results of the review of nutrients have therefore been summarised in three tables:

Table 1a: Well-established nutrient function statements common to all vitamins and minerals.

Table 1b: Well-established nutrient function statements specific to certain vitamins and minerals.

Table 2: Rejected nutrient function statements.

#### **IV. Recommendation by independent experts about the inclusion of statements to final list**

A list of the names of the independent experts (in this case, the JHCI Expert Committee) involved in this project has been included as Annex 1.

##### **Criteria for the inclusion of statements**

Statements were recommended for inclusion on the final list when the independent experts agreed that:

- i) they complied with the definitions for ‘well-established’, ‘nutrient function’ and ‘health statement’, as set out in Step 3; and
- ii) the wording of the statement was based on correct interpretation of the evidence; and
- iii) the functions allowed for a scientifically accurate health statement; and
- iv) there was sufficient data to substantiate the health statement; and
- v) there was consistent data to substantiate the health statement; and
- vi) there was a plausible mechanism.

##### **Reasons for the exclusion of statements**

Statements that did not meet all of the above criteria were recommended for rejection from the final list. The independent experts assigned one of the following reasons for exclusion, which correspond with the inclusion criteria, to each rejected statement:

- i) No (not a health statement)
- ii) No (inaccurate interpretation of evidence)
- iii) No (too imprecise)
- iv) No (data insufficient)
- v) No (data inconsistent)
- vi) No (no plausible mechanism)

Additionally, statements were rejected if the experts considered that the related function was captured by, or the result of, functions encapsulated in another statement. The reason for exclusion was recorded as follows, together with the code of the relevant included statement, as follows, as in Table 2, page 38:

- vii) No (see [*e.g.*] VA1b)

The independent experts also considered that a number of statements related to functions that were common to all the vitamins and minerals reviewed. Such statements were moved to Table 1a and appear in Table 2 with the following reason for rejection, as in Table 2, page 39:

- viii) No (see Table 1a)

##### **Exceptions**

The independent experts recommended that two statements that did not meet the above criteria were also included in the final list. The first was in relation to beta-carotene, but because it was considered to provide a valuable source of vitamin A for vegetarians it was recommended for inclusion (refer Table 1b, page 27).

The second was a statement in relation to fluoride, which did not strictly fit the criteria for either a 'normal structure' or 'normal function' statement for teeth, but because of its significant role in the maintenance of healthy teeth it was recommended for inclusion (refer F11a, Table 1b, page 37).

**V. Revision of the list of well-established nutrient function statements, in accordance with recommendations by the independent experts**

Where necessary, this part of the process involved refinements to the wording of the statements, for scientific accuracy, or a further review of the evidence in cases where the experts sought clarification about particular nutrient functions. Following these amendments, the list was prepared for ratification by a second independent party.

**VI. Ratification, by a second independent party, of the experts' recommendations**

After consideration of the experts' recommendations, a second independent party (in this case, the JHCI Council) endorsed the list of well-established nutrient function statements and agreed that a consistent and transparent approach had been applied throughout the process to generate the statements. A list of the names of the second independent party involved in this project has been included as Annex 1.

**VII. Completion of Step 6 of the Process to Define and Identify Well-established Health Statements**

The final list of well-established nutrient function statements, for the nutrients listed in Annex 1 to the Food Supplements Directive (2002/46/EC), is presented in Tables 1a and 1b.

## DISCUSSION AND RECOMMENDATIONS

This project has successfully developed, tested and adopted a robust and transparent process to define and identify well-established health statements. The application of the process has resulted in 82 well-established nutrient function statements and demonstrated that the process is workable. It is recommended that this process should now be used to identify well-established health statements for other dietary components and other types of health benefit, including those related to enhanced functions and functions that reduce the risk of developing disease. The process is likely to be useful not only in the development of a European-wide positive list of well-established health claims, but also in the identification of health statements that are not supported by a body of consistent, well-established data.

### Points to Note

It should be noted that during the review of nutrients some anomalies were encountered in the application of the process. The manner in which these were addressed is presented below:

- i) **Exceptions to the definitions and standard phraseology.** It was essential to clearly define the scope of the review (in this case to normal structural and functional roles for pre-specified nutrients), to facilitate the development of standardised statements and demonstrate the workability and reliability of the process. Two exceptions were made however, in relation to fluoride and tooth enamel and beta-carotene as a source of vitamin A (refer page 20 for details).
- ii) **Inconsistent use of reference material.** Whilst the process pre-determined the source documents to be used for reviewing all nutrients, this was not always possible. Many of the reports focused primarily on toxicity and safety data than on nutrient functions, therefore additional sources were required for some nutrients. On such occasions, guidance was sought from the independent scientists for additional reputable source documents.
- iii) **Identification of the primary role of the nutrient.** It was necessary to present statements in terms of the nutrient's direct function (for example vitamin C as a co-factor in collagen formation), rather than an indirect, or secondary function (for example, collagen's role in the structure of skin).
- iv) **Determination of a tangible effect in humans.** On a number of occasions it was not possible to determine the health outcome that resulted from the nutrient function. Such functions have been rejected on the basis that they did not meet the definition of a health statement; 'a statement related to a health benefit, or the avoidance of a health detriment' (refer to Table 2 for rejected statements).

## Issues requiring further consideration

**Quantification of statements.** The second part of this project was limited to identifying well-established health statements that related to quantities of nutrients obtainable from a normal diet, rather than functions based on pharmacological levels of intake. The remit of this project did not include quantification of the statements, and as such, it is recommended that work to quantify these, and other statements, be carried out in the future.

**Extrapolation from deficiency data.** A number of nutrient function statements in this report have been based on deficiency state data and therefore the assumption that the absence of clinical deficiency symptoms equates to a 'normal' function. However, further consideration ought to be given to whether these statements are true only in very specific circumstances and apply only during the disease or deficiency state.

**Risk assessment framework.** Application of the process developed under Objective 1 has demonstrated that it is relatively simple to identify scientifically valid statements of fact. What is more complicated is the determination of whether the statements can be applied to foods as a health claim, particularly when they relate to nutrients that are considered to be harmful when consumed at certain levels (for example sodium and vitamin A). A risk assessment framework should be developed to identify health statements that are likely to prove contentious in relation to particular nutrients and areas of concern to public health.

**From health statements to health claims.** This review has resulted in 82 well-established nutrient function statements, however not all of these statements will be applied to foods as health claims. The JHCI intends to consider each statement for its legal acceptability, to help ensure that the resulting claims are meaningful and easily understood by consumers and to produce guidelines for the application of the resulting claims. The context of the statements will need to be carefully considered, for example it should not be implied that 'more is better' in cases where evidence for the physiological function relates only to consumption of the Recommended Daily Amount (RDA). It is recommended that the Food Standards Agency undertake research into consumer understanding of the possible health claims resulting from the list.

## Summary of Recommendations

- i) That the process is now applied to other dietary components and other types of health benefits to develop a comprehensive list of well-established health statements.
- ii) That further work be carried out to quantify the well-established nutrient function statements.
- iii) That consideration be given to the accuracy in extrapolating deficiency state data to normal physiological functions.
- iv) That a risk assessment framework be developed in relation to particular nutrients and areas of concern to public health.
- v) That research be undertaken to ascertain likely consumer understanding of potential claims that may be developed from the list.

## **GENERAL REFERENCES**

Section 15, Food Safety Act 1990 (UK).

Section 1, Trade Descriptions Act 1968 (UK).

Food Labelling Regulations 1996 (as amended) (UK).

Joint Health Claims Initiative Code of Practice on Health Claims on Foods (December 2000).

Joint Health Claims Initiative Guidelines for Preparing Dossiers to Substantiate Health Claims (February 2002, version 1.0).

Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods (Brussels, 16.7.2003, COM(2003) 424 final).

JHCI Generic Claims Considered ([www.jhci.co.uk](http://www.jhci.co.uk)).

Directive 2002/46/EC of the European Parliament and of the Council of 10<sup>th</sup> June 2002 on the approximation of the laws of the Member States relating to food supplements, Annex 1.

British Journal of Nutrition's 'Directions to Contributors'.

Guidelines for the Use of Nutrition Claims (CAC/GL 23-1997). Codex Alimentarius, Food Labelling, Complete Texts, Revised 2001; Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Rome.



## RESULTS

### Presentation of the results

Each health statement presented in Table 1b or Table 2 has been assigned a code, which relates to the supporting quotes presented in Annex 4. Nutrients are listed in the order that they appear in Annex 1 of the Food Supplement Directive (2002/46/EC).

### Criteria for the inclusion of statements (check previous page and bring across)

Statements were recommended for inclusion on the final list when the independent experts agreed that:

- i) they complied with the definitions for ‘well-established’, ‘nutrient function’ and ‘health statement’, as set out in Step 3; and
- ii) the wording of the statements was based on correct interpretation of the evidence; and
- iii) the functions allowed for a scientifically accurate health statement; and
- iv) there was sufficient data to substantiate the health statement; and
- v) there was consistent data to substantiate the health statement; and
- vi) there was a plausible mechanism.

**Table 1a: Well-established nutrient function statements (common to all vitamins and minerals)**

Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
1. Reproduction		✓		✓	‘X’ contributes to normal reproduction.	Yes	Yes
2. Conception		✓		✓	‘X’ contributes to normal conception.	Yes	Yes
3. Development		✓	✓		‘X’ contributes to normal development.	Yes	Yes
4. Growth		✓	✓		‘X’ contributes to normal growth.	Yes	Yes
5. Body maintenance		✓		✓	‘X’ contributes to normal body maintenance.	Yes	Yes

**Table 1b: Approved well-established nutrient function statements (specific to certain vitamins and minerals)**

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>VITAMIN A</b>								
NB:								
a) Epidemiological studies have indicated that high levels of Vitamin A (retinol and retinoic acid) during pregnancy might increase the risk of birth defects <sup>#</sup>								
b) Beta-carotene can be converted to Vitamin A. Where beta-carotene is the main source the following statements could be preceded by: "Beta-carotene can be converted to Vitamin A. Vitamin A is necessary for / contributes to..." <sup>*</sup>								
VA1b	1b. Vision	✓			✓	Vitamin A is necessary for normal vision.	Yes	Yes
VA2	2. Skin and mucous membranes	✓		✓	✓	Vitamin A is necessary for the normal structure and function of the skin and mucous membranes (such as in the lung, intestines, nose, eyes and female reproductive tract).	Yes	Yes
VA4	4. Cell differentiation	✓			✓	Vitamin A is necessary for normal cell differentiation (such as in the immune system).	Yes	Yes
<b>VITAMIN D</b> (NB: Sufficient vitamin D can be synthesised in the body with adequate exposure to sunlight).								
VD1	1. Calcium and phosphorus absorption and utilisation	✓			✓	Vitamin D is necessary for the normal absorption and utilisation of calcium & phosphorus.	Yes	Yes

<sup>#</sup> *Safe Upper Levels for Vitamins and Minerals*. Expert Group on Vitamins and Minerals, May 2003 (<http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf>)

<sup>\*</sup> Exception; see page 21

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
VD2a	2a. Cell division		✓		✓	Vitamin D contributes to normal cell division.	Yes	Yes
VD3	3. Bone	✓		✓		Vitamin D is necessary for the normal structure of bone.	Yes	Yes
<b>VITAMIN E</b>								
VE1	1. Antioxidant activity	✓			✓	Vitamin E is necessary for cell protection from the damage caused by free radicals (such as the oxidation of polyunsaturated fatty acids in red blood cell membranes).	Yes	Yes
<b>VITAMIN K</b>								
VK1	1. Coagulation	✓			✓	Vitamin K is necessary for normal coagulation (blood clotting).	Yes	Yes
VK2	2. Bone		✓	✓		Vitamin K contributes to the normal structure of bone.	Yes	Yes
<b>THIAMIN</b>								
Th1	1. Carbohydrate metabolism	✓			✓	Thiamin is necessary for the normal metabolism of carbohydrates.	Yes	Yes
Th2	2. Neurological and cardiac systems	✓			✓	Thiamin is necessary for normal neurological and cardiac function.	Yes	Yes

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>RIBOFLAVIN</b>								
Ri1	1. Release of energy from food		✓		✓	Riboflavin contributes to the normal release of energy from food.	Yes	Yes
Ri2	2. Transport and metabolism of iron		✓		✓	Riboflavin contributes to the normal transport and metabolism of iron in the body.	Yes	Yes
Ri3	3. Mucous membranes		✓	✓		Riboflavin contributes to the normal structure of mucous membranes (such as the surface of the tongue, the mouth, eyes and intestines).	Yes	Yes
<b>NIACIN</b> (NB: Sufficient niacin can be synthesised in the body with an adequate dietary intake of protein or tryptophan.)								
Ni1	1. Release of energy from food	✓			✓	Niacin is necessary for the normal release of energy from food.	Yes	Yes
Ni4	4. Skin and mucous membranes	✓		✓	✓	Niacin is necessary for the normal structure and function of skin and mucous membranes (such as in the intestines).	Yes	Yes
Ni5	5. Neurological system	✓			✓	Niacin is necessary for normal neurological function.	Yes	Yes
<b>PANTOTHENIC ACID</b>								
Pa1	1. Fat metabolism	✓			✓	Pantothenic acid is necessary for the normal metabolism of fat.	Yes	Yes

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>VITAMIN B<sub>6</sub></b>								
VB <sub>6</sub> 1	1. Protein metabolism	✓			✓	Vitamin B <sub>6</sub> is necessary for the normal metabolism of protein.	Yes	Yes
VB <sub>6</sub> 2	2. Transport and metabolism of iron	✓			✓	Vitamin B <sub>6</sub> is necessary for the normal transport and metabolism of iron in the body.	Yes	Yes
VB <sub>6</sub> 4	4. Homocysteine metabolism		✓		✓	Vitamin B <sub>6</sub> contributes to the maintenance of normal blood homocysteine levels.	Yes	Yes
<b>FOLATE</b>								
Fo1	1. Cell division	✓			✓	Folate is necessary for normal cell division (such as in the gastrointestinal tract).	Yes	Yes
Fo2	2. Developing neural tube	✓		✓		Folate is necessary for the normal structure of the neural tube in developing embryos.	Yes	Yes
Fo4	4. Blood formation	✓			✓	Folate is necessary for normal blood formation.	Yes	Yes
Fo5	5. Homocysteine metabolism		✓		✓	Folate contributes to the maintenance of normal blood homocysteine levels.	Yes	Yes

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>VITAMIN B<sub>12</sub></b>								
VB <sub>12</sub> 1a	1a. Cell division	✓			✓	Vitamin B <sub>2</sub> is necessary for normal cell division (such as in the gastrointestinal tract).	Yes	Yes
VB <sub>12</sub> 1b	1b. Blood formation		✓		✓	Vitamin B <sub>2</sub> contributes to normal blood formation.	Yes	Yes
VB <sub>12</sub> 2	2. Neurological system	✓		✓	✓	Vitamin B <sub>2</sub> is necessary for the normal structure and function of the neurological system.	Yes	Yes
VB <sub>12</sub> 4	4. Homocysteine metabolism		✓		✓	Vitamin B <sub>2</sub> contributes to the maintenance of normal blood homocysteine levels.	Yes	Yes
<b>BIOTIN</b>								
Bi1	1. Fat metabolism and energy production		✓		✓	Biotin contributes to normal fat metabolism and energy production.	Yes	Yes
<b>VITAMIN C</b>								
VC1	1. Connective tissue	✓		✓	✓	Vitamin C is necessary for the normal structure and function of connective tissue (such as that required for normal gums, skin, healing processes, bone and cartilage).	Yes	Yes

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
VC5	5. Blood vessels	✓		✓	✓	Vitamin C is necessary for the normal structure and function of blood vessels.	Yes	Yes
VC9	9. Iron absorption		✓		✓	Vitamin C contributes to the absorption of iron from food.	Yes	Yes
VC10	10. Antioxidant activity		✓		✓	Vitamin C contributes to cell protection from the damage caused by free radicals (such as epithelial cell integrity).	Yes	Yes
VC12	12. Neurological system	✓			✓	Vitamin C is necessary for normal neurological function.	Yes	Yes
<b>CALCIUM</b>								
Ca1	1. Bones and teeth	✓		✓		Calcium is necessary for the normal structure of bones and teeth.	Yes	Yes
Ca2	2. Nerves and muscle	✓			✓	Calcium is necessary for normal nerve and muscle function.	Yes	Yes
Ca3	3. Coagulation	✓			✓	Calcium is necessary for normal coagulation (blood clotting).	Yes	Yes
<b>MAGNESIUM</b>								
Mg1	1. Energy metabolism	✓			✓	Magnesium is necessary for normal energy metabolism.	Yes	Yes

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
Mg3	3. Electrolyte balance	✓			✓	Magnesium is necessary for normal electrolyte balance.	Yes	Yes
Mg4	4. Nerve and muscle	✓			✓	Magnesium is necessary for normal nerve and muscle function.	Yes	Yes
Mg6	6. Bone and teeth	✓		✓		Magnesium is necessary for the normal structure of bone and teeth.	Yes	Yes
<b>IRON</b>								
Fe1	1. Oxygen transport	✓			✓	Iron is necessary for the normal transport of oxygen in the body.	Yes	Yes
Fe2	2. Energy production		✓		✓	Iron contributes to normal energy production.	Yes	Yes
Fe3	3. Metabolism of foreign substances		✓		✓	Iron contributes to the body's ability to metabolise drugs and other substances.	Yes	Yes
Fe5	5. Immune system	✓			✓	Iron is necessary for the normal function of the immune system.	Yes	Yes
Fe7	7. Blood formation		✓	✓		Iron contributes to normal blood formation.	Yes	Yes
Fe8	8. Neurological development in embryos	✓			✓	Iron is necessary for normal neurological development in embryos.	Yes	Yes



Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>COPPER</b>								
Cu1	1. Connective tissues		✓	✓		Copper contributes to the normal structure of connective tissues (such as in bone, lungs and the vascular system).	Yes	Yes
Cu2	2. Transport and metabolism of iron		✓		✓	Copper contributes to the normal transport and metabolism of iron in the body.	Yes	Yes
Cu5	5. Antioxidant activity		✓		✓	Copper contributes to cell protection from the damage caused by free radicals (for example, as a constituent of superoxide dismutase).	Yes	Yes
Cu4	4. Energy production	✓			✓	Copper is necessary for normal energy production.	Yes	Yes
Cu6	6. Neurological system	✓			✓	Copper is necessary for normal neurological function.	Yes	Yes
Cu7	7. Immune system	✓			✓	Copper is necessary for the normal function of the immune system.	Yes	Yes
Cu12	12. Skin and hair pigment	✓		✓		Copper is necessary for normal colouration of skin and hair.	Yes	Yes
<b>IODINE</b>								
I1	1. Production of thyroid hormones	✓			✓	Iodine is necessary for the normal production of thyroid hormones.	Yes	Yes

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
I3	3. Neurological development	✓		✓		Iodine is necessary for normal neurological development.	Yes	Yes
I4	4. Energy metabolism	✓			✓	Iodine is necessary for normal energy metabolism.	Yes	Yes
<b>ZINC</b>								
Zn1	1. Immune system	✓			✓	Zinc is necessary for the normal function of the immune system.	Yes	Yes
Zn2	2. Cell division	✓			✓	Zinc is necessary for normal cell division.	Yes	Yes
Zn7	7. Reproductive development		✓	✓		Zinc contributes to normal reproductive development.	Yes	Yes
Zn8	8. Skin and wound healing		✓	✓	✓	Zinc contributes to the normal structure of skin and normal wound healing.	Yes	Yes
<b>MANGANESE</b>								
Mn1	1. Bone formation		✓	✓		Manganese contributes to normal bone formation.	Yes	Yes
Mn2	2. Energy metabolism		✓		✓	Manganese contributes to normal energy metabolism.	Yes	Yes
Mn3	3. Antioxidant activity		✓		✓	Manganese contributes to cell protection from the damage caused by free radicals (such as the superoxide free radical).	Yes	Yes

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>SODIUM</b> (NB: It is essential that consumers continue to be encouraged to reduce sodium intake)								
Na1	1. Water and electrolyte balance	✓			✓	Sodium is necessary for normal water and electrolyte balance throughout the body.	Yes	Yes
Na4	4. Nutrient absorption	✓			✓	Sodium is necessary for the normal absorption of nutrients during digestion (such as the active transport of nutrients and water from the gut).	Yes	Yes
<b>POTASSIUM</b> (NB: It is essential that consumers continue to be encouraged to increase potassium intake)								
K1	1. Water and electrolyte balance	✓			✓	Potassium is necessary for normal water and electrolyte balance throughout the body.	Yes	Yes
<b>SELENIUM</b>								
Se1	1. Antioxidant activity	✓			✓	Selenium is necessary for cell protection from some types of damage caused by free radicals.	Yes	Yes
Se2	2. Utilization of iodine in the production of thyroid hormones	✓			✓	Selenium is necessary for the normal utilization of iodine in the production of thyroid hormones.	Yes	Yes
Se7	7. Immune system	✓			✓	Selenium is necessary for the normal function of the immune system.	Yes	Yes
<b>CHROMIUM</b>								

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>MOLYBDENUM</b>								
<b>FLUORIDE</b> (NB: The following statement relates to an enhanced function rather than an essential function)								
Fl1a	1a. Teeth		✓			Fluoride contributes to the maintenance of healthy teeth.*	Yes	Yes
<b>CHLORIDE</b>								
Cl1	1. Water and electrolyte balance	✓			✓	Chloride is necessary for normal water and electrolyte balance throughout the body.	Yes	Yes
Cl2	2. Stomach acid and digestion	✓			✓	Chloride is necessary for the normal production of hydrochloric acid in the stomach, which is required for digestion.	Yes	Yes
<b>PHOSPHORUS</b>								
P1	1. Bone and teeth	✓		✓		Phosphorus is necessary for the normal structure of bone and teeth.	Yes	Yes
P2	2. Cell membranes	✓		✓		Phosphorus is necessary for the normal structure of cell membranes, in the form of phospholipids.	Yes	Yes
P4	4. Energy metabolism	✓			✓	Phosphorus is necessary for normal energy metabolism.	Yes	Yes

---

\* Exception; see page 22

**Table 2: Rejected nutrient function statements**

**Reasons for the exclusion of statements**

Statements that did not meet all of the inclusion criteria were recommended for rejection from the final list. The independent experts assigned one of the following reasons for exclusion, which correspond with the inclusion criteria, to each rejected statement:

- i) No (not a health statement)
- ii) No (inaccurate interpretation of evidence)
- iii) No (too imprecise)
- iv) No (data insufficient)
- v) No (data inconsistent)
- vi) No (no plausible mechanism)

Additionally, statements were rejected if the experts considered that the related function was captured by, or the result of, functions encapsulated in another statement. The reason for exclusion was recorded as follows, together with the code of the relevant included statement, as follows:

- vii) No (see (e.g.) VA1b)

The independent experts also considered that a number of statements related to functions that were common to all the vitamins and minerals reviewed. Such statements were moved to Table 1a and appear in Table 2 with the following reason for rejection:

- viii) No (see Table 1a)

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>VITAMIN A</b>								
VA1a	1a. Eyes	✓			✓	Vitamin A is necessary for the normal function of the eye.	No (see VA1b)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
VA3	3. Embryonic development		✓	✓		Vitamin A contributes to normal embryonic development.	No (see Table 1a)	No
VA5	5. Growth	✓		✓		Vitamin A is necessary for normal growth.	No (see Table 1a)	No
<b>VITAMIN D</b>								
VD2b	2b. Skin		✓	✓		Vitamin D contributes to the normal structure of skin.	No (data inconsistent)	No
VD2c	2c. Immune system		✓		✓	Vitamin D contributes to the normal function of the immune system.	No (data inconsistent)	No
<b>VITAMIN E</b>								
VE2	2. Cell proliferation & differentiation		✓	✓		Vitamin E contributes to cell growth and multiplication.	No (see Table 1a)	No
VE3	3. Immune system		✓		✓	Vitamin E contributes to the normal function of the immune system.	No (data inconsistent; see VE1)	No
VE4	4. Vasodilation/circulation		✓		✓	Vitamin E contributes to the normal function of arteries.	No (data inconsistent)	No
<b>VITAMIN K</b>								
VK3	3. Arteries		✓		✓	Vitamin K contributes to the normal function of arteries.	No (data inconsistent)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
VK4	4. Embryonic development		✓	✓		Vitamin K contributes to normal embryonic development.	No (see Table 1a)	No
<b>THIAMIN</b>								
<b>RIBOFLAVIN</b>								
Ri4	4. Fetal growth		✓	✓		Riboflavin contributes to normal fetal growth.	No (see Table 1a)	No
Ri5	5. Eyes		✓	✓		Riboflavin contributes to the normal structure of eyes.	No (see R13)	No
Ri6	6. Red blood cells		✓	✓		Riboflavin contributes to the normal structure of red blood cells.	No (see Ri2)	No
<b>NIACIN</b>								
Ni2a	2a. DNA replication	✓			✓	Niacin is necessary for the normal repair and replication of DNA.	No (inaccurate interpretation of evidence)	No
Ni2b	2b. Growth		✓	✓		Niacin contributes to normal growth in the developing fetus.	No (see Table 1a)	No
Ni3	3. Fatty acid and steroid synthesis		✓	✓		Niacin contributes to the normal structure of some steroids, which are required to make hormones.	No (too imprecise)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>PANTOTHENIC ACID</b>								
Pa2	2. Molecule structure		✓	✓		Pantothenic acid contributes to the normal structure of numerous essential molecules in the body.	No (too imprecise)	No
<b>VITAMIN B<sub>6</sub></b>								
VB <sub>6</sub> 3	3. Hormones	✓			✓	Vitamin B <sub>6</sub> is necessary for the normal function of some hormones.	No (too imprecise)	No
<b>FOLATE</b>								
Fo3	3. Neurotransmitters	✓		✓		Folate is necessary for the normal structure of some neurotransmitters.	No (data inconsistent)	No
<b>VITAMIN B<sub>12</sub></b>								
VB <sub>12</sub> 3	3. Energy production		✓		✓	Vitamin B <sub>12</sub> contributes to normal energy production.	No (too imprecise)	No
<b>BIOTIN</b>								
Bi2	2. Fatty acids	✓			✓	Biotin is necessary for the synthesis of fatty acids, which are important for the normal structure of cell membranes.	No (see Bi1)	No



Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
Bi3a	3a. Cell proliferation	✓			✓	Biotin is necessary for normal cell proliferation.	No (see Table 1a)	No
Bi3b	3b. Growth		✓	✓		Biotin is contributes to normal growth in the developing embryo and infant.	No (see Table 1a)	No
<b>VITAMIN C</b>								
VC2	2. Wound healing	✓		✓		Vitamin C is necessary for the normal structure of wounds.	No (see VC1)	No
VC3	3. Scar tissue	✓		✓		Vitamin C is necessary for the normal structure of scar tissue.	No (see VC1)	No
VC4	4. Gums	✓		✓		Vitamin C is necessary for the normal structure of gums.	No (see VC1)	No
VC6	6. Skin	✓		✓		Vitamin C is necessary for the normal structure of skin.	No (see VC1)	No
VC7	7. Bone	✓		✓		Vitamin C is necessary for the normal structure of connective tissue in bone.	No (see VC1)	No
VC8	8. Joints		✓	✓		Vitamin C contributes to the normal structure of joints.	No (see VC1)	No
VC11	11. Carnitine	✓		✓		Vitamin C is necessary for the normal structure of carnitine.	No (see VC1)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
VC13	13. Metabolism of foreign compounds		✓		✓	Vitamin C contributes to the breakdown of undesirable chemicals.	No (see VC10)	No
VC14	14. Muscle function	✓			✓	Vitamin C is necessary for the normal function of muscles.	No (see VC1)	No
<b>CALCIUM</b>								
Ca4	4. Nerve transmission	✓			✓	Calcium is necessary for normal nerve signals and messages.	No (see Ca2)	No
Ca5	5. Cell wall permeability	✓			✓	Calcium is necessary for the normal permeability of cell membranes.	No (see Ca2)	No
Ca6	6. Hormone secretion		✓		✓	Calcium contributes to the normal release of hormones, such as insulin	No (see Ca2)	No
Ca7	7. Blood pressure		✓		✓	Calcium contributes to maintaining normal blood pressure.	No (data inconsistent)	No
Ca8	8. Digestion	✓			✓	Calcium is necessary for the normal function of enzymes, such as those required for digestion.	No (too imprecise)	No
<b>MAGNESIUM</b>								
Mg2	2. Cell replication		✓		✓	Magnesium contributes to normal cell replication.	No (see Table 1a)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
Mg5	5. Vitamin D metabolism	✓			✓	Magnesium is necessary for the normal activation of vitamin D in the body.	No (see Mg6)	No
<b>IRON</b>								
Fe4	4. DNA synthesis, growth		✓		✓	Iron contributes to normal DNA synthesis, required for growth.	No (see Table 1a)	No
Fe6	6. Taste		✓		✓	Iron contributes to normal taste function.	No (data insufficient)	No
<b>COPPER</b>								
Cu3	3. Red blood cells		✓	✓		Copper contributes to the normal structure of red blood cells.	No (see Cu2)	No
Cu8	8. Fetal development		✓	✓		Copper contributes to the normal development of the fetus, including the brain.	No (see Table 1a)	No
Cu9	9. Allergic reaction		✓		✓	Copper contributes to the normal control of an allergic reaction.	No (data inconsistent)	No
Cu10	10. Cholesterol and glucose metabolism		✓		✓	Copper contributes to the normal metabolism of glucose and cholesterol.	No (data inconsistent)	No
Cu11	11. Blood clots		✓	✓		Copper contributes to the normal structure of blood clots.	No (data inconsistent)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
<b>IODINE</b>								
I2	2. Growth	✓		✓		Iodine is necessary for normal growth.	No (see Table 1a)	No
<b>ZINC</b>								
Zn3	3. Enzyme function	✓			✓	Zinc is necessary for the normal function of numerous enzymes.	No (see Table 1a)	No
Zn4	4. General growth		✓	✓		Zinc contributes to normal growth.	No (see Table 1a)	No
Zn5	5. Neurological function		✓		✓	Zinc contributes to normal brain function	No (data inconsistent)	No
Zn6	6. Insulin action	✓			✓	Zinc is necessary for the normal synthesis and action of insulin.	No (data inconsistent)	No
Zn9	9. Wound healing		✓		✓	Zinc contributes to normal wound healing.	No (see Zn8)	No
Zn10	10. Antioxidant activity		✓		✓	Zinc contributes to cell protection from the damage caused by free radicals.	No (data inconsistent)	No
<b>MANGANESE</b>								
Mn4	4. pH regulation		✓		✓	Manganese contributes to the normal regulation of pH levels in the body	No (data insufficient)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
Mn5	5. Insulin action		✓		✓	Manganese contributes to the normal action of insulin, required for energy metabolism	No (data inconsistent)	No
<b>SODIUM</b>								
Na2	2. Blood pressure		✓		✓	Sodium contributes to normal blood pressure.	No (see Na1)	No
Na3	3. Nerves and muscle	✓			✓	Sodium is necessary for the normal function of nerves and muscle.	No (see Na1)	No
Na5	5. Metabolic rate		✓		✓	Sodium contributes to the body's normal metabolic rate.	No (see Na1)	No
<b>POTASSIUM</b>								
K2	2. Blood pressure		✓		✓	Potassium contributes to normal blood pressure.	No (see K1)	No
K3	3. Nerves and muscle		✓		✓	Potassium contributes to normal nerve and muscle function, including those involved in digestion.	No (see K1)	No
K4	4. Energy metabolism		✓		✓	Potassium contributes to normal energy metabolism, required for cell activity.	No (see K1)	No
K5	5. Secretion of insulin	✓			✓	Potassium is necessary for the normal secretion of insulin by the pancreas.	No (see K1)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
K6	6. Growth	✓		✓		Potassium is necessary for normal growth.	No (see Table 1a)	No
K7	7. pH regulation		✓		✓	Potassium contributes to normal pH regulation (acid-base balance).	No (see K1)	No
K8	8. Nutrient transfer	✓			✓	Potassium is necessary for the normal transfer of nutrients in and out of cells.	No (see K1)	No
<b>SELENIUM</b>								
Se3	3. Regeneration of molecules		✓		✓	Selenium contributes to the body's normal ability to re-use some molecules such as vitamin C.	No (not a health statement)	No
Se4	4. Muscle		✓		✓	Selenium contributes to normal muscle function.	No (data inconsistent)	No
Se5	5. Embryonic development		✓	✓		Selenium contributes to normal embryonic development.	No (see Table 1a)	No
Se6a	6a. Sperm development		✓	✓		Selenium contributes to the normal development of sperm.	No (data inconsistent)	No
Se6b	6b. Reproduction		✓		✓	Selenium contributes to normal reproduction.	No (data inconsistent)	No
<b>CHROMIUM</b>								
Cr1	1. Insulin regulation	✓			✓	Chromium is necessary for the normal regulation of insulin.	No (no plausible mechanism)	No

Reference #	Effect on	Necessary for	Contributes to	Normal structure	Normal function	Nutrient function statement	Recommended by Expert Committee (yes / no*)	Recommended by Council (yes / no*)
Cr2	2. Lipid metabolism		✓		✓	Chromium contributes to the normal metabolism of lipids.	No (see Table 1a)	No
Cr3	3. DNA synthesis		✓		✓	Chromium contributes to normal DNA synthesis and the expression of some genes.	No (see Table 1a)	No
<b>MOLYBDENUM</b>								
Mo1	1. Enzyme activity	✓			✓	Molybdenum is necessary for the normal activity of some enzymes in the body.	No (see Table 1a)	No
<b>FLUORIDE</b>								
F11b	1b. Tooth enamel	✓		✓	✓	Fluoride is necessary for the normal structure and function of enamel in teeth.	No (see F11a)	No
<b>CHLORIDE</b>								
<b>PHOSPHORUS</b>								
P3	3. pH regulation		✓		✓	Phosphorus contributes to the normal regulation of pH levels in the body.	No (too imprecise)	No
P5	5. Tissue growth	✓		✓		Phosphorus is necessary for the normal tissue growth, such as muscle.	No (too imprecise)	No
P6	6. Breast milk	✓			✓	Phosphorus is necessary for normal breast milk.	No (too imprecise)	No