

# DRAFT GUIDELINES

*July 2007*

**THESE GUIDELINES RELATE TO THE REGULATIONS GOVERNING THE LABELLING AND ADVERTISING OF FOODSTUFFS, R642 OF 20 JULY 2007**

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## GUIDELINE 1

### WHO DIETARY AND HEALTH GOALS

The WHO's recommendations on diet and health are as follows:

<b><u>Ranges of population nutrient intake goals</u></b>	
<b>Total fat</b>	15-30% energy
Saturated fatty acids (SFA)	<10% energy
PUFAs	6-10% energy
n-6 PUFAs	5-8% energy
n-3 PUFAs	1-2% energy
Trans fatty acids	<1% energy
MUFAs	By difference
<b>Total carbohydrate</b>	55 to 75%
Free sugars*	<10% energy
<b>Protein</b>	10-15% energy
<b>Cholesterol</b>	< 300 mg/day
<b>Sodium chloride (sodium)</b>	< 5 g/day (<2 g /day)
<b>Total Dietary Fiber</b>	>25 g/day
<b>Non-starch polysaccharides (NSP)</b>	>20 g/day
<b>Fruits and vegetables</b>	≥ 400 g/day

#### **Goals for physical activity**

A total of one hour per day on most days of the week of moderate-intensity activity, such as walking, is needed to maintain a healthy body weight, particularly for people with sedentary occupations.

#### **Goals for body mass index (BMI)**

BMI	Population (adult) mean of 21-23 kg/m <sup>2</sup>
	For individuals: 18,5 – 24,9 kg/m <sup>2</sup> and avoid weight gain of > 5 kg during adult life

\*Free sugars means all mono- and disaccharides added at any point in the processing of food

## GUIDELINE 2

### METHODS OF ANALYSIS

#### (1) METHOD OF DETERMINING NET PROTEIN DIGESTIBILITY-CORRECTED AMINO ACID SCORE (PDCAAS)

The protein digestibility-corrected amino acid score (PDCAAS) of a foodstuff is determined in accordance with to the methods described in sections 5.4.1. and 8.00 in the Protein Quality Evaluation Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Rome, 1990\* and the method described in Food Technology, April 1994, pp 74 – 77\*\*.

The following requirements summarize the calculation of the PDCAAS of a food protein:

1. The food's protein content, usually calculated using the factor 6,25 [or specific AOAC factor listed in the Guidelines, multiplied by the nitrogen (N) content of the food as determined by the AOAC method of analysis (AOAC, 1984). Where a food contains more than one protein source, the factor 6,25 shall be used to determine the protein content. Where a foodstuff contains only one protein source, the specific AOAC factor, listed in the Guidelines, shall be used.
2. The food's essential amino acid profile, determined by typical analytical procedures or high performance liquid chromatography (HPLC). The amino acid scoring pattern described in section 8.00, References \* and \*\*\* shall be used.
3. The food's true digestibility. The Department recognises that a database on digestibility values could be of assistance in implementing the PDCAAS method, and in reducing the expense of implementing this new methodology by eliminating the need for a bioassay. Therefore, the Department provides a limited database on published true digestibility values (determined using humans and rats) of commonly used foods and food ingredients, which manufacturers may use to calculate the PDCAAS of foodstuffs. For labelling purposes, in the case where a food contains more than one protein source, published, true digestibility values for estimating PDCAAS, as listed in the Guidelines, may be used, and where a foodstuff contains only one protein source, published PDCAAS values, listed in Table II, section 9 in the "Protein Quality Evaluation Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation.", Rome, 1990\* may be used.

4. How to calculate the PDCAAS of a food protein:

Analyse for proximate nitrogen (N) of test product.

Calculate protein content (N x 6,25 or specific AOAC factor).

Analyse for essential amino acid (EAA) profile or calculate EEA profile as follows:

Identify protein sources and calculate protein contribution per each protein source of test product; and

Compile EEA profile of each protein source from MRC or other recognised international food composition tables and convert data to express EEA values in mg/g protein.

Determine the amino acid score (uncorrected)

Uncorrected amino =  $\frac{\text{mg of EAA in 1 g of test protein}}{\text{mg of EAA in 1 g reference protein}^*}$

Acid score

**Reference protein**\* EAA profile = 1985 FAO/WHO 2 to 5 year old requirement pattern.

4.5 Calculate protein digestibility of test product.

4.6 Calculate the PDCAAS:

PDCAAS = Lowest uncorrected amino acid score x protein digestibility.

The **reference protein**\* contains (per 1g protein):

Histidine	19	mg
Isoleucine	28	mg
Leucine	66	mg
Lysine	58	mg
Methionine plus cystine	25	mg
Phenylalanine plus tyrosine	63	mg
Threonine	34	mg
Tryptophan	11	mg
Valine	35	mg

\*1985 FAO/WHO/UNU suggested pattern of amino acids requirements for preschool children (2-5 years)

### 5. Example: Calculation of the PDCAAS of soy-and-linseed bread, made with mixed protein sources

Step 1: Analyse for total nitrogen (N) and calculate protein content of test product

Analysed nitrogen (N) content of soy-and-linseed bread:	→	Protein = Nitrogen (N) x AOAC factor for mixed protein sources
2.194		= 2.194 x 6.25 = 13.71 g/100g bread

Step 2(a): Identify protein sources of test product and calculate protein contribution of each

Protein Sources	Source Profile		Ingred Protein (g/100g)	Content Profile				Explanatory Notes
	Recipe			Formulation		Test Product		
	(kg)	(%)	(g/100g)	(g/100g)	(%)	(g/100g)	(g/100g)	
	A	B	C	D	E	F	G	
White bread								
Wheat: flour	119.000	66.70	11.5	7.670	38.133	5.228	5.824	A Values from product recipe B Values = (A-value/Total recipe mass) x 100 C Values from food composition tables D Values = (B-value/100) x C-value E Values = (D-value/Total formula mass) x 100 F Values = (E-value/100) x Product protein content G Values = Summation per source group
Gluten	2.000	1.12	78.0	0.874	4.347	0.596		
Soya: Cuts (Grits)	34.000	19.06	40.0	7.623	37.897	5.196		
Flour	1.418	0.79	40.0	0.318	1.581	0.217	6.749	
Concentrate	5.000	2.80	70.0	1.962	9.753	1.337		
Linseed	17.000	9.53	17.5	1.667	8.290	1.137	1.137	
Total	178.418	100.00		20.114	100.000	13.71	13.71	

Step 2(b) Obtain EAA profile of each protein source from food composition tables and express values in mg/g protein

Composition	EEA Profile of Protein Sources						Explanatory Notes
	Wheat		Soya		Linseed		
	(g/100g)	(mg/g Prt)	(g/100g)	(mg/g Prt)	(g/100g)	(mg/g Prt)	
Protein	8.2		46.5		46.5		
Essential Amino Acids:							
Histidine	0.167	20.366	1.255	26.989	0.931	20.022	<u>Example:</u> 8.2 g wheat protein contains 0.167g histidine <u>Therefore, 1 g wheat protein contains:</u> $= (1/8.2) \times 0.167 \text{ g histidine}$ $= 0.020366 \text{ g histidine per 1 g wheat protein}$ $= 20.366 \text{ mg histidine per 1g wheat protein}$
Isoleucine	0.311	37.927	2.257	48.538	1.675	36.022	
Leucine	0.558	68.049	3.789	81.484	2.812	60.473	
Lysine	0.285	34.756	3.097	66.602	2.298	49.419	
Methionine & Cystine	0.316	38.537	0.647	13.914	1.022	21.978	
Phenylalanine & Tyrosine	0.622	75.854	2.428	52.215	3.108	66.839	
Threonine	0.227	27.683	2.021	43.462	1.500	32.258	
Tryptophan	0.118	14.390	0.676	14.538	0.502	10.796	
Valine	0.360	43.902	2.322	49.935	1.724	37.075	

Step 3: Calculate EAA content and uncorrected EAA score of test product

Composition	EEA Content of Test Product								Ref Protein	Test Product
	Wheat		Soya		Linseed		Total			
	(g/100g)		(g/100g)		(g/100g)		(g/100g)			
Protein content (from step 2)	5.824		6.749		1.137		13.71		EEA Content	Uncorrected EEA Score <sup>3</sup>
Essential Amino Acids:	Profile <sup>1</sup> (mg/g Prt)	Content <sup>2</sup> (mg/100g)	Profile <sup>1</sup> (mg/g Prt)	Content <sup>2</sup> (mg/100g)	Profile <sup>1</sup> (mg/g Prt)	Content <sup>2</sup> (mg/100g)	Profile <sup>1</sup> (mg/g Prt)	Content <sup>2</sup> (mg/100g)		
Histidine	20.366	118.611	26.989	182.150	20.022	22.764	323.526	23.6	19	1.242
Isoleucine	37.927	220.886	48.538	327.580	36.022	40.956	589.423	43.0	28	1.535
Leucine	68.049	396.316	81.484	549.935	60.473	68.758	1015.009	74.0	66	1.122
Lysine	34.756	202.420	66.602	449.498	49.419	56.190	708.107	51.6	58	0.890
Methionine & Cystine	38.537	224.437	13.914	93.905	21.978	24.990	343.332	25.0	25	1.002
Phenylalanine & Tyrosine	75.854	441.772	52.215	352.399	66.839	75.996	870.167	63.5	63	1.007
Threonine	27.683	161.225	43.462	293.328	32.258	36.677	491.230	35.8	34	1.054
Tryptophan	14.390	83.809	14.538	98.114	10.796	12.275	194.198	14.2	11	1.288
Valine	43.902	255.688	49.935	337.015	37.075	42.155	634.857	46.3	35	1.323
<p>1. EEA profile in mg/g of source protein as determined in step 2(b)                      e.g. Histidine from wheat source = 20.366 x 5.824 = 118.611 mg/100g</p> <p>2. EEA content per amount of source protein in 100 g of test product                      bread</p> <p>3. Uncorrected EEA Score of Test Product = (mg EAA in 1 g test protein) / (mg EEA in 1 g reference protein) 1.242                      e.g. Histidine Score = 23.6/19 =</p>										

Step 4: Calculate protein digestibility of test product

Protein Sources	Protein Content Profile (%)	True Protein Digest Value	Test Protein Digest (%)	Explanatory Notes
	A	B	C	
White bread				
Wheat: flour	38.133	97	36.989	A Values from protein content profile of test product as determined in step 1 B Values from the Guidelines C Values = (A-value/100) x B-value
Gluten	4.347	98	4.260	
Soya: Cuts (Grits)	37.897	91	34.486	
Flour	1.581	84	1.328	
Concentrate	9.753	95	9.265	
Linseed	8.290	85	7.046	
<b>Totals</b>	<b>100.000</b>		<b>93.374</b>	

Step 6: Calculate protein digestibility corrected amino acid score (PDCAAS) of test product

PDCAAS = Lowest uncorrected amino acid score of test product x Protein digestibility of test product:	0.890	x	93.374	=	83.150
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References:

\* Protein Quality Evaluation Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation.", Rome, 1990, FAO Food and Nutrition Paper No. 51.

\*\* Protein Quality Evaluation by Protein Digestibility-Corrected Amino Acid Scoring,

\*\*\* Joint FAO/WHO/UNU Expert Consultation. Energy & Protein Requirements. WHO Tech. Rept. Ser. No. 724.

World Health Organization, Geneva, Switzerland (1985).

Food Technology, April 1994, pp 74 – 77.

**FACTORS FOR CONVERTING TOTAL NITROGEN TO PROTEIN**

	FACTOR
MEAT, POULTRY AND FISH	6,25
EGGS:	
*WHOLE	6,25
*ALBUMIN	6,32
*VITELLIN	6,12
MILK AND MILK PRODUCTS	6,38
CASEIN	6,40
HUMAN MILK	6,37
SOYA	6,25
BEANS	6,25
NUTS:	
*ALMOND.	5,18
*BRAZIL AND GROUNDNUT	5,46
*OTHERS	5,30
GELATIN	5,55
OIL SEEDS	5,30
CEREALS:	
*DURUM WHEAT	5,70
*WHEAT:	
**WHOLE	5,83
**BRAN	6,31
**EMBRYO	5,80
**ENDOSPERM	5,70
*RICE	5,95
*BARLEY, OATS AND RYE	5,83
*MILLET	6,31
*MAIZE	6,25
CHOCOLATE AND COCOA	4,74
MUSHROOMS	4,38
YEAST	5,70
COMPOUND FOODS (MIXED PROTEINS)	6,25

### TRUE PROTEIN DIGESTIBILITY VALUES

MAJOR PRODUCT GROUP	PRODUCT	TRUE PROTEIN DIGESTIBILITY VALUE
Cereals and grains:		
Barley	Barley	90
Maize (Corn)	Corn, extruded cereal	62
	Corn, flake	70
	Corn, puffed cereal	76
	Corn, whole	89
	Corn, meal	84
	Millet	Millet
Oats	Oat flakes	70
	Oatmeal	90
	Oat, quick oatmeal	82
Rice	Rice	91
	Rice germ	87
	Rice, brown, cooked	72
	Rice, high protein	85
	Rice, milled, cooked	86
	Rice, polished	87
	Rice, crisped, cereal	77
	Sorghum	Sorghum, cooked
Triticale	Triticale	90
Wheat	Bread	96
	Bread, coarse, brown	91
	Bread, white	98
	Bread, whole wheat	92
	Bran	75
	Endosperm	98
	Flour, 90% extracted	89
	Flour, 80% extracted	92
	Wheat germ	81
	Gluten	98
	Puffed wheat	84
	Shredded wheat	73
	White flour	97
	Wheat, whole	87

**TRUE PROTEIN DIGESTIBILITY VALUES**

<b>MAJOR PRODUCT GROUP</b>	<b>PRODUCT</b>	<b>TRUE PROTEIN DIGESTIBILITY VALUE</b>
	Wheat, hot, cereal	85
	Wheat, 40% bran flakes	69
Dairy Products:		
Casein	Acid casein	95
	Casein	96
Cheese	Cheddar	99
	Cottage	99
Lactalbumin	Lactalbumin	94
Milk	Skim	94
	Whole	94
	Whole, powdered	95
Whey	Whey protein	95
Egg and egg products:		
	Egg albumin	97
	Egg, flakes	92
	Egg, powdered, dried	93
	Egg, dried	98
	Egg, powdered, defatted	100
	Egg, scrambled	96
	Egg, spray dried	92
	Egg, whole unprocessed	97
Legumes and oilseed products:		
Beans ( <i>Mucunoa Spp</i> )	Beans, velvet	68
Beans ( <i>Phaseolus Lunatus</i> )	Beans, butter	57
	Beans, lima	78
Beans ( <i>Phaseolus Vulgaris</i> )	Beans, black	69
	Beans, brown, cooked	79
	Beans, common	82
	Beans, haricot	71
	Beans, kidney	81
	Beans, Natal round yellow	80
	Beans, pinto, canned	73
	Beans, red	78
	Beans, snap, frozen	82
	Beans, spotted, sugar	81

### TRUE PROTEIN DIGESTIBILITY VALUES

MAJOR PRODUCT GROUP	PRODUCT	TRUE PROTEIN DIGESTIBILITY VALUE	
Beans ( <i>Vicia faba</i> )	Beans, sugar	69	
	Beans, sugar, speckled	78	
	Beans, white, kidney	78	
	Beans, broad	87	
	Beans, faba	86	
Cottonseed	Cottonseed	78	
Flaxseed	Cottonseed meal	80	
	Flaxseed	85	
	Lentils ( <i>Culinaris</i> )	Lentils	85
	Lupins ( <i>Lupinus Albus</i> )	Lupine	76
	Peanut products	Peanut butter	95
		Peanut flour	93
		Peanuts	87
		Peanut meal	91
	Peas ( <i>Cajanus Cajan</i> )	Pigeon peas	76
		Pigeon peas, raw	41
		Peas ( <i>Cicer Arietinum</i> )	Chick peas, canned
	Peas ( <i>Pisum sativum</i> )_	Pea concentrate	94
		Peas	88
		Peas, green, frozen	94
		Pea flour	88
Peas ( <i>Vigna unguolata</i> )	Cowpeas	79	
Sesame	Sesame seed, dehulled	82	
Soy products	Soybean	91	
	Soy concentrate	95	
	Soy flour	84	
	Soy flour, defatted	87	
	Soy isolate	96	
	Soy protein, spun	100	
Sunflower	Sunflower seed	82	
	Sunflower seed flour	90	
Meat and meat products:			
Beef	Beef	95	
	Beef, low fat, ground	91	
	Beef, powdered, defatted	97	

### TRUE PROTEIN DIGESTIBILITY VALUES

MAJOR PRODUCT GROUP	PRODUCT	TRUE PROTEIN DIGESTIBILITY VALUE
	Beef, salami	98
	Beef, stew	89
	Beef, steak	97
	Beef, tenderloin, roasted	91
Fish and seafood:	South African hake (haddock)	100
	Sardine	95
	Tuna, canned	90
Luncheon meats:	Canned frankfurters	97
	Chicken frankfurters	97
	Sausage	94
Pork:	Pork, loin and tenderloin	98
Poultry:	Chicken	100
	Chicken, dark meat	92
	Chicken, light meat	93
	Turkey breast, roasted	91
Miscellaneous foods:	Macaroni cheese, canned	94
Nuts and nut products:	Cashew	85
	Coconut meal, defatted	80
	Pecan	71
Starchy roots and tubers:	Potato	89
Vegetables:	Cabbage	88
	Kale	85
	Rape	85
	Mustard	82
	Turnip leaves	86
	Mushrooms	90

## GUIDELINE 2 (continued)

### METHODS OF ANALYSIS

#### (2) METHOD OF DETERMINING THE FAT CONTENT OF FOODSTUFFS

##### 2.1 Total fat

The total fat content of a foodstuff is determined in accordance with the method described in the latest edition of “Official Methods of Analysis of the Association of Analytical Chemists” published by the Association of Analytical Chemists of the United States of America, unless another validated method related to the particular product is used, and the method is validated and accredited by SANAS or another international accreditation body.

##### 2.2 Analysis of Trans-fatty acids

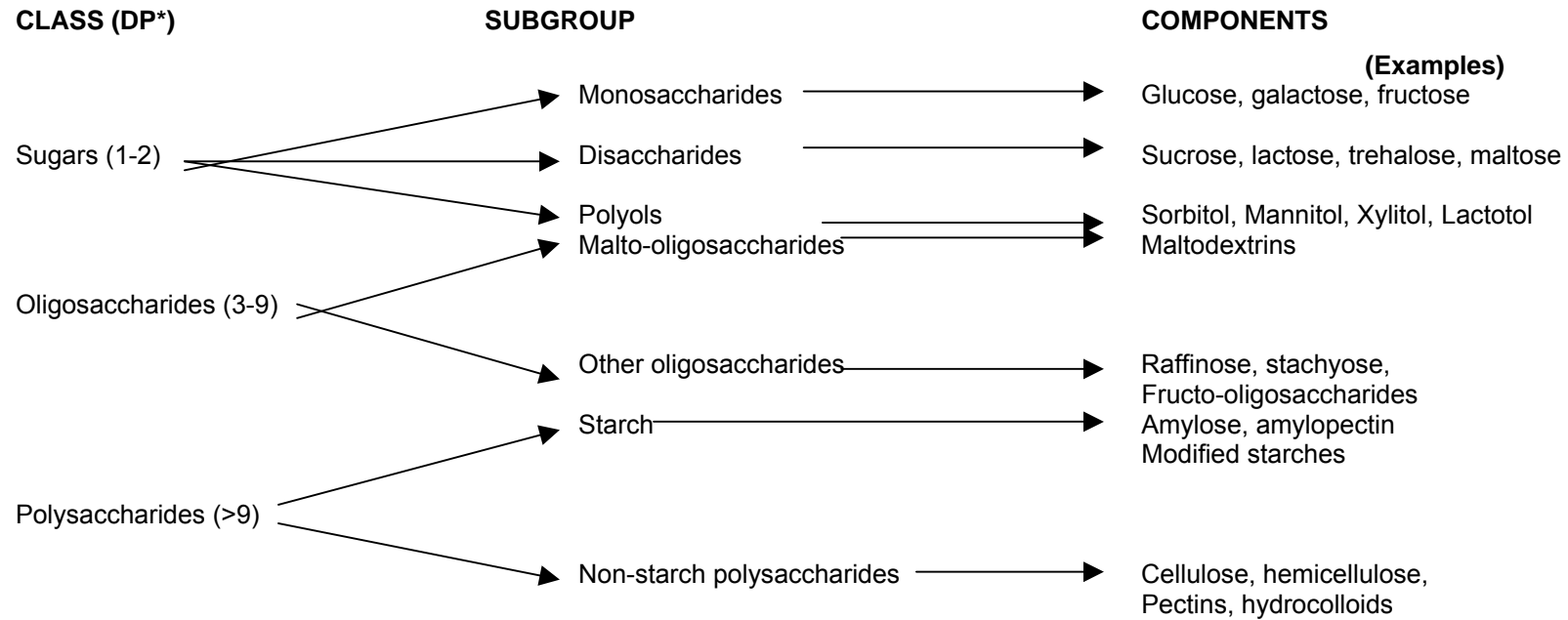
The definition for trans fats may be the first definition to exclude the two major *trans*-fatty acids occurring naturally in foods from animal sources that have potential health benefits, namely *trans*-Vaccenic acid and conjugated linoleic acid. By not mentioning “from animal origin” within the definition, the definition would allow for any trace amounts of these *trans*-fatty acids that may be present in industrially formed *trans*-fats.

Gas-liquid chromatography is probably the most popular and preferred technique. It is widely available and allows identification of individual fatty acids when using suitable standards. The official “AOAC method 996.06 - Fat (Total, Saturated, and Unsaturated) in Foods” (Official Methods of Analysis of AOAC International, 17<sup>th</sup> Edition, Revision 1, 2002, chapter 41.1.28A) can still be used for extraction and methylation. The only suggested difference is lengthening the capillary column SP-2340<sup>TM</sup> used to at least 100m to improve resolution between fatty acids allowing for better identification and more accurate quantification. There are also alternative competitive capillary columns on the market, which are just as efficient. However, suitable validation and verification checks should always be performed prior to their use.

As with most analytical procedures, gas chromatography separates compounds based on their chemical structure and/or functional groups. Due to the fact that the chemical structure of both industrially made and naturally occurring *trans*-fatty acids are identical, it is not possible to differentiate between these two groups.

### GUIDELINE 3

#### THE MAJOR DIETARY CARBOHYDRATES



DP\* = Degree of polymerisation

## GUIDELINE 3 (Continued)

### THE MAJOR DIETARY CARBOHYDRATES

#### RECOMMENDED METHODS OF ANALYSIS

##### 1. Glycaemic carbohydrate:

For purposes of energy evaluation, a standardised, direct analysis of available carbohydrate (by summation of individual carbohydrates) (FAO, 1997; Southgate, 1976) is preferable to an assessment of available carbohydrate by difference (total carbohydrate by difference minus dietary Fiber). Direct analysis allows separation of individual mono—and disaccharides and starch, which is useful in determination of energy values. Direct analysis is considered the only acceptable method for analysis of carbohydrate in functional foods, or foods for which a reduced energy content, slimming, Glycaemic Index value or any other type of carbohydrate claim is made.

However, it is recognised that this method is expensive, therefore companies and laboratories are encouraged to start implementation of this preferred method as soon as possible. The Department will allow the less preferable method (b) below for another 3 years after which method (a) will become mandatory.

Carbohydrates or glycaemic carbohydrates namely, all mono-, di- and malto-oligosaccharides/maltodextrins, starch (amylose, amylopectin and modified starch), glycogen and sugar alcohols and can be determined either by -

(a) adding together all the analytical values for all mono-, di- and malto-oligosaccharides/maltodextrins, starch (amylose, amylopectin and modified starch), glycogen and sugar alcohols, which is considered the gold standard method; or

(b) calculation by difference by subtracting from 100 the average quantity expressed as a percentage of water, protein, fat, dietary Fiber (non-starch polysaccharides (NSP), lignin, added resistant starch, non-digestible oligo-saccharides, e.g., fructo-oligosaccharides and galacto-oligosaccharides), polydextrose, pyrodextrins, raffinose and stachyose), ash, alcohol, glycerol, and organic acids;

## 2. Dietary fiber and prebiotics

### Definition of dietary fibre

The definition of dietary fibre is more clearly linked to fruits, vegetables and wholegrain cereals. To achieve this aim, the definition should include the following:

1. A source element identifying that dietary fibre is an intrinsic component of these food groups.
2. A chemical element identifying the component to be measured.

Based on the rationale described below the following definition is proposed:

*'Dietary fibre consists of intrinsic plant cell wall polysaccharides'.*

Rationale for defining dietary fibre as 'intrinsic plant cell wall polysaccharides'

The established epidemiological support for the health benefits of dietary fibre is based on diets that contain fruits, vegetables and wholegrain cereal foods, which have the characteristic of containing plant cell walls. It is this food component that should form the basis of a dietary fibre definition as it provides a consistent indicator of the plant foods promoted in guidelines, intake of which has been used to establish population reference values for dietary fibre. Using this approach, dietary fibre is defined as a natural food component and no further criteria are required. The structural polysaccharides are the major part of plant cell walls, and by determining this characteristic component it is possible to indicate the presence of other beneficial substances, such as micronutrients and phytochemicals that are present in the plant. This approach is preferable to the determination of all the individual parts of plant cell wall material, which is both impractical and would not add to the nutritional message that is provided by focusing on the polysaccharides of the plant cell wall. Therefore, lignin and other substances are not included in the definition.

Other carbohydrates share the feature of resisting digestion in the small intestine, but these do not provide a consistent indicator of plant rich diets, and they can be affected by food processing or may be added to food. Until recently, there has not been wide-scale use of fibre-like ingredients as supplements, and the current epidemiological evidence base for dietary fibre rich foods cannot be extrapolated to diets containing such preparations. To include them within a dietary fibre definition would clearly represent a conflict with reference intake values and health claims, which are derived mainly from these population studies.

The inclusion criteria based on the demonstration of specified physiological properties is neither appropriate nor manageable within a dietary fibre definition. Instead, resistant starch, oligosaccharides and fibre supplements (prebiotics) should be researched and, if shown to be beneficial to health, be promoted in their own right. Considering the variation in chemical and physiological properties involved, the best approach is to validate and if appropriate, establish health claims on an individual basis.

The above definition does not include non digestible oligosaccharides, which have a DP mostly between 3 and 9. This group of carbohydrates, which can be called short chain carbohydrates, have chemical, physical and physiological properties that are distinct from the polysaccharides of the plant cell wall, e.g. water solubility,

organoleptic properties, effects on the gut microflora (prebiotic), immune function and calcium absorption making them a unique group of carbohydrates, which should be measured separately. They have not, hitherto, been considered to be part of dietary fibre.

Non-digestibility in the small intestine groups together a wide variety of carbohydrates that includes polyols, oligosaccharides, some starch, non starch polysaccharides, and in many populations, lactose. This detracts from the essential role of dietary fibre as plant cell wall carbohydrate found in wholegrain cereals, fruits and vegetables. Furthermore, each of these various carbohydrates has distinct properties other than non-digestibility, which should be measured and exploited separately from dietary fibre for their own benefits to health. Non-digestibility cannot be measured in the laboratory. Therefore, there is no method that can support such a definition. "Digestibility" has a very different connotation when used to describe the digestible energy of foods. Although there is no formally agreed international definition of digestibility for humans in the field of energy values of food, "digestibility is defined as the proportion of combustible energy that is absorbed over the entire length of the gastrointestinal tract". Patterns of carbohydrate digestibility in the human gut can vary not only amongst different carbohydrates, but also from person to person and, therefore, the term "digestibility" is probably best reserved for total digestion and absorption from the whole gut. Digestion should be seen as an integrated whole gut process. Most nutrients and food components are defined and measured as chemical substances, e.g. fat, protein, vitamins, minerals and not by their alleged functions.

Dietary fibre defined as 'intrinsic plant cell wall polysaccharides' includes the phrase "intrinsic". This emphasizes that dietary fibre reflects fruits, vegetables and wholegrain cereal foods. The "carbohydrate polymers which have been obtained from food raw materials by physical, enzymic or chemical means" or "synthetic carbohydrate polymers" were not included, because, again, it was felt that the emphasis should be on the role of dietary fibre reflecting a natural plant-rich, whole food diet. Other sources of non glycaemic carbohydrates would best be served by individual health claims that take into account their specific efficacy and dosage issues.

### **Methods of analysis**

Methods of analysis are a secondary issue, and their suitability should be assessed by how well they measure the defined food component. Defining dietary fibre as 'intrinsic plant cell wall polysaccharides' provides the analyst with a clear objective and the method or choice of methods should be those that most accurately and reproducibly identify and measure these polysaccharides. As part of the scientific update on the issues related to measuring dietary fibre, the NSP and AOAC gravimetric approaches were compared, as summarized in Table 2 below. This comparison clearly identifies the strengths and limitations of the two main approaches to the measurement of dietary fibre. The comparison addresses: 1) general principles of the procedures; 2) practical methodological issues; 3) suitability as measures of dietary fibre; 4) the impact their use would have on public health; 5) food processing; and 6) nutrition research.

The Englyst method, is the preferred method of choice. Both the Englyst and the AOAC methodologies are recognised as acceptable methods of analysis. However, the Englyst method is a reliable, accurate and specific

method of analysis for non-starch polysaccharides (NSP), whereas the AOAC method is not. The NSP procedure as the most suitable in respect of performance and suitability as a measure of dietary fibre. However, the NSP methods is the method of choice for infant formula.

**TABLE 1**

<b>METHOD</b>	<b>QUANTIFIED COMPOUNDS</b>	<b>REFERENCE</b>	<b>TYPE</b>	<b>CHAPTER*</b>
Englyst method <i><u>(method of preference)</u></i>	Non-starch polysaccharides			
AOAC 991.43	Soluble + insoluble polysaccharides (including RS 3) and lignin	Lee et al	Enzymatic-gravimetric	32.1.17
AOAC 995.16	Beta-glucans	McCleary & Codd, 1991	Enzymatic	32
AOAC 2002-02	Resistant starch and algal Fiber	McCleary & Monaghan, 2002	Enzymatic	45.4.15
AOAC 985.29	Soluble & insoluble polysaccharides (including RS 3) & lignin)	Prosky <i>et al.</i> , 1992	Enzymatic gravimetric	45.4.07
AOAC 994.13	Soluble & insoluble polysaccharides (including RS 3) & lignin)	Theander <i>et al.</i>	Enzymatic chemical	45.4.11
AOAC 999.03	Fructans (oligofructans, inulin derivatives, fructooligosaccharides)	McCleary & Blakeney, 1999 McCleary <i>et al.</i> , 2000	Enzymatic & colorimetric	45.4.06B
AOAC 997.08	Fructans (oligofructans, inulin derivatives, fructooligosaccharides)	Hoebregs, 1997	Enzymatic & HPAEC	45.4.06A
AOAC 2001.02	Trans-galacto-oligosaccharides	De Slegte	HPAEC-PAD	45.4.12
AOAC	Total dietary Fiber in		Enzymatic and	45.4.13

2001.03	foods containing resistant maltodextrin		gravimetric & Liquid chromatography	
AOAC 2000.11	Polydextrose	Craig <i>et al.</i> , 2001	HPAEC	45.6.06C

- Official Methods of Analysis of AOAC International. 17<sup>th</sup> edition. Volume II. Editor Horwitz

All the above methods are approved AOAC techniques. These methods have the advantage of being used worldwide as well as being easily used in routine analysis.

The AOAC 985.29 and 991.43 are the general methods for measuring 'total dietary fibre' in most foods. The other methods can be used for complementary assessment of other fibre components/fractions not measured by the general methods due to their solubility in aqueous alcohol or for analysis of certain foods or raw materials for which the standard methods may be less suitable. The methods for total or soluble+insoluble dietary fibre give satisfactory results for foods that contain neither added non-digestible oligosaccharides (e.g. FOS) nor resistant starch<sup>3</sup> fractions RS1 and RS2 which are not measured by these AOAC method.

The AOAC 991.43 includes part of the resistant starch fractions (retrograded starches, RS3). Therefore, in order to include total RS, it is necessary to analyse RS independently and correct for the RS in the fibre residue. Resistant starch (RS) is defined as the fraction of starch not absorbed in the small intestine. It consists of physically enclosed starch (RS1), certain types of raw starch granules (RS2) and retrograded amylose (RS3). Modified starches used as food additives may also be partially resistant (RS4).

When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects.

**TABLE 2: COMPARISON OF THE NSP AND THE GRAVIMETRIC AOAC METHODS WITH RESPECT TO PERFORMANCE AND SUITABILITY AS A MEASURE OF DIETARY FIBRE**

	<b>NSP procedure<sup>8</sup></b>	<b>Gravimetric AOAC procedure<sup>9</sup></b>
<b>1. GENERAL PRINCIPLES<sup>10</sup></b>		
<b>Stated Aim</b>	To measure polysaccharides that do not contain the alpha 1-4 glucosidic linkages	To measure the sum of indigestible polysaccharides and lignin.

	characteristic of starch (i.e. non starch polysaccharides).	
<b>Analytical Principle</b>	<p>Complete dispersion and enzymatic hydrolysis of starch.</p> <p>Precipitate residue in 80% ethanol and isolate by centrifugation.</p> <p>Hydrolyse and measure NSP as sum of constituent sugars by either colorimetry or chromatography (GC).</p>	<p>Partial enzymatic hydrolysis of starch and protein.</p> <p>Precipitate residue in 80% ethanol and isolate by filtration.</p> <p>Record total residue weight and then determine and subtract ash and protein contents.</p>
<b>Information Provided</b>	Values for total, soluble and insoluble NSP, with the option of detailed information on constituent sugars by the GC version.	Weight of total, soluble and insoluble residue containing carbohydrate and noncarbohydrate material in unknown proportions.
<b>Effect of Food Processing</b>	As a chemically distinct food component, NSP is minimally affected by normal food processing.	A range of materials are recovered in the residue, which is highly dependent on food processing (e.g. retrograded starch, Malliard reaction products).
<b>Is Stated Aim Achieved</b>	Yes. The procedure completely removes starch and sugars and provides a specific determination of NSP.	No, not consistently. In addition to NSP, this procedure measures a variable amount of resistant starch, which may not relate to the true extent of physiological starch digestion. In addition to lignin, the non carbohydrate part can include food processing artefacts.
	<b>NSP procedure<sup>8</sup></b>	<b>Gravimetric AOAC procedure<sup>9</sup></b>
<b>2. METHODOLOGY</b> <sup>30, 11, 12</sup>		
<b>Specific Reagents And Equipment</b>	<p><u>Enzymes:</u> Heat stable amylase, (EC 3.2.1.1), pullulanase (EC 3.2.1.41), pancreatin (these enzymes should be devoid of NSP hydrolytic activities), pectinase (EC 3.2.1.15).</p> <p><u>Analysis vessels:</u> screw cap test tubes.</p> <p><u>Equipment:</u> Centrifuge and either spectrophotometer or GC system.</p>	<p><u>Enzymes:</u> Heat stable amylase, (EC 3.2.1.1), protease, amyloglucosidase (EC 3.2.1.1). These enzymes should be devoid of NSP hydrolytic activities.</p> <p><u>Analysis vessels:</u> 400 ml beakers and fritted glass crucibles.</p> <p><u>Equipment:</u> Vacuum manifold, muffle furnace and Kjeldahl equipment.</p>
<b>Practical Issues</b>	All the steps of this procedure	Batch sizes are limited by the

	are conducted in test tubes, which makes it well suited to the analysis of large batch sizes. It is important to ensure complete starch dispersion and hydrolysis, which is achieved by a combination of physical, chemical and enzymatic steps. The chemical end-point determination techniques are the same as those used in the measurement of other carbohydrates (e.g. sugars, starch). The procedure takes 1 day with the colorimetric measure or 1.5 days for the GC measure.	difficulties of handling large numbers of 400 ml beakers. The selective removal of starch other than RS is difficult or impossible to achieve within this procedure. The method is labour intensive due to: preparation and repeated weighing of the crucibles; numerous pH checks; manual transfer and filtration of residues; subsidiary ash and Kjeldahl methods. The procedure takes 1.5-2 days or more with longer filtration times.
<b>Environmental Impact</b>	Only small amounts of solvent waste generated.	Large amounts of solvent waste are generated.
<b>Suitability For Use In Developing Countries</b>	The NSP procedure only requires standard laboratory equipment including a spectrophotometer for the colorimetric version.	The gravimetric procedure requires specialist glassware, muffle furnace and Kjeldahl equipment for the measurement of nitrogen.
<b>Traceability</b>	The primary standard is a representative mixture of the individual monosaccharides of NSP.	No primary standard is available as the procedure does not measure a chemically distinct component.
<b>Method Specificity</b>	Only NSP is measured, with no interference from other substances.	Any added material or food processing artefacts recovered in the residue are a potential source of interference.
<b>Method Reproducibility</b>	A range of certified reference materials are available (e.g. BCR). The method CV is less than 5%.	A range of certified reference materials are available (e.g. BCR). The method CV is less than 5%.
<b>3. DETERMINATION OF DIETARY FIBRE</b> <sup>6,7,16, 26, 13</sup>		
<b>Associated Definition and Measurement Task</b>	Intrinsic plant cell wall polysaccharides.	Indigestible carbohydrate (DP >3) and lignin.
<b>Definition Rationale</b>	This definition is targeted specifically at the fruits, vegetables and whole grain products that are consistently linked with health benefits. These foods have the characteristic feature of containing plant cell walls, which mainly consist of	There are numerous versions of this definition, which have the common feature of placing the emphasis on escaping digestion in the small intestine. The definition is not restricted to carbohydrates as it encompasses lignin and other substances associated with the

	<p>structural polysaccharides. The definition is focused on this carbohydrate component, which can be quantified in chemical terms. Other non-carbohydrate components are not included as they can neither be determined specifically nor would their inclusion enhance the definition as an indicator of these foods. The definition recognises that the benefits of a natural fibre rich diet are not due to any single component, but rather the effect of synergistic elements including micronutrients, phytochemicals and low energy density.</p>	<p>plant cell wall. In addition to the plant cell wall polysaccharides, the indigestibility criterion has the implication of including resistant starch and other extracted or synthesized carbohydrates, including non-digestible oligosaccharides. However, as this grouping can include a wide range of substances it has been suggested that there should also be a demonstrated physiological effect for a specific material to be included.</p>
<p><b>Scientific Evidence For Rationale</b></p>	<p>This is a food based rationale, which is strongly supported by the epidemiological evidence for the health benefits of fruits, vegetables and whole grain products. Retaining a distinct dietary fibre term identifying plant rich diets with their unique health benefits reinforces the food based dietary guidelines. This distinction allows the properties of other non glycaemic carbohydrates to be researched and if appropriate promoted in their own right.</p>	<p>For the existing epidemiological evidence relating to the last few decades this definition provides a reasonable indicator of plant rich diets, as supplementation with other types of non glycaemic carbohydrate preparations was uncommon. However, this is not always the case for individual manufactured products. Specific physiological properties have been associated with individual supplements, but these vary depending on type, making it difficult to consider them within a single definition. The long term health effects/safety remain to be established.</p>
<p><b>Potential discrepancies between definitions and determinations</b></p>	<p>For plant foods, the NSP content is a measure of 'intrinsic plant cell wall polysaccharides'. In a few plants NSP can occur as gums and alginates, but these are not typical foods and are more likely to occur as ingredient extracts. When extracted or synthesized NSP are present in products then these will be known by the manufacturer and can be deducted from the NSP measurement to obtain a value for the intrinsic plant cell wall polysaccharides. The presence of specific extracts can often be identified by their NSP</p>	<p>As the AOAC gravimetric procedure measures a range of indigestible materials of varied composition and origin it does not provide a consistent measure of plant cell wall material. It can include non-carbohydrate food processing artifacts (e.g. Maillard reaction products) that are not part of any dietary fibre definition. The residual starch recovered can be misleading, as it does not relate to physiologically resistant starch, for which separate measurement is required. It does not recover non digestible oligosaccharides,</p>

	<p>constituent sugar profile. With the plant cell wall polysaccharide definition, non digestible oligosaccharides and RS are separate groupings. Their content in foods is measured specifically and they do not conflict with the NSP measurement.</p>	<p>resistant maltodextrins or all resistant starch, and therefore by itself does not provide a measure of the indigestible carbohydrates proposed for inclusion. These substances require separate analysis if they are to be included.</p>
<p><b>Suitability as a measure of dietary fibre</b></p>	<p>The intrinsic plant cell wall polysaccharide definition provides a clear link to the plant rich diet shown to be beneficial to health. The NSP procedure provides measurements that are suitable for this definition.</p>	<p>The indigestible carbohydrate and lignin definition does not consistently identify plant rich diets. Neither does the AOAC gravimetric procedure provide a consistent measurement of the material included in this definition.</p>
<p><b>4. IMPACT ON PUBLIC HEALTH</b><sup>6,7,16,26,33</sup></p>		
<p><b>Nutrition Labelling</b></p>	<p>A dietary fibre value describing intrinsic plant cell wall polysaccharides would guide consumers to the selection of plant rich foods. If other sources of non glycaemic carbohydrates are present, then there would be scope for these to be labelled specifically.</p>	<p>The labelling with AOAC gravimetric values has the potential to mislead consumers, as the material measured is not a consistent indicator of plant rich foods, and in some cases includes food processing artefacts. By grouping all indigestible carbohydrates within a single undifferentiated nutrition label, there is less opportunity to identify any supplements present, which tend to have specific functional properties.</p>
<p><b>Health Claims</b></p>	<p>The health claims for dietary fibre are largely based on the epidemiological evidence, which relates to fibre from plant rich diets. When appropriate, specific health claims should be established for individual non glycaemic carbohydrate supplements, thereby acknowledging their specific functional properties and taking account of variations in their effective and safe dosages.</p>	<p>It is inappropriate to apply the epidemiological evidence as a basis for health claims in combination with a definition that includes AOAC gravimetric values of unknown composition, as well as a range of supplemented materials with varied functional properties. There is the potential for inappropriate health claims for materials with either no effect or detrimental properties, which would undermine the position of dietary fibre as a beneficial food component.</p>
<p><b>Population Reference Intakes</b></p>	<p>The population reference intake values for dietary fibre are largely based on the epidemiological evidence that</p>	<p>The use of this definition could result in a situation where the consumer selects supplemented products on the</p>

	<p>minimally refined plant rich diets are associated with a lower incidence of several diseases. The intrinsic plant cell wall polysaccharide definition ensures that dietary fibre intakes contributing towards the reference value would consistently reflect both the epidemiological evidence and the intended message of the dietary guidelines.</p>	<p>basis that they will contribute towards the reference intake value, although in reality this would not be a true reflection of the intention of the dietary guidelines. This raises two concerns; 1) that the supplemented product is unjustly promoted on the back of the epidemiological evidence; and 2) that if direct substitution of products occurs, then the consumption of the intended target food groups may be diminished.</p>
<b>5. IMPACT ON FOOD INDUSTRY</b>	<p>Although NSP values are generally lower than those for the gravimetric procedure, this should not make a difference to the marketing of the majority of products, as population reference intakes and health claims would be established on the same basis. The emphasis would be on manufacturers to incorporate minimally refined plant ingredients into products to achieve health claims for dietary fibre. There would be a positive opportunity to market other types of non glycaemic carbohydrates with respect to their specific functional properties.</p> <p>For food labelling purposes, there would be significant cost savings with the analysis of NSP compared to the AOAC gravimetric analysis.</p>	<p>With this definition, there would be less impetus for the manufacturer to incorporate unrefined plant ingredients, as it would be possible to elevate the dietary fibre content through processing or supplementation instead. However, it would be difficult for the consumer to distinguish between these different types of product if they carried identical health claims. This may be perceived as conflicting with the intended aim of reference intake values and dietary guidelines which are targeted at plant rich diets. Grouping the varied supplements together limits the opportunities for manufacturers to promote the specific functional properties of individual products.</p> <p>As gravimetric values are influenced by food processing, food labelling cannot be based on food table values of component ingredients.</p>
<b>6. IMPACT ON NUTRITION RESEARCH</b>	<p>Food composition data has a crucial role in nutrition research, as only with precise and informative descriptions is it possible to address the mechanisms responsible for the relation between diet and health. The intrinsic plant cell wall polysaccharide definition provides a firm link with the minimally refined plant rich diet consistently associated with health benefits. This food</p>	<p>As the AOAC gravimetric procedure does not measure a specified food component it does not provide the precise and informative data required for nutrition research. Neither does the procedure provide any details of what has been measured. Values can consist of plant cell wall material, retrograded starch, supplements and noncarbohydrate artefacts in</p>

	<p>component can be described in chemical terms, including an indication of the types of polysaccharides present from their constituent sugar composition, providing the means with which to explore functional properties. Maintaining this distinct definition of dietary fibre not only facilitates research into the benefits of plant rich diets, but also encourages specific research into other types of non glycaemic carbohydrates. Only with detailed information on distinct substances will it be possible for future epidemiological studies to establish the intakes and effects of different types of non glycaemic carbohydrates. The emphasis is on providing a nutritional approach to the description of the carbohydrate composition of foods.</p>	<p>unknown proportions. It does not provide a consistent indicator of plant rich diets. Nor is it a reliable measure of indigestible carbohydrates as it includes non-carbohydrate components, but not all resistant starch or non-digestible oligosaccharides. Therefore, at best it provides a crude tool for nutrition research, but one that is prone to confound the interpretation of results. A definition based on the gravimetric method and indigestible carbohydrates within a single undifferentiated grouping will not provide the detailed information required by future epidemiology studies to establish the intakes and health effects of different types of non glycaemic carbohydrates. Nutrition research is better served by detailed information on specific food components.</p>
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**Comparison of the NSP and the gravimetric AOAC methods with respect to performance and sustainability as a measure of dietary fibre**

1. Englyst H N, Quigley M E, Hudson G J, (1994) *Determination of Dietary Fiber as Non-starch Polysaccharides with Gas-Liquid Chromatographic, High-performance Liquid Chromatographic or Spectrophotometric Measurement of Constituent Sugars*, Analyst, 119, 1497–1509.
2. AOAC (2000) Methods 985.29 and 991.45. Official methods of analysis 17th Ed W Horwitz, AOAC International, Gaithersburg, MD, USA
3. Englyst, H.N., Quigley, M.E., Englyst, K.N., Bravo, L. & Hudson, G.J. (1996). *Dietary Fibre. Measurement by the Englyst NSP procedure. Measurement by the AOAC procedure. Explanation of the differences.* Journal of the Association of Public Analysts, 32, 1-52.
4. Wood, R., Englyst, HN, Southgate, DAT, Cummings JH (1993). *Determination of dietary fibre in foods - collaborative trials.* IV. Comparison of Englyst GLC and colorimetric measurement with the Prosky procedure. Journal of the Association of Public Analysts, 29, 57-141.
5. Pendlington, A.W., Meuree-Vanlaethem, N. & Brookes, A. (1996). *The method specific certification of the mass fraction of dietary fibre in lyophilised haricot beans, carrot, apple, full fat soya flour and bran breakfast cereal reference materials.* **CRMs 514, 515, 516, 517 & 518. Office for Official Publications of the European Communities, Luxembourg**
6. USDA/DHHS. (2005) *Nutrition and your health: dietary guidelines for Americans.* Washington, DC. CL 2007/3-CCNFSDU page 12
8. Englyst H N, Quigley M E, Hudson G J, (1994) ‘Determination of Dietary Fiber as Non-starch Polysaccharides with Gas-Liquid Chromatographic, High-performance Liquid Chromatographic or Spectrophotometric Measurement of Constituent Sugars’, Analyst, 119, 1497–1509.
9. AOAC (2000) Methods 985.29 and 991.45. Official methods of analysis 17th Ed W Horwitz, AOAC International, Gaithersburg, MD, USA
10. Englyst, H.N., Quigley, M.E., Englyst, K.N., Bravo, L. & Hudson, G.J. (1996). *Dietary Fibre. Measurement by the Englyst NSP procedure. Measurement by the AOAC procedure. Explanation of the differences.* Journal of the Association of Public Analysts, 32, 1-52. CL 2007/3-CCNFSDU page 13
11. Wood, R., Englyst, HN, Southgate, DAT, Cummings JH (1993). *Determination of dietary fibre in foods - collaborative trials.* IV. Comparison of Englyst GLC and colorimetric

measurement with the Prosky procedure. *Journal of the Association of Public Analysts*, 29, 57-141.

12. Pendlington, A.W., Meuree-Vanlaethem, N. & Brookes, A. (1996). The method specific certification of the mass fraction of dietary fibre in lyophilised haricot beans, carrot, apple, full fat soya flour and bran breakfast cereal reference materials. CRMs 514, 515, 516, 517 & 518. Office for Official Publications of the European Communities, Luxembourg

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13. USDA/DHHS. (2005) *Nutrition and your health: dietary guidelines for Americans*. Washington, DC.

CL 2007/3-CCNFSDU page 15

### **3. Glycogen:**

Hutchison, G.I., Nga, H.H., Kuo, Y.L. & Greenfield, H. (1987): *Composition of Australian Foods*. 36. Beef, lamb and veal offal. *Food Technol. Aust.* 39: 223-7.

### **4. References:**

*Carbohydrates in Human Nutrition* (1997): Report of a Joint FAO/WHO Expert Consultation, Rome.

*Food energy – Methods of Analysis and Conversion Factors*, FAO Food and Nutrition Paper 77, Report of a technical workshop, Rome, 3 – 6 December 2002.

Greenfield H., and Southgate, D.A.T. (1992): *Food Composition Data*, London: Elsevier Science Publishers.

Southgate, D.A.T. 1976. *Determination of food carbohydrates*, London, Applied Science Publishers.

### **References to methods in the table:**

AOAC 985.29:

Prosky L, Asp N-G, De Vries JW, Schweizer TF, Harland B. Determination of total dietary fiber in foods and food products: collaborative study. *J Assoc Off Anal Chem* 1985;68:677-679.

AOAC 991.43:

Lee SC, Prosky L, De Vries J. Determination of soluble and insoluble dietary fiber in foods. Enzymatic gravimetric method, MES-TRIS buffer: collaborative study. *J AOAC Int* 1992;75:395-416.

AOAC 994.13:

Theander O, Aman P, Westerlund E, Andersson R, Petterson D. Total dietary Fiber determination as neutral sugar residues, uronic acids, and Klason lignin (The Uppsala method): Collaborative study. *J AOAC Int* 1995;78:1030-1044.

## GUIDELINE 4

### HIDDEN ALLERGENS

#### 1. LABEL TERMINOLOGY THAT MAY INDICATE THE PRESENCE OF EGG PROTEIN

* Albumin	* Lysozyme
* Binder	* Ovalbumin
* Coagulant	* Ovomucin
* Emulsifier	* Ovomuroid
* Globulin	* Ovovitellin
* Lecithin	* Vitellin
* Livetin	

#### 2. LABEL TERMINOLOGY THAT MAY INDICATE THE PRESENCE OF MILK PROTEIN

* Artificial butter flavour	* High protein flavour
* Butter	* Lactalbumin
* Butter fat	* Lactalbumin phosphate
* Buttermilk solids	* Lactose
* Caramel colour	* Milk derivate
* Caramel flavouring	* Milk solids
* Casein	* Natural flavouring
* Caseinate	* Rennet casein
* Cheese	* Sour cream (or solids)
* Cream curds	* Sour milk solids
* De-lactosed whey	* Whey or whey powder
* Dry milk solids	* Whey protein concentrate

#### 3. LABEL TERMINOLOGY THAT MAY INDICATE THE PRESENCE OF SOY PROTEIN

* Bulking agent
* Emulsifier
* Hydrolysed vegetable protein (HVP)
* Lecithin#*
* Miso
* MSG**
* Protein
* Protein extended
* Stabiliser
* Textured vegetable protein (TVP)

- \* Thickener
- \* Tofu
- \* Vegetable broth
- \* Vegetable gum
- \* Vegetable starch

# Mostly produced from soy but may be manufactured from egg

\*\* Sometimes produced from soy or wheat but now mostly by synthetic means

#### 4. LABEL TERMINOLOGY THAT MAY INDICATE THE PRESENCE OF WHEAT PROTEIN

- \* All-purpose flour
- \* Bleached and unbleached flour
- \* Bulgur (cracked wheat)
- Bran
- \* Couscous
- \* Durum wheat/flour
- \* Enriched flour
- \* Farina
- \* Gelatinised starch# (or pre-gelatinised)
- \* Gluten or Vital gluten
- \* Graham flour
- \* High protein flour
- \* Kamut
- \* Malt
- \* Miller's bran
- \* Modified food starch or modified starch#
- \* Semolina
- \* Spelt
- \* Starch
- \* Vegetable gum#
- \* Vegetable starch#
- \* White flour

# May indicate the presence of soy protein or may be manufactured from cassava (tapioca), maize or rice.

## METHODS OF ANALYSIS FOR GLUTEN

The recommended method for analysis of gluten is the Enzyme-Linked Immunoassay R5 Mendez (ELISA) Method as described in Codex Stan 118/1981, as revised in 2004 onwards.

### **GUIDELINES FOR A MANUFACTURER ON HOW TO IMPLEMENT AN ALLERGEN CONTROL POLICY (ACP)**

The following guidelines are proposed as a possible approach to allergen control for food manufactures. Since many variations on it could achieve acceptable results based on a company's specific needs, these steps should not be considered a definitive protocol but rather an attempt to assist food manufacturers with some guidelines, specifically smaller manufacturers with little or no experience in these matters, to develop their own allergen control policy.

#### **ALLERGEN CONTROL POLICY (ACP)**

An allergen control policy should be designed by an individual company according its specific needs, as part of the ACP program. The first step in an allergen control should be to identify all possible allergen sources and possible areas of allergen cross-contamination. These could include:

- a) Raw materials:
  - Ingredients
  - Sub-ingredients, e.g. natural flavours, other allergen-derived additives or ingredients
  - Reworked ingredients, e.g. peanut-containing biscuit dough re-worked into plain biscuit dough
  - Processing aids, e.g. wheat starch
  - Packaging materials, e.g. wheat derivative used in packaging material
- b) Cross-contact: shared equipment, utensils, work surfaces, staff members.

#### **PROCESSESING PROCEDURES**

The company should ensure that the correct processing methods/procedures are followed and should not allow allergen cross-contamination. This can be done by for example, manufacturing an "allergen-free" food and allergen containing food in separate areas of the factory or by making an allergen-containing product last in the production run.

#### **ALLERGEN AUDIT**

An ACP audit, as part of the HACCP study, can identify possible problem areas and their potential severity. An allergen audit can be done in a similar way as a hygiene audit. The Regulations relating to the application of the Hazard Analysis and Critical Control Point System (HACCP system), No R.908 of 27 June 2003, published under the Act, can be used as a guideline, but applying the information to allergens. During an allergen audit all areas of manufacture must be inspected, for example, in the receiving area it must be checked that allergen containing food or ingredients are stored separately or in airtight containers.

## **SUPPLIER CONTROL**

Specification sheets for each ingredient or additive should be drawn up to ensure an appropriate allergen control policy could be implemented.

## **SUPPLIER INFORMATION QUESTIONNAIRES**

An allergen questionnaire should be drawn up and sent to all suppliers to complete containing for example a request for information on the following:

- Information about ingredients and additives supplied to the company. Does it contain allergens or ingredients or additives derived from allergens?
- The allergen content of the raw ingredients/additives the supplier receive/use.
- Processing procedures (Do the following procedures take allergens and allergen control into consideration?):
  - Storage
  - Transport
  - Preparation
  - Cleaning
  - Shared production line or equipment
  - Rework
  - Allergen control measures already in place

This is where the product information in terms of ingredients, additives, allergens, traceability et cetera, specifically the Supplier Ingredient Information files, as explained in GUIDELINE 11 becomes essential. The information obtained from the questionnaire should be compiled into a Supplier Ingredient Information file for every ingredient or additive used in the manufacturing of a foodstuff by the specific company.

## **LABELLING AND PACKAGING**

Labels must identify all common allergens present in the product, and any advisory statements must be verifiable and in the legislatively prescribed forms. If necessary, checks must be in place to ensure that the correct labels are placed on products and that they are packaged in the correct containers. There must also be no leaks in the packaging.

## **COMPANY ALLERGEN POLICY**

When the following protocols are documented for a company's HACCP system, allergens must be kept in mind. This can assist with allergen control policymaking. The following should incorporate allergen control measures:

- Premises and equipment design for easy cleanup
- Sanitation in standard operating procedures
- Sanitation and control during receiving and storage

- Sanitation and control of distribution points
- Separate preparation areas
- Education/staff training
- Traceability protocols

## **SAMPLING**

There are currently no guidelines indicating the amount of samples that need to be sent for allergen testing. If the company has testing protocols or sampling procedures in place, they can use these if they prefer. However, companies may consider the following when selecting the sample size:

- The size of the production run and number of batches
- Shared production lines and equipment between products containing allergens and so-called allergen-free products
- Any allergen control programme already in place
- Suspected contamination
- Consumer complaints

## GUIDELINE 5

### RULES ON QUANTITATIVE INGREDIENT DECLARATIONS (QUID)

#### 1. SCOPE OF QUID

The requirement to give QUID declarations will in principle apply to all food, including beverages, which contains more than one ingredient.

#### 2. WHEN QUID DECLARATIONS ARE NOT REQUIRED

(a) A QUID declaration will not apply to constituents which are naturally present in foods and which have not been added as ingredients. Examples are caffeine (in coffee), vitamins and minerals (in fruit juice).

(b) A QUID declaration will not apply to foods, which, although mentioned in the name of a food, have not been used in its manufacture or preparation. Examples are “Cream Crackers” – a customary name used to describe a dry biscuit which never contains cream, or “Lemon Creams” – another customary name used to describe a sweet biscuit which never contains cream or real lemons in any form, or chicken flavour crisps – where the chicken flavour comes from one or more ingredients which are not chicken, or cream of mushroom soup powder – a customary name for a soup powder which contains no cream and either a mushroom flavour and/or a very small amount of real mushroom and which has a smooth texture.

(c) A QUID declaration is not required for an ingredient/category of ingredient which, although it appears in the name of the food, is not likely to influence the customer’s choice, because the variation in quantity is either not essential to characterise the food or does not distinguish it from similar foods, e.g., malt whisky or cornflakes.

(d) A QUID declaration is not required for an ingredient/category of ingredients which although it appears in the name of the food, has been used as a typical ingredient but in small quantities (less than 2%) mainly for the purpose of flavouring and of which consumers don’t expect a high content of the ingredient(s) because of the nature of the product. An example is “Oxtail soup powder” which contains only a minute amount of dried meat.

(e) A QUID declaration is not required for canned fish and marine products, canned meat, frozen fish and seafood products, agricultural fishery products and agricultural products for which compositional standards already exist under the Standards Act, 1993 (Act 29 of 1993), and the Agricultural Products Standards Act, 1990 (Act 119 of 1990), and the Liquor Products Act, 1989 (Act No. 60 of 1989).

(f) A QUID declaration is not required for canned products, which declare both the drained net weight and the net weight on the label, because the QUID can be calculated from the weight indications already given. Examples include -

- \* a single type of fruit in juice;
- \* a single type of vegetable in water; and
- \* mixtures of vegetables/fruit in water/juice where no ingredient in the mixture significantly predominates by weight.

The exemption does not apply if, on mixed ingredients products, one or more ingredient(s) is / are either emphasised in some way on the label or predominates by weight, because the amount of the ingredient can then not be calculated from the weight indications already given.

(g) In the case of mixtures of fruit or vegetables or nuts, etc, referred to in regulations 18, 22 and 23 where no ingredient in the relevant mixture predominates significantly by weight, a QUID declaration would not be required.

(h) Subject to regulation 19 an additional QUID declaration will not in addition be required for the sweetening agent as a result of the indication “with sweetener(s)” or “sweetened with...”.

(i) A QUID declaration will not be required for vitamins and/or minerals that are added to foodstuffs for enrichment or fortification purposes, if their content is indicated in nutrition labelling.

(j) A QUID declaration will not be required for an ingredient or category of ingredients that is used in small quantities for the sole purpose of flavouring, provided that section 5 of the Act (concerning false or misleading descriptions) is not infringed in any manner. This exemption applies to flavourants, such as quinine in tonic water, which are additives, and garlic and other herbs and spices if used at a level of 2% or less by weight calculated from the recipe at the mixing bowl stage, excluding carriers and dilutants.

(k) A QUID declaration should not be confused with nutrition labelling and does not replace nutrition labelling.

(l) A QUID declaration is not required for single ingredient foodstuffs.

(m) A QUID declaration is not required for a foodstuff with more than one ingredient, where the emphasised ingredient is the main ingoing ingredient and appears in the name of the product and comprises 95% or more of the mixture at the time of manufacture.

### **3. WHEN QUID DECLARATIONS ARE REQUIRED**

- (a) Where the emphasised ingredient or category of ingredients -
- (i) appears in the name of the food; and
  - (ii) is usually associated with that name by the consumer:

(i) The first part of this provision would require a QUID declaration where the ingredient or category of ingredients appears in the name of the food -

(aa)

The ingredient is included in the name of the food	Examples* would include
	<p>“<u>Chicken</u> and <u>mushroom</u> pie”, “<u>chicken</u> polony”, “<u>olive oil</u> margarine”, <u>tomato</u> sauce”, “<u>honey</u> and <u>oats</u> biscuits, “<u>banana</u> loaf”,</p>

\* In the abovementioned examples it is the ingredients underlined which would require quantification.

(bb)

The category of ingredients is included in the name of the food	Examples** are:
	“vegetable/fruit pie”, “nut loaf”

\*\* In the abovementioned examples the QUID declaration need only relate to the total vegetable, fruit or nut content of the product.

(cc) When the name of a compound ingredient appears in the name of the food, it is the compound ingredient, which would require quantification. Examples are “seafood lasagne” or “biscuits with a cream filling”. If an ingredient of the compound ingredient is also mentioned, e.g., “seafood lasagne with prawns” and “biscuits with a cream filling containing eggs”, it should also be quantified.

(ii) The second part of this provision would require a QUID declaration on products where the ingredient or category of ingredients is usually associated with the name of the food. This is most likely to

apply when products are described by the use of customary names without additional descriptive names.

As a guide for deciding which ingredients might usually be associated with a product identified by a customary name alone, it might prove helpful to consider what an appropriate descriptive name for the product might be, were this to be given. QUID should then be applied to the main or prominent ingredients identified, provided they do not qualify for exemption from QUID. For illustrative purposes only the following examples are given:

<b>Product</b>	<b>Example of description</b>	<b>QUID for</b>
"Cottage Pie"	Minced beef topped with mashed potatoes	Minced beef

The intention is not that all ingredients associated by the consumer with a particular product name should require a QUID declaration under this part of this provision, or that each name under which a food is sold is ultimately linked to a specific ingredient requiring a QUID declaration. For example, "cider" would not require a QUID declaration for apples, nor "crisps" a QUID declaration for potato. Although this provision does not impose an automatic obligation to indicate the quantity of meat for "ham", a QUID declaration will be required for all hams, other processed meats and fresh meats that contain added, injected water, or injected water-additives mixtures. Only a very limited number of products which have been dried or dry-cured and have a meat content significantly in excess of 100% (e.g. Parma ham, Serrano ham, Jambon de Bayonne) will not require a QUID declaration.

(b) Where the ingredient or category of ingredients is emphasised on the labelling in words, pictures or graphics.

- (i) This requirement is likely to be triggered when a particular ingredient is given emphasis on the label otherwise than in the name of the food. For example by means of flashes such as -
- \* "with extra chicken"
  - \* "made with butter"
  - \* "with real Cheddar cheese"
- or by the use of different size, colour and/or style of lettering to refer to particular ingredients anywhere on the label other than in the name of the food.
- (ii) When pictorial representation is used to emphasise selectively one or a few ingredients, for example, fish casserole with a prominent picture or illustration of only a selection of the fish ingredients. However, this emphasis provision may not be triggered by the following:
- (aa) When a pictorial representation of a food as offered for sale is given;
  - (bb) when a pictorial representation takes the form of a "serving suggestion";

- (cc) when a pictorial representation is descriptive of the agricultural origin of certain ingredients without emphasising the quantity of the ingredients concerned (e.g., a picture of wheat or hops on a beer label);
- (dd) when a pictorial representation presents all the food ingredients (with the exception of minor ingredients such as seasonings and additives) without emphasising any particular one;
- (ee) in the case of warnings aimed at allergy sufferers (e.g., a warning statement about the presence of nuts in a product); and
- (ff) in the case of a food mix, a pictorial representation of what should be made from the product, having regard to the instruction given.

(c) Ingredients used in concentrated or dehydrated form, which are reconstituted during manufacture.

Regulation 21 permits ingredients used in concentrated or rehydrated form which are reconstituted at the time of manufacture to have their order in the ingredients list determined as if they had been used as “whole” ingredients (e.g., reconstituted dried skimmed milk used in a milk pudding or dairy dessert). This same principle applies to the QUID declaration, which may be based on the weight of the “whole’ ingredient.

#### 4. EXPRESSION OF QUANTITY

(a) Foods in general:

- (i) The quantity of an ingredient or category of ingredients should generally be expressed as a percentage. The percentage may be rounded to the nearest whole number, or in those cases where it is below 5%, to the nearest 0,5 decimal place.
- (ii) The percentage should normally be calculated by using the same method as that used for determining the order in the list of ingredients. This means that the weight of an ingredient to be quantified would need to be divided by the total weight of all of the ingoing ingredients (except the weight of any added water or volatile ingredients lost in processing). For example, the fish content of a “fish finger” would be calculated as follows:

Ingredients	Weight	Formula
		$\frac{70}{112} \times 100 = 62,5 \%$
Fish	70 g	

Batter	20 g	
Crumb	20 g	
Total before frying	110 g	
Frying oil taken up	7 g	
Total mixing bowl	117 g	
Water lost from batter during frying	-5 g	
Total of ingredients	112 g	

However, care should be taken to ensure that the figure quoted is that which best represents the amount of the ingredient, or category of ingredients, at the time of use in the preparation of the food. Manufacturers should control process variability in accordance with good manufacturing practice in order to ensure that, as far as is practicable, individual consumers are not misled.

- (iii) QUID declarations should relate to the ingredient as identified in the list of ingredients. Ingredients identified, for example, as “chicken”, “milk”, “egg”, or “banana”, should be quantified as raw/whole, as the names used imply use of the basic food because they carry no indication that they have been processed. Ingredients identified by names, which indicate they have been used other than in their raw/whole form, e.g., “roast chicken”, “skimmed milk”, “crystallised fruit”, should be quantified as used. Declarations of processed ingredients may be supplemented with “raw equivalent” declarations since this would help consumers compare similar products which have used ingredients in different forms. Where declarations for ingredients of compound ingredients are required, these may relate to the ingredient either as a percentage of the compound ingredient or as a percentage of the food. The basis of the declaration should be made clear to the consumer and should be consistent with the method used for ingredient listing.

(b) Foods which lose moisture following heat or other treatment

QUID declarations on products (such as cakes, biscuits, pies and cured meats) the composition of which has been changed by cooking or other treatments involving loss of moisture should be based on the amount of the ingoing ingredient expressed as a percentage of the weight of the final product. For example, the butter content of a “butter cookie” would be calculated as follows:

Ingredients	Weight	Formula
		$\frac{50}{169} \times 100 = 29.6\%$

Flour	100 g	
Sugar	35 g	
Butter	50 g	
Eggs	10 g	
Total mixing bowl	195 g	
Total after baking	169 g	

Where this calculation would lead to declarations exceeding 100%, the declarations should be replaced with statements giving the amount of the ingredients used to make 100 g/ml of the final product (e.g., “made with X g/ml of Y per 100 g/ml”). Concentrated or dehydrated products intended to be reconstituted before consumption otherwise covered by this provision may alternatively follow the provision described in the paragraph 4 (c) (i) below.

(c) Foods sold in concentrated or dehydrated form which are intended to be reconstituted using water by the consumer before consumption:

- (i) QUID declarations on concentrated or dehydrated products intended to be reconstituted before consumption (including dry mixes for cakes and desserts) may relate to the ingredients in the reconstituted product if the ingredient listing information is also given on this basis. Although the provision applies to products that are intended to be reconstituted by the addition of water, a similar approach may also be used for those products, which are intended to (or which may optionally) be reconstituted by the addition of other liquids (e.g., milk or stock) if the ingredient listing information is also given on this basis.
- (ii) In deciding whether to give ingredient listing and QUID information based either on the dehydrated or reconstituted product, consideration should be given to avoiding giving QUID and any nutrition labelling information for industry sectors, to ensure that a common practice is adopted for all similar products, to enable consumers to make appropriate comparisons.

## GUIDELINE 6

### STANDARD OPERATING PROCEDURE FOR THE DETERMINATION OF THE GLYCAEMIC INDEX (GI)

#### PART A:

**NOTE:** The FAO/WHO Expert Consultation on Carbohydrates in Human Nutrition document of 1998 recommended a procedure that most of the international GI research centers currently follow and that was also followed in the inter-laboratory GI study, the article of which was published in the 2003 issue of the European Journal of Clinical Nutrition, **57**, pp. 475 – 482. Until such time as an international standard has been finalised for the testing of the glycaemic index of foods, for the purposes of standardisation, this operating procedure for the determination of the glycaemic index (GI) has been set to be used as the South African standard. The South African standard is based on the article on Glycaemic index methodology, published in 2005 in Nutrition Research Reviews, **18**, pp 145 – 171. Every endeavour has been made to follow international protocol.

In the South African Regulations Relating to the Labelling and Advertising of Foodstuffs: **Glycaemic index (GI) is defined as:** *The blood glucose responses of carbohydrate foods i.e., the incremental area under the curve (IAUC) for the increase in blood glucose after the ingestion of 50 g of glycaemic (available) carbohydrate in an individual food (unless the total volume exceeds 300 ml when 25 g of glycaemic (available) carbohydrate from the individual food and the reference food will be acceptable) in the 2 hours for healthy and 3 hours for diabetic individuals from the start of the test meal, as compared with ingestion of the same amount of glycaemic (available) carbohydrate from glucose taken with 300 ml of water spread over a 10-15 minute period, tested in accordance with a defined procedure by an accredited laboratory in the same individuals under the same conditions using the fasting blood glucose concentrations as a baseline; and*

**Glycaemic load (GL) is defined as:** *The glycaemic load of a specific food serving is an expression of how much impact or power the food will have in affecting blood glucose levels and is calculated as follows:*

$$GL = \frac{\text{Carbohydrate content (in grams) per serving} \times GI}{100}$$

#### PROCEDURE

1. General ethical principles and science-based practices should be applied throughout the process.
2. Decide on exact food to be tested (composition of test meal). The details must be written in the final report and be included on Appendix A.
3. Decide how it will be prepared, purchased and stored for the duration of the test. The details must be written in the final report.
4. Determine how much food will provide 50 g glycaemic carbohydrate (see Appendix A)

5. Decide on type of subjects [healthy and/or IDDM and/or NIDDM, age (subjects shall be older than 18 years), BMI]. Subjects may be made up of singular groups, e.g., non diabetics or diabetics or mixed groups, e.g., non diabetics and diabetics together:
  - (a) No pregnant and lactating women may be included.
  - (b) Diabetics used as subjects should
    - i. have a normal renal function;
    - ii. be well controlled with an HbA<sub>1c</sub> within the optimal South African reference range, namely <7 - 8% (Ref: SEMDSA Guidelines for diagnosis and management of diabetes mellitus, 2002).
  - (c) The details of the type of subjects must be written in the final report.
6. Recruit a minimum of 10 subjects based on willingness to comply with protocol and inclusion and exclusion criteria, since Truswell, AS, recommended this requirement in his article: Glycaemic Index of foods (European J of Clin Nutr 1992, 46: Suppl. 2, S91 – 101).
7. All subjects must give signed informed consent to participate in the study.
8. All medication, including complementary or natural medicines and the use of nutritional supplements used by subjects before and during the test, should be the same during the reference and the test period. Records should be kept of all medications used by all subjects and be available on request.
9. All known factors that influence glucose responses should be minimised as far as possible and should remain consistent in both the reference and test-food testing periods. This includes factors such as stress levels, smoking and alcohol intake.
10. If new test subjects are recruited to test food products, randomisation of volunteers to treatments should be done, i.e., the three glucose tests should be randomly alternated with the test foods in the different subjects.
11. All subjects must receive all test foods and the standard.
12. The total carbohydrate intake for the three days prior to the testing should be in line with the prudent diet and therefore contain at least 50% of total energy as CHO, 30% fat and 20% protein, as recommended for the pre-evening meal by Gresse A. & Vorster H.H.: The Glycaemic index and second meal effect of a typical African meal in black non-insulin dependent diabetic subjects. (SA J Fd Sc Nutr 1992; 4: 64 – 69).
13. Any of the standard pre-test meals described in Appendix B can be chosen and given as the evening meal the previous night and must be consumed 10 to 12 hours before testing.
14. The pre-test meal is defined (see Appendix B). The selected pre-test meal must be detailed in the final report. Any of the prescribed pre-test meals may be used by the subjects for any test, seeing that they are about identical in composition of macronutrients.
15. Subjects should not consume anything other than water from 22:00 the night prior to testing. (*This is what all medical laboratories recommend the night before a glucose tolerance test is done the next day*). However, no water or other liquids should be taken on the morning of the test, except for the amount that is allocated with the test food, as it has been shown that this can dilute blood plasma and affect blood glucose concentration.
16. Subjects should not do any unusual physical activity for 24 hours prior to the test and physical activity should remain consistent in both the reference and test-food testing periods.
17. Subjects should arrive at the testing center by car and not be physically active during testing.

18. Subjects should remain stationary during the duration of the test.
19. Baseline capillary glucose measurement should be taken after an overnight fast of 10 to 12 hours.
20. GI tests should not be conducted by test subjects closer than two, but preferably three days apart.
21. Capillary glucose must be measured in compliance with Good Laboratory Practice Guidelines and in strict adherence to prescribed methodology as follows:
  - (a) Wash hands with soap and warm water.
  - (b) Never use alcohol swabs to disinfect the finger.
  - (c) Prick the side of the finger and let the hand hang by the side to allow the blood to gravitate to the finger. Squeeze the finger gently (Hand may be held in warm water to improve blood flow before the finger is pricked).
  - (d) Apply only one large drop of blood to the test pad on the pad on the blood glucose sensor electrode (in the case of a blood glucose sensor) OR put two to three large drops of blood (in the case of the YSI analyser) in the test tube containing the required amount of anticoagulant.
  - (e) In the case of the YSI analyser: Wait for the sipper to appear, after the appropriate button had been pressed. Place the test tube under the sipper and press the appropriate button. Wait for the sipper to take up the blood. Remove the test tube once the sipper has removed itself from the tube. Wait for the blood glucose reading to appear on the blood glucose measuring device and note it down on the provided form.
  - (f) Never "milk" the finger to get a larger drop of blood.
  - (g) The appropriate calibration must be done and appropriate glucose controls must be used to ensure the accurate functioning of glucose measuring devices. One control measurement must be done per instrument per test day.
22. Test foods and standards must be prepared and the precise amount given to each subject according to the randomisation schedule. Subjects must consume the test foods or standard within the first 10-15 minutes after the fasting value was obtained and the timer has been started. Capillary finger-prick blood samples are taken for normal subjects fasting and at 15, 30, 45, 60, 90 and 120 minutes after the START of the test meal and for diabetic subjects fasting and at 30-min intervals for 3 hours The test meal is started within a few minutes of the fasting blood sample (it doesn't have to be immediately after, but should be within 5 min. or so). The timer starts with the first bite of the test meal – so the first blood sample is 15 min. after the first bite (or start) of the test meal. The standard for healthy volunteers must consist of 50 g glucose powder (in cases where dextrose monohydrate is used as glucose, 55 g dextrose monohydrate is to be used since it contains 10% water) dissolved in 300 ml water. For diabetic subjects the standard must consist of the same load but the monitoring period is longer.
23. Number of measurements:
  - (a) The reference food requires 3 measurements.
  - (b) The test food requires 1 measurement.
  - (c) Testing of the reference food must be redone every 6 months if the same subjects are used on a regular basis.
24. Timings: Capillary blood glucose samples must be taken as follows:

Non-diabetic subjects:

Reference: Taken with 300 ml of water within and spread out over the first 15-minute period. Clock to be started with the start of drinking/eating of the reference food and blood samples to be drawn at 15, 30, 45, 60, 90, and 120 min. thereafter,

Test food: The test food must be eaten within and spread out over the first 15-minute period. Clock to be started with the start of eating/drinking of the test food and blood samples to be drawn at 15, 30, 45, 60, 90, and 120 min. thereafter.

Diabetic subjects:

Reference: Taken with 300 ml of water within and spread out over the first 15-minute period. The clock will be started with the start of drinking the reference food and blood samples will be drawn at 15, 30, 45, 60, 90, 120, 150, and 180 min. thereafter.

Test food: The test food must be eaten within and spread out over the first 15-minute period. The clock will be started with the start of eating/drinking the test food and blood samples will be drawn at 15, 30, 45, 60, 90, 120, 150, and 180 min. thereafter.

The whole area under the blood glucose curve(AUC) and above the baseline (fasting) value i.e. area A in Figure 1, must be calculated using the relevant mathematical methods as shown below Figure 1, which is the formula recommended by the FAO/WHO document, since it is most valid and produces the least variable results of the valid methods.

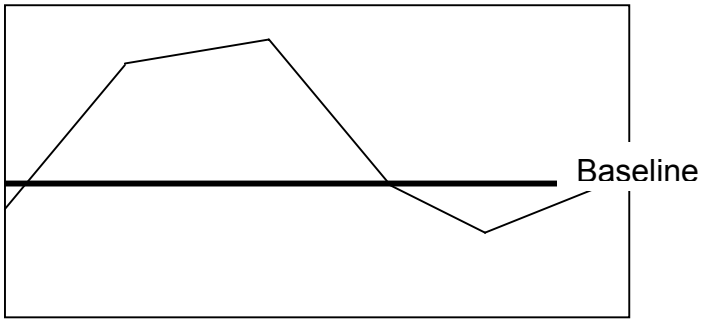


Figure 1. The area under the blood glucose curve above the baseline (fasting) value

Mathematical Methods to calculate the AUC above baseline (area A in Fig. 1):

Assuming that at times  $t_0, t_1, \dots, t_n$  the blood glucose concentrations are  $G_0, G_1, \dots, G_n$ , respectively.

$$AUC = \sum_{x=1}^n A_x \quad \text{where, } A_x = \text{the AUC for the } x\text{th time interval}$$

and the  $x$ th time interval is the interval between times  $t_{x-1}$  and  $t_x$

For the first time interval: (i.e.,  $x=1$ )

$$\text{if } G_1 > G_0, A_1 = (G_1 - G_0) \times (t_1 - t_0) / 2$$

$$\text{otherwise, } A_1 = 0$$

For other time intervals: (i.e.,  $x > 1$ )

$$\text{if } G_x > G_0 \text{ and } G_{x-1} > G_0, A_x = \{[(G_x - G_0) / 2] + (G_{x-1} - G_0) / 2\} \times (t_x - t_{x-1}) / 2$$

$$\text{if } G_x > G_0 \text{ and } G_{x-1} < G_0, A_x = [(G_x - G_0)^2 / (G_x - G_{x-1})] \times (t_x - t_{x-1}) / 2$$

$$\text{if } G_x < G_0 \text{ and } G_{x-1} > G_0, A_x = [(G_{x-1} - G_0)^2 / (G_{x-1} - G_x)] \times (t_x - t_{x-1}) / 2$$

$$\text{if } G_x < G_0 \text{ and } G_{x-1} < G_0, A_x = 0$$

25. The final report must include the following information:

- Mean GI values
- Standard deviation
- Confidence intervals
- Individual raw data

26. All data generated must be kept by the testing facility for at least five years and must be available upon request. Data required on a standard form for each individual test is given in Appendix A.

**APPENDIX A**

**GLYCAEMIC INDEX TESTING – INFORMATION FORM**

Product to be tested \_\_\_\_\_ Date of test \_\_\_\_\_

Name of subject \_\_\_\_\_

Informed consent signed (yes/no) \_\_\_\_\_

Method of preparation

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Percentage energy from carbohydrate of test food

Total carbohydrate of food \_\_\_\_\_ g/100 g analytical method \_\_\_\_\_

Dietary Fiber \_\_\_\_\_ g/100 g analytical method \_\_\_\_\_

Lignin and/or fructo-oligosaccharides and/or galacto-saccharides and/or polydextrose and/or pyrodextrins and/or raffinose and/or stachyose and/or resistant starch (if applicable) \_\_\_\_\_ g/100 g analytical method

\_\_\_\_\_

Glycaemic carbohydrate \_\_\_\_\_ g/100g analytical method \_\_\_\_\_

Amount of test food that will provide 50 g glycaemic carbohydrate: \_\_\_\_\_ g food

**Subject information**

Healthy	Yes / No	Male		Age	years
NIDDM	Yes / No	Female		BMI	Kg/m <sup>2</sup>
IDDM	Yes / No				
If diabetic					
	HbA <sub>1c</sub>				%
	Normal renal function	Yes / No			

Medication usage

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Nutritional supplements usage

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**Test results**

Name of glucose measuring device used for test \_\_\_\_\_

Calibration strip lot No. \_\_\_\_\_

Name of control solution used \_\_\_\_\_

Expiry date of control solution \_\_\_\_\_ (e.g., January 2004)

Range of control solution \_\_\_\_\_ (e.g., 5,3-5,8 mmol/L)

Control value 1 \_\_\_\_\_

**Capillary glucose in mmol/L**

Time in minutes	Glucose reading	Unit
0		mmol/L
15		mmol/L
30		mmol/L
45		mmol/L
60		mmol/L
90		mmol/L
120		mmol/L
150		mmol/L
180		mmol/L
		mmol/L

Only in diabetics

Only in diabetics

Area under the blood glucose response curve \_\_\_\_\_

Test results, including the mean GI values, standard deviation, confidence intervals and individual raw data shall be given to food companies who shall keep it on record for law enforcement purposes. Actual blood glucose readings of the test subjects shall be available to food companies upon request.

## **APPENDIX B**

### **PRE-TEST MEAL**

#### **FOR GLYCAEMIC TESTING**

**NOTE:** It is recognised that there is currently no international standard for the testing of the glycaemic index or for the pre-test meal. However, the FAO/WHO Expert Consultation on Carbohydrates in Human Nutrition document of 1998 recommended a procedure that most of the international GI research centers currently follow and that was also followed in the inter-laboratory GI study, the article of which was published in the 2003 issue of the European Journal of Clinical Nutrition, **57**, pp. 475 – 482. Until such time that an international standard has been set for the testing of the glycaemic index of foods, for the purposes of standardization, this pre-meal formulation will be used as the South African standard. However, every endeavour has been made to follow international protocol. The pre-test meals for glycaemic index testing in South Africa are defined below and may not be deviated from.

- The following meals are the meals (according to gender) to be used as the pre-test meal subject to the requirements of paragraphs 13 and 14 of this Guideline.
- They are to be used as the evening meal prior to the glycaemic testing and must be eaten 10 to 12 hours before testing.

The rationale behind these pre-test meals is as follows:

- Their energy contents are approximately a third of what medium active women and men, respectively, would need (divided over three meals per day).
- Their total carbohydrate content each is 75 – 100 g glycaemic carbohydrate for women and men, respectively (*See lengthy discussion before*).
- The dietary Fiber content of these meals is relatively low to minimise the second meal effects (Jenkins and co-workers, and others, have shown that a high Fiber intake in preceding meals, even overnight, influences the glucose response to a test of the following meal.)
- The GI of these meals is estimated to be intermediate (also to minimise effects on the test meal, therefore aiming to keep variations as low as possible.)

MEAL 1 (Men)					
Amount	Foods	CHO (g)	Fat (g)	Protein (g)	Energy (kJ)
3x30 g	White bread	44,4 g	1,6 g	7,7 g	947
60 g	Cheddar cheese	1,3 g	16,4 g	14,9 g	899
20 g (4 t)	Jam	20 g	-	-	340
15 g (3 t)	Flora margarine	-	12,2	-	464
250 ml	Fat free milk	12,2 g	0,5 g	8,4 g	326
100 g	Banana	21,8 g	0,5 g	1,0	384
Total		99,7 g	31,2 g	32,0 g	3360
kJ		1695 kJ	1186 kJ	544 kJ	
% total kJ		50%	34%	16%	
MEAL 1 (Women)					
Amount	Foods	CHO (g)	Fat (g)	Protein (g)	Energy (kJ)
2x30 g	White bread	29,6 g	1,07g	5,1 g	631
30g	Cheddar cheese	0,65g	8,2g	7,45g	450
10 g (2 t)	Jam	10 g	-	-	170
7.5g (2 t)	Flora margarine	-	6,1	-	232
250 ml	Fat free milk	12,2 g	0,5 g	8,4 g	326
100 g	Banana	21,8 g	0,5 g	1,0	384
Total		74,25g	16,37g	21,95 g	2193
kJ		1262,3 kJ	622,1 kJ	373,15kJ	
% total kJ		56%	28%	16%	

***Ideally, lower fat products should be used, e.g., lower fat cheese like In Shape or Mozzarella, Flora Lite instead of Flora margarine and low fat milk (2%) instead of full cream milk. The calories and % nutrients should come to more or less the same. The reason for this is that diabetic subjects could be encouraged to resume eating high fat products like cheddar cheese, regular margarine and full cream milk if these are used for pre-test meals.***

MEAL 2 (Men)					
Amount	Foods	CHO (g)	Fat (g)	Protein (g)	Energy (kJ)
190 g cooked	Macaroni	43,7 g	0,8 g	6.5 g	884
60 g	Cheddar cheese	1,3 g	16,4 g	14.9 g	899
100 g	White sauce, medium thick, whole milk and margarine	7,8 g	11,1 g	3.2 g	599
2 x 70 g	Apple	18 g	0,4 g	0,4 g	326
200 ml	Yoghurt, low fat, sweetened	30 g	3,0 g	7,6 g	750
Total		100,8 g	31,7 g	32,6 g	3458
kJ		1714	1205	554	
% total kJ		50%	34%	16%	
MEAL 2 (Women)					
Amount	Foods	CHO (g)	Fat (g)	Protein (g)	Energy (kJ)
100 g cooked	Macaroni	23 g	0,4g	3,4 g	465
30 g	Cheddar cheese	0,7 g	8,2g	7,5g	450
50 g	White sauce, medium thick, whole milk and margarine	3,9g	5,55g	1,6 g	300
1x 80 g	Apple	10g	0,2g	0,2g	186
200 ml	Yoghurt, low fat, sweetened	30 g	3,0 g	7,6 g	750
Total		67,6g	17,4 g	20,3g	2151
kJ		1149,2	661,2	345,1	
% total kJ		53%	31%	16%	

MEAL 3 (Men)					
Amount	Foods	CHO (g)	Fat (g)	Protein (g)	Energy (kJ)
2	Hamburger rolls	60 g	2.2 g	10.2 g	1200 kJ
1,5	Hamburger patties (Weighless)	3g	14,9	24g	1023,3
10 g (2 t)	Flora Lite margarine	-	5g	-	190
100 g	Salad (tomato, cucumber, lettuce, gherkin)	5g	-	=	105
1 slice (40 g)	Pineapple	4,5g	0,2g	0,2g	82,8
1 medium	Onion (100 g)	7g	0,2g	1,2g	158
15 ml	Chutney, tomato sauce or mustard sauce	3,7g	0,05g	0,2g	58,8
20 g	Plain chocolate	12g	6,1g	1,7g	448,2
Total		95,2g	28,7g	37,3g	3266,1
kJ		1618,4	1090,6	634,1	
% total kJ		48%	33%	19%	

MEAL 3 (Women)					
Amount	Foods	CHO (g)	Fat (g)	Protein (g)	Energy (kJ)
1	Hamburger roll	30 g	1,1 g	5,1 g	600 kJ
1	Hamburger pattie (Preferably Weighless)	2 g	9,9 g	16 g	682,2
5 g (1 t)	Flora Lite margarine	-	2,5 g	-	95
100 g	Salad (tomato, cucumber, lettuce, gherkin)	5 g	-	=	105
1 slice (40 g)	Pineapple	4,5 g	0,2 g	0,2 g	8,8
1 small	Onion (50 g)	3,5 g	0,1 g	0,6 g	79
15 ml	Chutney, tomato sauce or mustard sauce	3,7 g	0,05 g	0,2 g	58,8

20 g	Plain chocolate	12 g	6.1 g	1.7 g	448,2
Total		60,7g	20 g	23,8g	2151
kJ		1031,9	760	404,6	
% total kJ		47%	35%	18%	

<b>APPENDIX C</b>
<b>LABORATORY CERTIFICATION AND QUALITY CONTROL</b>

NOTE: It is recognised that there is currently no official international certification system of GI testing laboratories. However, international recommendations for the certification of GI testing laboratories have been made, based on the results of the interlaboratory GI study, the article of which was published in the 2003 issue of the European Journal of Clinical Nutrition, **57**, pp. 475 – 482. Until such time as an international certification system of GI testing laboratories has been set up, for the purposes of certification, the following criteria has been set to be used as the South African standard. However, every endeavour has been made to follow international protocol.

The criteria are as follows:

1. The laboratory shall prepare specific documented procedures and implement them. It should cover all facets of the national GI testing standard operating procedure, as described in this document.
2. Records that indicate compliance to the specific procedures should be kept for a minimum period of five years.
3. The mean CV for repeated tests of the reference food for each subject should be less than or equal to 30%.
4. The acceptable standard deviation for any specific GI test is 20 or less and should a test result indicate a higher standard deviation, the product must be retested.
5. If a food company should change the formulation or processing of a food product or food ingredient carrying a GI category claim or logo, the product should be retested in order to legitimise the GI claim.

## **PART B**

1. Pre-packed foodstuffs such as raw maize meals, wheat flours, Maltabella porridge flour, oats, uncooked barley, rice, pasta, dry legumes etc. that are sold as such but need further cooking before they are ready to eat, shall, in cases where the Glycaemic Index is indicated on the label in accordance with the requirements of regulation 59, bear a statement to the effect that the Glycaemic Index category refers to the cooked product.
2. The said statement shall be reflected in the table with nutritional information under the heading “Nutritional information” as part of the serving size indication.
3. Where applicable, where there is a marked difference in the GI category in the same foodstuff when eaten cold and when eaten hot as a result of the development of resistant starch, this information may also be indicated.



## GUIDELINE 7

### EVALUATION OF PROBIOTIC BACTERIA FOR USE IN FOODSTUFFS AND NUTRITIONAL SUPPLEMENTS AND METHODS FOR THE DETERMINATION OF THE NUMBER OF VIABLE COLONY-FORMING-UNITS IN FOODSTUFFS AND NUTRITIONAL SUPPLEMENTS

In accordance with Regulation 63, proof that the following requirements of a proposed probiotic foodstuff or nutritional supplement have been complied with, shall be submitted to the Director-General prior to market appearance:

#### 1. IDENTIFICATION OF THE GENUS, SPECIES AND STRAIN<sup>1</sup>

(a) The genus of the bacteria shall be identified.

(b) The species and specific strain of the probiotic shall be identified using both the genotypic<sup>2</sup> (DNA/DNA homology, comparison of 16S rRNA, Pulsed Field Gel Electrophoresis [PFGE] and PCR-based Denaturing Gradient Gel Electrophoresis [DGGE]) and the phenotypic<sup>3</sup> characteristics (the morphology, assimilation and fermentations patterns). Determination of the presence of extra-chromosomal genetic elements such as plasmids can contribute to strain typing and characterisation. An independent laboratory shall conduct the above-mentioned identification.

(c) The nomenclature of the bacterium must conform to the current, scientifically recognised names as specified in the following sources:

1. Based on the report of a Joint FAO/WHO Working group on Guidelines for the Evaluation of Probiotics in Food, London, Ontario, Canada, 30 April and 1 May 2002, and a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties in Food including Powder milk with Live Lactic Acid Bacteria, Cordoba, Argentina, 1 to 4 October 2001.

2. **Genotypic** means the genetic information contained in each cell of an organism and passed on from generation to generation. Also called the genetic potential of the organism.

3. **Phenotypic** means the sum of the characteristics manifested or expressed by an organism as contrasted with the set of genes possessed by it.

(i) Approved lists of Bacterial Names (Int.J.Syst. Bacteriol, 1980, 30:225-420) also available in <http://www.bacterio.cict.fr/>.

(ii) Validation lists, published in the International Journal of Systematic and Evolutionary Microbiology (or International Journal of Systematic Bacteriology, prior to 2000).

(d) Any person or company who uses incorrect names that could lead consumers and regulatory authorities to make incorrect assumptions about the identity of the real bacterium used shall be guilty of an offence.

(e) All strains shall be deposited in an internationally recognised culture collection and proof thereof must be on record for law enforcement purposes.

## **2. SCREENING FOR THE SAFETY OF POTENTIAL PROBIOTIC MICROORGANISMS (PHASE I) <sup>1</sup>**

*In vitro* tests for particular strains are critical to assess the safety of probiotic microorganisms but are not necessarily sufficient for proving the functionality of a probiotic bacterium in the human body. Therefore appropriate target-specific *in vitro* tests that correlate with *in vivo* results (human trials) shall be conducted. The information accumulated to show that a strain is a probiotic, including positive and negative clinical trial evidence, shall be published in peer-reviewed scientific or medical journals, provided that the research was conducted in accordance with the scientific approach of the FAO/WHO guidelines.

1. Based on the report of a Joint FAO/WHO Working group on Guidelines for the Evaluation of Probiotics in Food, London, Ontario, Canada, 30 April and 1 May 2002, and a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties in Food including Powder milk with Live Lactic Acid Bacteria, Cordoba, Argentina, 1 to 4 October 2001.

(a) In determining the safety of a probiotic bacterium, the following *in vitro* tests at least shall be conducted to characterise the probiotic strains:

(i) Determination of drug and/or antibiotic resistance patterns (chromosomal, transposon or extra-chromosomal).

(ii) Assessment of certain metabolic activities such as D-lactate production, bile salt de-conjugation, etc.

(iii) Assessment of side effects during human studies.

Post-market surveillance of adverse incidents in consumers by manufacturers would add a measure of confidence in the safety of the probiotic.

(iv) Determination of the hemolytic activity is required.

(v) Assessment of lack of infectivity by a probiotic strain in immuno-compromised animals would add a measure of confidence in the safety of the probiotic.

(b) All strains shall have Generally Recognized as Safe (GRAS) status.

(c) If the strain under evaluation belongs to a species that is a known to produce substances/metabolites toxic to mammals, the strain shall not be allowed as a probiotic in food.

### 3. ASSESSMENT OF EFFICACY (PHASE II)<sup>1</sup>

In determining the efficacy of a probiotic bacterium, the following *in vitro* tests at least shall be conducted to characterise the probiotic strain:

(a) Resistance to gastric acidity.

(b) Bile acid resistance.

(c) Adherence to mucus and/or human epithelial cells and cell lines.

(d) Antimicrobial activity against known human pathogenic microorganisms.

(e) Ability to reduce pathogen adhesion to surfaces.

1. Based on the report of a Joint FAO/WHO Working group on Guidelines for the Evaluation of Probiotics in Food, London, Ontario, Canada, 30 April and 1 May 2002, and a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties in Food including Powder milk with Live Lactic Acid Bacteria, Cordoba, Argentina, 1 to 4 October 2001.

#### **4. METHODS FOR THE IDENTIFICATION AND ENUMERATION OF PROBIOTIC BACTERIA IN FOODSTUFFS AND NUTRITIONAL SUPPLEMENTS**

##### **(a) Identification of probiotic bacteria**

Identification of probiotic bacteria should include molecular biology based genotyping such as DNA/DNA homology, comparison of 16S rRNA, Pulsed Field Gel Electrophoresis [PFGE] and PCR-based Denaturing Gradient Gel Electrophoresis [DGGE]) and the phenotypic characteristics (the morphology, assimilation and fermentations patterns).

##### **(b) Enumeration of probiotic bacteria**

The recommended method to determine the number of viable bacteria (colony-forming-units) shall be performed in a Forma Scientific Anaerobic Cabinet (USA) under anaerobic conditions consisting of an atmosphere of 10% hydrogen, 30% carbon dioxide and a balance of nitrogen. The products shall be assessed on a five-fold replicate basis. The growth medium shall be based on MRS (Oxoid) components.

(c) When another method is used, a complete description of the method shall be attached to the analysis report.

(d) Any method used shall have accreditation with SANAS or another recognised international accreditation authority that is a member of the International Laboratory Accreditation Cooperation (ILAC) and part of the International Laboratory Accreditation Arrangement.

#### **5. GENERAL REQUIREMENTS**

Documentation in triplicate shall be submitted to the Directorate: Food Control of the Department of Health for pre-market approval of a foodstuff or nutritional supplement comprising probiotic(s) and shall be organised in an identical/similar order to that outlined in this Guideline.

## GUIDELINE 8

### APPROVED FUNCTION CLAIMS

NUTRIENT	FUNCTION CLAIM
Beta-carotene	Can be converted to Vitamin A in the body. Functions as a tissue antioxidant and so keeps cells healthy.
Biotin	Plays a role in the formation of fatty acids. Helps the body with the transformation of fats and carbohydrates into energy. Contributes to healthy normal growth and body maintenance. Involved in fatty acid formation, energy transformation from fats, carbohydrates & proteins. Aids in utilisation of other B-complex vitamins.
Boron	Needed for healthy bones. Necessary for calcium-, phosphorus- and magnesium metabolism. Needed for muscle growth. Enhances brain function and promotes alertness. Plays a role in utilization of energy from fats and sugars
Calcium	Helps maintain healthy bones and teeth, and a healthy nervous system. Important for healthy regular heartbeat, Needed for muscular growth and contraction and prevents muscle cramps. Essential in blood clotting.
Choline	Needed for proper transmission of nerve impulses from brain through central nervous system. Aids in hormone production. Aids in fat and cholesterol metabolism. Needed for brain function and memory.
Chromium	Involved in metabolism and maintenance of blood sugar. Vital in synthesis of cholesterol, fats and proteins.
Co-enzyme Q10	Vital because it aids in the production of ATP, an immediate source of cellular energy. Plays a role in maintaining a healthy heart.
Copper	Aids in formation of bone. Aids in formation of haemoglobin and red blood cells. Works in balance with zinc and vitamin C to form elastin for a healthy skin. Involved in hair and skin colouring. Involved in healing process and energy production. Involved in taste sensitivity. Needed for healthy nerves and joints.
Dietary Fiber	Plays a role in keeping the gut healthy.
Docosahexaenoic acid (DHA)	Essential for intellectual/ neural development of baby. Can be beneficial for cardiovascular system.
Fiber that has effects on glucose and lipid absorption	Plays a role in glucose absorption and maintaining a healthy blood cholesterol level.
Fiber that has more pronounced effects on bowel habits	Plays a role in glucose absorption and keeping the gut healthy.
Folate	Helps to form body proteins, genetic material and red blood cells. Folate is essential for the normal development of the unborn baby. Needed for energy production; involved in protein metabolism.
Iodine	Needed for a healthy thyroid gland. Prevents goitre which untreated will lead to mental retardation. Important for physical

	and mental development.
Iron	Helps maintain healthy red blood cells, which play a role in oxygen transportation. Required for a healthy immune system.
Lycopene	A carotenoid which acts as a tissue antioxidant and so keeps cells healthy
Lutein	A carotenoid, which acts as a tissue antioxidant, specifically important for eye health.
Magnesium	Helps to utilise carbohydrates, proteins, fats & minerals; aids as vital catalyst in enzyme activity, especially those enzymes involved in energy production. Helps maintain a healthy muscle and nervous system. Assists in calcium and potassium uptake and plays role in formation of bone. Plays role in transmission of nerve and muscle impulses, therefore preventing irritability nervousness. Aids in maintaining proper pH balance and normal body temperature.
Manganese	Needed for protein and fat metabolism and used in energy production. Needed for healthy nerves and immune system. Needed for blood sugar regulation. Required for normal bone growth, and for the formation of cartilage and lubrication of joints. Required for reproduction. Needed for utilisation of vitamin B2 and vitamin E and works with B-vitamins to give overall feeling of well being. Aids in formation of mother's milk.
Molybdenum	Promotes normal cell function. Aids in activation of certain enzymes. Supports bone growth and strengthening of teeth.
Niacin	Helps the body change the food you eat into energy. Essential for growth.
Omega-3 fatty acids	Plays an important role in the normal development of the unborn baby and during the first year of life.
Pantothenic acid	Plays a role in the metabolism of fatty acids, glucose and proteins for energy production and is necessary for healthy nervous system.
Phosphorus	Helps maintain healthy bones. Plays a part in energy metabolism within cells. Needed for cell growth and to convert food to energy. Needed for blood clotting. Needed for contraction of heart muscle and normal heart rhythm. Needed for kidney function. Assists body to utilise vitamins.
Potassium	Important for healthy nervous system. Important for regular heart rhythm and maintenance of stable blood pressure. Aids in proper muscle contraction. Works with sodium to control body's water balance. Aids in transmitting electrochemical impulses.
Protein	Helps build and repair body tissues and plays a role in protecting the body against disease
Selenium	Functions as a tissue antioxidant thereby keeping cells healthy. Protects unsaturated fatty acids against oxidation in the body (natural antioxidant). Protects immune system by preventing formation of free radicals that can damage body. Regulates effects of thyroid hormone on fat metabolism. Together with vitamin E, aid in production of antibodies to maintain healthy heart & liver. Needed for pancreatic function. Needed for tissue elasticity.
Vanadium	Needed for cellular metabolism and plays role in growth and bone and teeth formation. Plays a role in reproduction. Inhibits cholesterol synthesis. Have the ability to improve insulin utilization, resulting in improved blood sugar tolerance

Vitamin A	Important for the maintenance of good vision, normal growth and a healthy gut and immune system.
Vitamin B <sub>1</sub> (Thiamine)	Helps the body change the food you eat into energy. Maintains growth and healthy nerve function.
Vitamin B <sub>2</sub> (Riboflavin)	Helps the body change the food you eat into energy. Essential for growth.
Vitamin B <sub>6</sub> (Pyridoxine)	Helps the body change the food you eat into energy. Plays a role in protein metabolism. Essential for growth.
Vitamin B <sub>12</sub>	Contributes to a healthy nervous system and is necessary to form red blood cells. Required for the normal functioning of all cells.
Vitamin C Ascorbic acid	Plays a role in maintaining a healthy immune system, gums, skin and connective tissue. Helps with the absorption of iron from food. Functions as a tissue antioxidant thereby keeping cells healthy/Antioxidant/Works with vitamin E and beta-carotene to find and attack free radicals. Aids in tissue growth and repair. Protect against infection.
Vitamin D	For the maintenance of healthy bones and teeth. Helps the body utilise calcium and phosphorus, which are necessary for the normal development and maintenance of strong bones and teeth. Protects against muscle weakness. Involved in regulation of heartbeat. Enhances immunity. Necessary for thyroid function. Necessary for normal blood clotting.
Vitamin E	Functions as a tissue antioxidant thereby keeping cells healthy. Helps maintain a healthy immune system. Protects unsaturated fatty acids and vitamin A against oxidation in the body (natural antioxidant). In combination with vitamin E, beta-carotene, and selenium, associated with a reduced risk of significantly reduced total cancer mortality. Prevents cardiovascular diseases, reduces blood pressure; Promotes normal blood clotting and healing. Necessary for tissue repair, promotes healthy skin and hair. Protects other fat-soluble vitamins and aids in utilisation of vitamin A. Protects normal blood circulation. Protects against damage to red blood cells.
Zeaxanthin	A carotenoid which acts as a tissue antioxidant and so keeps cells healthy
Zinc	Essential for growth and maintains a healthy immune system. Important in prostate gland function and growth of reproductive organs. Required for protein synthesis and collagen formation. Vital for bone formation. Promotes healing of wounds. Helps to fight and prevent formation of free radicals. Needed for normal taste and smell. Protects liver from chemical damage. Is a constituent of insulin & many vital enzymes. Sufficient intake and absorption of zinc is needed to maintain proper vitamin E levels in blood and increases the absorption of vitamin A.

## GUIDELINE 9

**LIST OF CATEGORY NAMES UNDER THE AGRICULTURAL PRODUCTS STANDARDS ACT, 1990 (ACT 119 OF 1990) AND THE STANDARDS ACT, 1990 (ACT 29 OF 1993) IN WHICH THE WORD “REDUCED” OR “LIGHT” APPEARS, WHICH IS NOT REGARDED AS A COMPARATIVE CLAIM**

- **Extra fruit jam**
- **Reduced sugar jam**
- **Extra fruit jelly**
- **Reduced sugar jelly**
- **Reduced sugar marmalade**
- **Reduced oil mayonnaise**
- **Reduced oil salad cream**
- **Reduced oil salad dressing**
- **Light tuna (referring to the colour of the meat)**
- **Any other category name that may be created/determined under any law**

### **EXAMPLES OF CORRECT AND INCORRECT CHOICES OF FOODSTUFFS FOR MAKING A COMPARATIVE CLAIM**

#### **Notes:**

**The principle is always to compare “apples with apples”**

#### **Examples of incorrect comparisons:**

- A soft drink with a fruit juice
- A fruit nectar with a fruit juice
- Grape juice with an orange and apple juice blend
- Pretzels with potato crisps
- Cheese curls with potato crisps
- Cream cheese with cottage cheese
- Cheddar cheese with mozzarella cheese
- A soft drink with an alcoholic cider
- Honey with syrup
- Orange with a banana
- A smoothie made with yoghurt and fruit with a milkshake

- Ice cream with frozen dessert
- Margarine with a medium fat spread
- Jelly babies with chocolate
- Breakfast cereal with cooked porridge

**Examples of correct comparisons:**

- Vienna sausage of one brand name with another brand name Vienna sausage (e.g., difference in fat content)
- A doughnut with chocolate topping with a doughnut with a caramel topping
- One iced tea with another iced tea (difference in sugar content or energy value)
- One brand name of frozen potato chips with another brand name of frozen potato chips (difference in added fat content)
- Bacon with lower sodium content with a bacon with the nearest higher sodium content.

The following example refers:

- Bacon with sodium level of 500 mg /100 g compared to -
  - Bacon with 600 mg sodium/100 g
  - Bacon with 750 mg sodium/100 g
  - Bacon with 945 mg sodium/100 g
  - Average of the above-mentioned 3 types
- One brand name beer with another brand name beer (difference in carbohydrate content or alcohol content)

## GUIDELINE 10

### SAMPLING PROCEDURE FOR THE PURPOSES OF GENERATING NUTRITION DATA BY ANALYSIS AND VERIFICATION

The best practice process of selecting the sample to be sent for analysis is a **random**<sup>a</sup> one. However, there are two alternative types of sample selection processes that may also be used and that are considered acceptable. The decision to use one of these alternative methods will be based on the belief that they provide data of greater accuracy for the average product in question. The first is when a **representative**<sup>b</sup> sample is taken and the second situation is where a **stratified**<sup>c</sup> sample is used.

Other sampling methods, such as those based on **selective**<sup>d</sup> or **convenience**<sup>e</sup> sampling methods are not acceptable.

#### 1. Definitions

- (a) **“Random”** samples are preferred as all products have an equal chance of selection and there is no bias in sampling. Consideration is given to representative and stratified methods of sampling, as it is acknowledged that some circumstances may require this in order to give a more representative average for nutritional data.
- (b) **“Representative”** samples result from a sample plan that can be expected to reflect adequately the properties of interest of the parent population. An example would be a flaked cereal with multiple ingredients, such as dried fruit with more than one type of flaked grain, where a formulation-based proportion sample is prepared. This sample would then be representative of the formulated breakfast cereal, which may not always have the exact proportions in every box coming off the production line. This may allow the reporting of data on carbohydrates to reflect the ideal contributions made from ingredients, as opposed to random samples taken where the fruit content was not as per formulation and may give lower sugar values.
- (c) **“Stratified”** samples consist of portions taken from identical subparts of the parent population. Within each subpart, however, the samples are taken randomly. An example would be in the analysis of the protein fractions of oats, where there are seasonal variations. The parent population in this case would be the oat crop over the past 12 months, the subparts could be the months making up each of the four seasons. The selection of a sample from each of those four seasons, however, would need to be totally random. This would permit the protein value to accurately reflect the seasonal variation of the product, as opposed to a random sample that may be drawn in one particular season.
- (d.) **“Selective”** samples are deliberately chosen by using a sampling plan that screens out materials with certain characteristics and/or selects only material with other relevant characteristics.
- (e) **“Convenience”** samples are chosen on the basis of accessibility, expediency, cost, efficiency or other reasons not directly concerned with sampling parameters.

## **2. Number of samples required for submission to the analytical laboratory**

(a) For products of relative homogenous composition a minimum of three (3) samples from different batches according to the specific, relevant sampling plan (e.g., random sampling, stratified sampling or representative sampling) shall be taken. An example is e.g., pasta etc.

(b) For more variable non-homogenous products, primary produce or prepared foodstuffs, a minimum of twelve (12) samples from various batches according to the specific, relevant sampling plan (e.g., random sampling, stratified sampling or representative sampling) shall be taken. Examples are margarine, muesli, composite cereals, ready-to-eat meals etc.

(c) Individual samples shall be collected from the final packaging line and stored appropriately (see guidelines under Handling) until the required number of samples have been collected to submit to the laboratory for analysis.

## **3. Preparation of composite sample that is used for analysis (to be done by the laboratory)**

The laboratory shall -

(i.) include in the laboratory analysis report the following information:

- Number of samples;
- product name;
- batch numbers;
- barcode if available; and
- date of manufacture or a date of durability where a date of manufacture is not available, of each sample submitted;

(ii.) prepare a composite sample from all the samples for analysis by drawing equal portions (minimum portion is 100 g) from each sample;

(iii.) analyse the composite sample in duplicate and take the mean of the two analysis figures as the final result: Provided that neither result shall deviate by more than 5% of the mean.

## **4. Handling**

All due care shall be taken to ensure the stability of nutrients and to reduce the risk of contamination when selecting samples and sending them to the laboratory for analysis. "All due care" refers to consideration being given to the need for samples to be protected from light, oxygen, temperature, humidity, microbiological spoilage, moisture loss or gain or cross contamination. Not all factors may require action, but they should all be uniformly considered when preparing a sample to go to the laboratory.

## **5. Verification (claim versus no claim)**

### **(a.) Claims**

When making a claim, ongoing verification by analysis is required.

(i) An audit system shall be implemented by the manufacturer for all of the quantitative nutritional claims made and quantitative nutritional information required to substantiate these claims. Claims shall be verified by analysis in such a manner that each nutrient concerned shall be analysed every three (3) years.

(ii) However, for a newly introduced product the analysis required for full quantitative verification of all claims shall be completed within 12 months of the product being made available for sale, after which the audit requirement mentioned above shall come into effect.

(iii) When any change in the product formulation is made the procedure in paragraph (i) shall apply.

(iv) Where a claim is made for a range of products which, in terms of nutritional composition, can be expected to be identical (e.g., different flavours of a soft drink with a common base formulation), only a single product from the range would need verification.

(b) **No claims**

Where nutritional information is not obtained from the MRC Food Composition Tables or another reputable international database, the nutritional information for products that do not carry any claims but that indicate such information on the label should be verified every three (3) years.

## GUIDELINE 11

### PRODUCT INFORMATION IN TERMS OF INGREDIENT/ADDITIVES TRACEABILITY

#### 2 examples of Supplier Ingredient Information Files

#### 1. CALCIUM PROPIONATE

##### MATERIAL TECHNICAL AND NUTRITIONAL DATA SHEET

##### CALCIUM PROPIONATE

<b>Supplier:</b>	
<b>Product:</b>	

<b>Document Date</b>
<b>May 2007</b>

##### Identification

##### **Chemical Names**

Calcium propionate

Calcium propanoate

##### **Chemical Formula and Weight**

$C_6H_{10}CaO_4$

Wt: 186.22

$Ca(CH_3CH_2COO)_2$

##### **ID Numbers**

CAS No: 4075-81-4

INS No: E 282

##### Description and Application

**Description:** A crystalline powder produced by reaction of lime and propionic acid.

**Application:** Used as a preservative in bread production. It is active against many mould species but have a limited inhibitory effect on yeast species. The inhibitory effect on bacteria is limited to retarding the growth of *Bacillus subtilis* (rope) in bread.

**Labelling:** Preservative (calcium propionate)

##### Sensory Information

**Form:** Solid - Crystalline powder

**Colour:** White

**Odor:** Faint odour of propionic acid

##### Material Breakdown

##### **Ingredients**

**Derived from (where applicable)**  
%

Calcium propionate 100% Synthetic product

Diluents/Carriers/Anticaking agents None

Other processing aids (specify) None

##### Country of Origin

A product of South Africa made with local materials, only

**Packaging, Storage and Shelf life**

**Unit size:** 1 x 25 kg (net)

**Packaging:** Woven polypropylene bag with polyethylene liner

**Storage:** Store tightly closed in a cool (<25°C), dry area (<50% R.H.); away from direct sunlight.

**Shelf life:** Day of manufacture plus 24 months in unopened packaging under specified storage conditions

**Date/Batch:** Batch code (day of production): yyyy/mm/dd

**Technical Properties**

**Solubility:** Freely soluble in water. Soluble in ethanol.

**Hygroscopicity:** Mildly hygroscopic

**Thermal Decomp:** Above 250°C

**Technical Specifications**

<b>General:</b>	<b>Codex Standard</b>	<b>Manufacturer's Specification</b>	<b>COA</b>
Assay (dry basis)	Min: 98.0%	Min: 98.0%	√
Loss on drying	Max: 4.0% (105°C for 2 h)	Max: 5.0%	√
Water-insoluble matter	Max: 0.30%	Max: 0.10%	√
pH-Value (1 in 10 sol)	Range: 7.5 - 10.5	Range: 7.0 - 9.0	√
Magnesium (as MgO)	Approx: 0.40%	Max: 0.40%	√
Particle size	No Codex standard	Through 1 000 µm: 100%	√
Bulk density (kg/ℓ)	No Codex standard	Tapped: 0.35 - 0.38 kg/ℓ	√
<b>Metals:</b>	<b>Codex Standard</b>	<b>Manufacturer's Specification</b>	<b>COA</b>
Heavy metals (as Pb)	Max: 10 mg/kg	Max: 10 mg/kg	√
Lead (Pb)	Max: 5 mg/kg	Not tested	-
Iron (Fe)	Max: 50 mg/kg ppm.	Not tested	-
Fluoride (F)	Max: 30 mg/kg	Max: 30 mg/kg	√
Arsenic (As)	No Codex standard	Max: 3 mg/kg	√

**Typical Nutritional Information per 100g Calcium Propionate**

<b>Composition</b>	<b>Value Standards and Specifications</b>
Moisture (g)	4.00 Loss on drying: 5.0% (maximum)
Protein (N x factor) (g)	0.00
Carbohydrates (g)	0.00
Total fat (g)	0.30 AOAC method 920.85
Total dietary fibre (g)	0.00
Ash (g)	30.03
Other compounds (g)	65.67 Mostly non-nutritive volatiles (calculated by difference)
<b>Total (g)</b>	<b>100.00</b>
Sodium (mg)	20

### Food Allergen Information

<b>Contains:</b>	<b>Yes</b>	<b>No</b>	<b>Specify source (if applicable)</b>
Fish or fish derivatives (e.g. caviar)		X	
Crustaceans (e.g. shrimp) or derivatives		X	
Molluscs (e.g. oyster) or derivatives		X	
Milk or milk derivatives (e.g. lactose, whey)		X	
Egg or egg derivatives (e.g. albumin)		X	
Wheat or wheat derivatives (e.g. gluten)		X	
Rye / Barley / Oats or derivatives (e.g. malt)		X	
Soya or soya derivatives (e.g. soya lecithin)		X	
Tree nuts ( <i>excluding palm/coconut</i> ) or derivatives		X	
Peanuts or peanut derivatives		X	

### Food Intolerance Information

<b>Contains:</b>	<b>Yes</b>	<b>No</b>	<b>Specify level and source (if applicable)</b>
Sulphur dioxide (SO <sub>2</sub> )		X	
Sulphites (SO <sub>3</sub> )		X	
Benzoic acid / benzoates		X	
BHA (Butylated hydroxyanisole)		X	
BHT (Butylated hydroxytoluene)		X	
TBHQ (Tertiary butylhydroquinone)		X	
Glutamates (e.g. MSG, L-glutamic acid)		X	
Tartazine		X	
Alcohol (ethanol, only)		X	

### Vegetarian Status

<b>Suitable for:</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Strict vegetarian diet	√		} All material derived from non-animal origin
Lacto-vegetarian diet	√		
Ovo-vegetarian diet	√		
Lacto-ovo vegetarian diet	√		

### Religious Status

<b>Religious group:</b>	<b>Suitable</b>	<b>Certified</b>	<b>Comments</b>
Halal (Muslim diet)	Yes	Yes	Certificate available on request
Kosher (Jewish diet)	Yes	Yes	Certificate available on request

**Genetic Modification Status**

Guaranteed GMO-Free

**Manufacturer's Warrant**

The information contained in this document is to the best of our knowledge accurate.

We guarantee that our product complies with our sales specification as confirmed with Certificates of Analyses.

Name of compar

Document control offic

E-mail addres

2. SUGAR: SUCROSE< LIGHT BROWN (RAW)

**MATERIAL TECHNICAL AND NUTRITIONAL DATA SHEET**

**SUGAR: SUCROSE, LIGHT BROWN (RAW)**

**RM041**

<b>Supplier:</b>	
<b>Product:</b>	

<b>Document Date</b>
21 May 2007

**Identification**

**Chemical Names**

**Chemical Formula and Weight**

**ID Numbers**

Sucrose

$C_{12}H_{22}O_{11}$

Wt: 342.30

CAS No: 57-50-1

$\beta$ -D-fructofuranosyl- $\alpha$ -D-glucopyranoside

INS No: NA

**Description and Application**

**Description:** Partially purified sucrose, which is crystallised from partially purified cane juice, without further purification, but which does not preclude centrifugation or drying, and which is characterised by sucrose crystals covered with a film of cane molasses.

**Application:** Primarily used in the baking and canning industry.

**Labelling:** Sugar (sucrose), Brown sugar, Brown cane sugar, Nutritive sweetener

**Sensory Information**

**Appearance:** Solid – Crystalline

**Colour:** Light brown

**Odour:** Odourless

**Material Breakdown**

**Ingredients**

%

**Derived from (where applicable)**

Raw (brown) sugar

100%

Sugar cane

Diluents/Carriers/Anticaking agents

0%

Other processing aids (specify)

0%

**Country of Origin**

A product of South Africa made with local sugar cane, only.

**Packaging, Storage and Shelf life**

**Unit size:** 1 x 25 kg (net)

**Packaging:** Multi-ply paper bag

**Storage:** Store tightly closed in a cool (<25°C), dry area.

**Shelf life:** Unlimited if stored under specified conditions

Date marking: Not applicable

Batch coding: **Example:** 0610:25 030      06      10:25      030  
Year      Time      Day of year  
2006      10h25      30 Jan

#### Technical Properties

**Solubility**      Very soluble in water. Slightly soluble in alcohol  
**Hygroscopicity:**      Hygroscopic - Protect from moisture and high humidity  
**Melting point:**      Approximately 185°C  
**Thermal Decomp:**      Unknown

#### Technical Specifications

<b>General:</b>	<b>Codex Standard</b>	<b>Manufacturer's Specification</b>	<b>COA</b>
Polarisation	White sugar: 99.70°Z (min)	Brown sugar: 99.39°Z (min)	√
Loss on drying	White sugar: 0.10% (max)	Brown sugar: 0.10% (max)	√
Colour (ICUMSA)	White sugar: 60 IU (max)	Brown sugar: 600 to 1000 IU	√
Particle size	No Codex standard	Mean size: 820 µm	-
Bulk density (kg/ℓ)	No Codex standard	Approximately: 0.850 kg/ℓ	-
<b>Metals:</b>	<b>Codex Standard</b>	<b>Manufacturer's Specification</b>	<b>COA</b>
Heavy metals (as Pb)	Max: 5 mg/kg	Max: 5 mg/kg	-
Lead (Pb)	Max: 0.5 mg/kg	Max: 5 mg/kg	-
Arsenic (As)	Max: 1 mg/kg	Max: 1 mg/kg	-

#### Typical Nutritional Information per 100g Brown (Raw) Sugar

<b>Composition</b>	<b>Unit</b>	<b>USA Tables</b>	<b>Manufacturer's Analysed Values</b>	
Moisture	(g)	1.77	0.1	SABS AOAC Method (2005)
Protein (N x factor)	(g)	0.00	0.9	SABS Method 5435/E142D(2005)
Carbohydrates	(g)	97.33	98.9	Calculated by difference
- of which sugars	(g)	(92.6)	(98.9)	SABS Method 5435/E142D(2005)
Total fat	(g)	0.00	0.1	SABS Method 5435/E142C(2005)
Total dietary fibre	(g)	0.00	0	SABS Method 5435/E142D(2005)
Ash	(g)	0.90	0	SABS Method 5435/E142A(2005)
<b>Total</b>	<b>(g)</b>	<b>100.00</b>	<b>100.00</b>	
Sodium	(mg)	39	0	Method not accredited

#### Food Allergen Information

<b>Contains:</b>	<b>Yes</b>	<b>No</b>	<b>Specify source (if applicable)</b>
Fish or fish derivatives (e.g. caviar)		X	
Crustaceans (e.g. shrimp) or derivatives		X	
Molluscs (e.g. oyster) or derivatives		X	

Milk or milk derivatives (e.g. lactose, whey)	X
Egg or egg derivatives (e.g. albumin)	X
Wheat or wheat derivatives (e.g. gluten)	X
Rye / Barley / Oats or derivatives (e.g. malt)	X
Soya or soya derivatives (e.g. soya lecithin)	X
Tree nuts ( <i>excluding palm/coconut</i> ) or derivatives	X
Peanuts or peanut derivatives	X

#### **Food Intolerance Information**

<b>Contains:</b>	<b>Yes</b>	<b>No</b>	<b>Specify level and source (if applicable)</b>
Preservative: Sulphur dioxide (SO <sub>2</sub> )		X	
Preservative: Sulphites (SO <sub>3</sub> )		X	
Benzoic acid / benzoates		X	
Antioxidant: BHA (Butylated hydroxyanisole)		X	
Antioxidant: BHT (Butylated hydroxytoluene)		X	
Antioxidant: TBHQ (Tertiary butylhydroquinone)		X	
Glutamates (e.g. MSG, L-glutamic acid)		X	
Colourant: Tartazine		X	
Alcohol (ethanol, only)		X	

#### **Vegetarian Status**

<b>Suitable for:</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Strict vegetarian diet	√		} All material derived from non-animal origin.
Lacto-vegetarian diet	√		
Ovo-vegetarian diet	√		
Lacto-ovo vegetarian diet	√		

#### **Religious Status**

<b>Religious group:</b>	<b>Suitable</b>	<b>Certified</b>	<b>Comments</b>
Halaal (Muslim diet)	Yes	Yes	Certificate available on request
Kosher (Jewish diet)	Yes	Yes	Certificate available on request

#### **Genetic Modification Status**

Derived from genetically modified cane sugar

#### **Manufacturer's Warrant**

The information contained in this document is to the best of our knowledge accurate.

We guarantee that our product complies with our sales specification as confirmed with Certificates of Analyses.

Name of company:

Document control officer:

E-mail address:

## GUIDELINE 12

### GUIDELINES FOR THE MANNER OF EXPRESSION OF ENERGY, NUTRIENT OR OTHER SUBSTANCES VALUES FOUND IN FOODSTUFFS AND NUTRITIONAL SUPPLEMENTS IN THE TABLE WITH NUTRITIONAL INFORMATION

When nutrient values, obtained as a result of analysis, are prepared for the nutritional information table for labelling purposes, the nutrient value and the Minimum Daily Requirement percentage (MDR), declared in the table with nutritional information shall, in the case of protein, any amino acid, dietary fibre, vitamins, minerals, bioflavonoids, carotenoids and other substances found in nutritional supplements never be more than physically analysed and, in the case of fat, any fatty acid, trans fat, any sugar, and sodium never be less than physically analysed for, and shall be rounded off appropriately as indicated in the table below.

INFORMATION	DESCRIPTION	UNIT	MANNER OF EXPRESSION
Energy value	"KiloJoules", Total kiloJoules', "Total energy", Total kJ	The amount is expressed in kilojoules per serving of stated size	The amount is rounded off- (a) if it is less than 5 kJ as "0 kJ"; (b) if it is 5 kJ or more but less than 30 kJ to the nearest multiple of 1 kJ; and (c) if it is 30 kJ or more to the nearest multiple of 5 kJ.
Amount of fat	"Fat", "Total fat"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) (i) if it is 0.5 g or less as "0 g", provided no other fatty acid is declared in an amount greater than 0 g, in which case it shall be declared as "< 0.5 g" (ii) in all other cases to the nearest multiple of 0.1 g; (b) if it is more than 0.5 g but not more than 5 g to the nearest multiple of 0.5 g; and (c) if it is more than 5 g to the nearest multiple of 1 g.
Amount of saturated fatty acids	"Saturated fat", "Saturated Fatty acids", Saturated", "Saturates"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is 0.1 g or less as "0 g"; (b) if it is more than

			0.1 g but not more than 5 g, to the nearest multiple of 0.1 g; and (c) if it is more than 5 g to the nearest multiple of 1 g.
Amount of trans fat	"Trans fat"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is 0.1 g or less as "0 g"; (b) if it is more than 0.1 g but not more than 5 g to the nearest multiple of 0.1 g; and (c) if it is more than 5 g to the nearest multiple of 1 g.
Amount of polyunsaturated and monounsaturated fatty acids	Polyunsaturates", "Polyunsaturated fatty acids", "Monounsaturates", "Monounsaturated fatty acids"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off if it is more than 0 g to the nearest multiple of 1 g.
Amount of omega 3 fatty acids	"Omega-3 fatty acids"	The amount is expressed in milligrams (mg) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 5 mg as "0 mg "; and (b) if it is 5 mg or more to the nearest multiple of 1 mg.
Amount of cholesterol	"Cholesterol"	The amount is expressed in milligrams (mg) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is 5 mg or less to "0 mg"; and (b) if it is more than 5 mg to the nearest multiple of 5 mg.
Amount of sodium	"Sodium"	The amount is expressed in milligrams (mg) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 5 mg to "0 mg"; (b) if it is 5 mg or more but not more than 120 mg to the nearest multiple of 1 mg; and (c) if it is more than 120 mg to the nearest multiple of 5 mg.
Amount of carbohydrate	"Carbohydrate" , "Total carbohydrate"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 0.5 g to "0 g"; and (b) if it is 0.5 g or

			more, to the nearest multiple of 1 g.
Amount of fiber or dietary fiber	"Fiber", "Dietary fiber"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 0.5 g to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
Amount of soluble fibre	"Soluble fiber"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 0.5 g to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
Amount of insoluble fiber	" Insoluble fiber"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 0.5 g to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
Amount of sugars	"Sugars"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 0.5 g to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
Amount of protein	Protein"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 0.5 g to the nearest multiple of 0.1 g; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
Amount of (name of amino acid)	"Name of amino acid" e.g., "Methionine"	The amount is expressed in milligrams (mg) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is less than 1 mg to the nearest multiple of 0.1 mg; and (b) if it is 1 mg or more, to the nearest multiple of 1mg
Amount of vitamins	"Name of vitamin" e.g., "Vitamin A" or "Vit A"	The amount is expressed in milligrams (mg) or micrograms (mcg) or international units (IU), as appropriate, per single serving and per 100 g/ml for foodstuffs	The amount is rounded off- (a) if it is 5 % or less of the RDA don't declare; and (b) if it is more than 5% of the RDA, to the nearest multiple of 0.1 mg/ $\mu$ g or the nearest IU , whatever

			is appropriate.
Amount of minerals,	"Name of elemental mineral e.g., "Iron"	The amount is expressed in milligrams (mg) ) or micrograms (µg), as appropriate, per single serving and per 100 g/ml for foodstuffs	The amount is rounded off- (a) if it is 5 % or less of the RDA don't declare; and (b) if it is more than 5% of the RDA, to the nearest multiple of 0.1 mg/µg, whatever is appropriate.
Amount of bioflavonoids or carotenoids	"Name of carotenoid or bioflavonoid" e.g., "Betacarotene" or "Isoflavone"	The amount is expressed in milligrams (mg) ) or micrograms (µg), as appropriate, per single serving and per 100 g/ml for foodstuffs	The amount is rounded off- In all cases if it is more than 0 mg/µg , whatever is appropriate, to the nearest multiple of 0.01 mg/µg, as the case may be.
MDR		The amount is expressed in percentage (%) per single serving	The amount is rounded off to the nearest 1%

## GUIDELINE 13

### GUIDELINES FOR PREPARING DOSSIERS TO SUBSTANTIATE HEALTH CLAIMS FOR PRE-MARKET APPROVAL BY THE DEPARTMENT

#### CONTENTS

1. *Introduction*
2. Overview of Dossier Content
- 3 A Systematic Approach to Reviewing the Evidence
- 4 Types of Evidence
5. Summarising the Evidence
6. Documenting the Search for Evidence
- 7 The Scientific Expert Committee on Health Claims (SECHC)

#### **Annex 1:**

Checklist for Meeting Dossier Requirements

#### **Annex 2:**

Help notes: Reviewing the Evidence Systematically

#### **Annex 3:**

Source and Nature of Scientific Evidence

## 1. INTRODUCTION

These guidelines relate to the scientific substantiation of health claims, specifically Enhanced Function Claims and Reduction of Diseases Risk Claims in the case of foodstuffs and Enhanced Function Claims in the case of nutritional substances. The Guidelines focus on practical steps to prepare a dossier to demonstrate that the weight of evidence that supports the claim. Annex 3 provides additional information to help ensure that claims comply with legal requirements and do not confuse consumers; therefore it is recommended that these guidelines be utilised in conjunction with Annex 3. Interested parties are also urged to contact the Directorate: Food Control for claim-specific advice early in the process as requirements may vary according to the nature of the claim.

It is important to note that for foodstuffs there is no absolute delimitation between “function claims” on the one hand and “enhanced function/other function claims” on the other hand. A “new” function of a nutrient may initially be regarded as enhanced function claim until generally recognised as a “nutrient function claim” or even a “reduction of disease risk claim”, depending on the level of supporting scientific evidence at a particular point in time. A function of a non-nutrient would be regarded as an “enhanced function” according to Codex, but as science advances, it may later become a function claim.

An overview of the approach for processing dossiers can be summarised as follows:

- (a) Interested party initiates early discussions with the Directorate: Food Control about viability of health claim.
- (b) Interested party prepares and submits a dossier of evidence to the Directorate: Food Control for validation of health claim according to the guidelines provided in these Guidelines.
- (c) The Directorate: Food Control Secretariat undertakes preliminary assessment of dossier to ensure its completeness prior to submission to an *Ad hoc* independent Expert Committee. The Secretariat accepts or rejects a dossier. In the case of a dossier being rejected the Secretariat will inform the interested party in writing of the shortcomings. It remains the interested party's choice to resubmit the dossier or not. In the case where a dossier is not resubmitted within the next 3 months from the date of the above-mentioned communication, the process will automatically be terminated at this stage.
- (d) By receipt of the written confirmation mentioned above, to proceed with the evaluation process explained in paragraph (e) below, the Directorate: Food Control may request 3 or more copies of the approved dossier from the interested party.
- (e) A completed dossier is then posted to each scientist on the *Ad hoc* Scientific Expert Committee for assessment of the scientific validity of the health claim.
- (f) The *Ad hoc* Scientific Expert Committee advises Directorate: Food Control of its recommendation about the validity of the health claim.
- (g) The Directorate: Food Control considers the expert recommendation in light of legal and consumer perception issues.
- (h) The Directorate: Food Control finalizes decision to adopt or reject a particular health claim, based on the information stipulated in paragraphs (f) and (g) above.

- (i) The Directorate: Food Control officially informs the interested party of its decision regarding the outcome of the health claim evaluation in writing.

Another purpose of the dossier is to provide the *Ad hoc* Scientific Expert Committee with a review of the evidence relevant to the claim, including information regarding its application and likely impact in SA, so it can make a recommendation based on the totality of the facts. The Committee must first be assured that the dossier has been prepared in a balanced and unbiased way before it can proceed with assessing the validity of the evidence.

The *Ad hoc* Scientific Expert Committee will be appointed by the Minister of Health on an *Ad hoc* basis and the identity of the members will not be disclosed to any applicant. All members shall sign a Confidentiality and Non-disclosure Agreement before final confirmation of appointment. The members serving on this Scientific Expert Committee will be chosen according to their individual expertise and the subject of the claim under investigation. An application fee as determined by the Department will be applicable for each application. Only one claim request per dossier would be permitted. Certain credibility assurance steps were built into the process to ensure, as far as possible, that there will be no direct communication between the applicant and the selected scientists about the evaluation of the claim during the evaluation process which could damaged the credibility and un-biased final opinion expressed by the scientists. The Department reserves the right to withdraw an approval already granted void if substantiated information should come to their attention that any role players did not abide by the rules specified above.

The information on the following pages outlines a step-by-step transparent approach to preparing dossiers, which, if undertaken and documented objectively, will enable the Directorate: Food Control to process claims most efficiently.

## **2. OVERVIEW OF DOSSIER CONTENT**

**The dossier should follow the format below:**

### **(a) Systematic Review of the Evidence**

The purpose is to demonstrate that all evidence relevant to the health claim has been included, is credible and has been reviewed in an objective and transparent manner.

#### **Introduction**

An overview of the relevant health issue and how the claim will benefit consumers:

- (j) Summary which states the following:
- The wording of the proposed, draft health claim (must comply with SA legislation);
  - The proposed efficacious level of the nutrient(s) that is(are) the subject of the claim per serving of the food product that the claim is intended to be used for;
  - The summary referred to above shall be accompanied by the following documentation:
    - The draft label, complete with nutritional information table
    - The true, certified copy of the original laboratory analysis report from a laboratory which has accreditation for each method used to analyse the nutrients indicated on the report, including a complete reference of the methods

- A true, certified copy of the original letter from the Accreditation Authority to confirm that the laboratory has the required accreditation.
- At the back, complete copies of the studies as published

**(b) Methodology**

- Scientific question arising from the health claim
- Definitions of terminology used in health claim/scientific questions
- Search terms and search history – electronic and hand searches
- Inclusion and exclusion criteria
- Tabulated summary of papers included and excluded
- List of references included in the final review

**Individual summaries of evidence**

- Objective review of evidence according to summary protocol
- Summaries grouped by study type

**(c) Supplementary Information**

The following information is required to set the claim in the context of the SA diet and demonstrate how it will be applied to products and promotional material.

- Current SA intakes of the relevant dietary component
- Expected impact on overall diet in SA
- Potential implications for consumers in relation to the claim
- Recommended consumption patterns for achieving the health effect and how this will be communicated to consumers
- Additional information which it may be necessary to communicate to consumers
- Examples of products likely to carry the claim in SA
- Examples of alternative wordings of the claim that may be used
- Demonstration of compliance with legal requirements and nutrition principles embodied by these regulations.
- Any other information as set out in point 6 ('Documentation of Evidence').

### 3. A SYSTEMATIC APPROACH TO REVIEWING THE EVIDENCE

The following steps should be completed in their entirety to demonstrate that the dossier was prepared in a balanced and unbiased manner, with a documented methodology for including and excluding all relevant evidence, regardless of its outcome. Such transparency is essential to the progress of the claim submission. Help Notes with additional information have been provided in Annex 2 (attached).

#### ***STEP 1: Propose the suggested wording of the health claim\****

The wording must comply with relevant SA legislation.

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.

#### ***STEP 2: Define and determine a scientific question to focus the search for evidence***

This allows the inclusion of medical terminology, which may be prohibited in the health claim, but is acceptable to assist with defining the search terms. The scientific question should propose the linkage between the food and the physiological effect that brings about the health benefit.

#### ***STEP 3: Define the keywords for searching for evidence in databases***

Search terms should be broad to ensure full coverage of potentially relevant evidence.

#### ***STEP 4: Develop Reference List 1 from the results of the search***

This will include relevant and irrelevant studies, expert reviews, consensus documents etc, which will be short-listed for inclusion under Step 6.

#### ***STEP 5: Formulate broad inclusion and exclusion criteria***

These criteria will ensure transparency and objectivity when selecting evidence for the review. The criteria should be linked directly to the health claim and scientific question identified in Steps 1 & 2 (above).

#### ***STEP 6: Split Reference List 1 into two categories – those references that meet the inclusion criteria and those that meet the exclusion criteria. Evidence to be included in the next step forms Reference List 2.***

References that meet the exclusion criteria should also be noted.

#### ***STEP 7: Retrieve and review the abstracts for Reference List 2.***

Further define the inclusion and exclusion criteria for relevance to the claim if necessary

#### ***STEP 8: Split Reference List 2 into two categories – those references that meet the refined inclusion criteria and those that meet the exclusion criteria. Evidence to be included in the next step forms Reference List 3***

References that meet the refined exclusion criteria should also be noted.

**STEP 9: Retrieve the full texts for all articles in Reference List 3 and briefly review to ensure relevance to the health claim and scientific question.**

Reject and note any articles that, on reviewing the full text, meet the exclusion criteria rather than the inclusion criteria.

**STEP 10: The remaining articles form Reference List 4. Undertake a detailed review of each of these and summarise the article according to the Summary Protocol (attached).**

**STEP 11: Group the summaries according to study type, regardless of the result, and present an overview of results.**

**STEP 12: Include an additional section in the dossier that provides supplementary information to support the claim submission.**

This should include potential implications, impact on the SA diet, current intakes of the relevant dietary component, typical products for use of the claim, and potential variations in use of the claim.

#### **4. TYPES OF EVIDENCE**

The Directorate: Food Control recognises that types of evidence will vary depending on the nature of the claim. Systematic reviews or meta-analyses, which have been conducted according to a transparent and systematic approach (e.g. Cochrane Review), and meet the inclusion criteria for the dossier, will be considered most credible and given the highest weighting. If such evidence is unavailable, non-systematic consensus documents and expert reviews, including some FDA reports can be submitted, although these reports should be supplemented with other data, as necessary, which has been selected according to the inclusion/exclusion criteria, to add weight to the submission. Mechanistic data, when available, should be included to demonstrate a plausible explanation of how the health benefit is achieved.

TABLE 1: Types of Evidence

	Not available	Excluded	Included
<b>1. Systematic Approaches:</b>			
• Intervention trials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Observational studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2. Non systematic consensus documents:</b>			
• Authoritative statements by government appointed expert committees and other credible bodies.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>3. Other data (as necessary):</b>			
• Randomised controlled clinical trials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Other human intervention trials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Cohort studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Case-control studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Mechanistic studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following table may be useful to complete and submit with the dossier to highlight the types of evidence included in the review.

## 5. SUMMARISING THE EVIDENCE

Extracting the relevant data objectively and presenting the results in a clear, concise manner enables the Scientific Expert Committee to find key information quickly and proceed with the assessment most efficiently. All relevant evidence noted in Reference List 4 (Step 10, above) should be summarised, including primary studies, pooled-analyses (meta-analysis), expert reviews and consensus documents such as FDA submissions or other reports. Summaries should be presented by study type (refer Table 1) to ensure greatest comparability of results.

Individual summaries should be kept brief and address each of the following points:

- a) Title of the study
- b) Authors
- c) Journal reference
- d) Objective of the study
- e) Study type/design

***If the study type/design is a pooled analysis (systematic review or meta-analysis) of many studies, then include:***

- (i) Inclusion/exclusion criteria for the studies, and
- (ii) Data extraction from the studies

- f) Study population
- g) Baseline characteristics of subjects and controls
- h) Duration of the study
- i) Location of the study
- j) Methodology
- k) Dietary assessment technique
- l) Outcome measurement and other relevant measurements
- m) Statistics
- n) Results
- o) Points to note/further comments

## 6. DOCUMENTING THE SEARCH FOR EVIDENCE

Information should be included under the following headings to provide a clear statement of how the evidence was obtained and selected for the review. Such information will help demonstrate that the review has been undertaken in a balanced and unbiased way and represents the totality of the evidence.

Information should be included to identify:

1. Scientific question to focus the review
2. Criteria for including evidence:
  - The evidence for the substantiation of a claim should characterise and describe the food or food component to which the claimed effect is attributed.
  - Substantiation of a claim should be based primarily on human intervention data. The design of studies should include the following considerations:
    - Study groups that are representative of the target group
    - Appropriate controls both for the intervention itself, and for the subject Groups
    - An adequate duration of exposure and follow up to demonstrate the intended effect
    - Characterisation of the target groups' background diet and other relevant elements of lifestyle
    - An amount of the food or food component consistent with its intended pattern of consumption
    - The effect of the food matrix and dietary context on the bioequivalence of the compound
    - Monitoring of compliance with intake of food or ingredient under test
    - The statistical power to test the hypothesis
  - When the true endpoint of a claimed benefit cannot be measured directly, studies should use valid markers.
  - Markers should be:

- biologically valid in that they have a known relationship to the final outcome and their variability within the population is known
- methodologically valid with respect to their analytical characteristics
- Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported.

3. Criteria for excluding evidence

4. Keywords and date range for electronic database search. Data shall not be older than 5 years, e.g. if the search is conducted in 2004 that oldest data may not be older than 1999.

5. Keywords and date range for reputable journal hand search of recently published papers

6. List of references resulting from search and table of search results in numerical terms (refer Table 2 for example).

7. Reference list of the evidence included in final review (grouped according to study type), including author(s), title and journal reference.

8. No less than 5 acceptable studies shall be included in the final dossier.

**TABLE 2: Example of Table for Search Results**

<b>YEAR SEARCHED</b>	<b>ARTICLES FOUND</b>	<b>ABSTRACTS READ</b>	<b>FULL ARTICLES RETRIEVED</b>	<b>INCLUDED IN FINAL REVIEW</b>
2004	31	7	1	1
2003	39	15	1	1
2001	19	2	2	1
2000	21	1	1	0
1999	8	0	0	0
Etc		0	0	0

## **ANNEX 1**

### **CHECKLIST FOR MEETING DOSSIER REQUIREMENTS**

The dossier should consist of two key sections:

- The systematic review of evidence
- Supplementary information

Use the checklist below as a guide to completing each section. Each of the points should be completed before submitting the dossier to the Directorate: Food Control.

#### **SECTION 1: Systematic review**

- An overview of the health issue and benefits of the claim has been provided.**
- The proposed health claim and related scientific question have been stated.**
- Terminology used in the health claim has been clearly defined and is consistent with definitions used in the evidence.**
- Broad search terms have been used to capture variations in scientific terminology.**
- Inclusion and exclusion criteria has been clearly stated and adhered to (i.e. the criteria explains why evidence has been included or excluded from the review).**
- All evidence that meets inclusion criteria has been included, regardless of the outcome.
- All references resulting from the search have been documented and categorised according to the Framework for Reviewing Evidence.
- Each reference included in the review has been summarised objectively, without interpretation of the results.
- Summaries of references included in the review have been grouped according to study type (rather than according to outcome).
- A detailed account of the process followed to search and review the evidence has been documented.
- The evidence is of good quality and in accordance with well-established scientific methods.

- Subjects are representative of the general population, or target population as appropriate.
- The evidence relates to intake levels of the dietary component that can be achieved by the average consumer via realistic quantities in food products.**
- Feeding patterns and serving sizes reflect consumption patterns that can be achieved by the average consumer.**

**SECTION 2: Supplementary Information**

- The claim been set in the context of the South African diet and has consideration been given to how the claim will impact on the overall diet.
- Potential implications and any possible adverse effects have been considered.
- Information about current intakes in SA has been provided.
- Recommended consumption patterns, to demonstrate how consumers obtain the benefits from the dietary component at the levels as shown to be effective by the evidence, have been included.
- Examples of typical products likely to carry the claim and any alternative wordings of the claim are noted.
- Consideration of the claim against the legal requirements has been documented.

**If it is not possible to include all information as suggested above, a brief explanation should be provided to demonstrate that consideration has been given to these issues.**

## **ANNEX 2**

HELP NOTES: Reviewing the Evidence Systematically

The following Helps Notes are intended for use with (3), 'A Systematic Approach to Reviewing the Evidence'.

### **1. Defining the health claim and corresponding scientific question**

- a) A clearly defined health claim is required before the scientific questions relating to that claim can be formulated. This may require preliminary discussions with the Directorate: Food Control to help clarify the issues.
- b) The scientific question will help formulate the search terms and inclusion/exclusion criteria because terminology, which would be considered medicinal as a health claim, may be used freely. However, the scientific question must not alter the meaning of the claim.
- c) Terminology and quantities of intake must be clearly defined to ensure consistency and comparability of individual study results.
- d) A successful search relies on a carefully considered and well-defined health claim and corresponding scientific question.

**CHECK: Is the health claim or scientific question open for interpretation? Redefine if necessary.**

### **2. Keywords and search terms**

- a) To provide a scientific focus and ensure maximum efficiency when searching the evidence, clear search terms are required and must relate explicitly to the proposed health claim.
- b) Alternative terminology for keywords should be considered if the search results do not seem particularly relevant, or if few references are found (the database thesaurus can help with this). Consider terms in relation to exposure/intervention and outcome measures.

**CHECK: Are the search terms sufficiently broad to retrieve all relevant information? If no, consider alternative words.**

### **3. Searching for Evidence**

- a) Relevant databases include Medline, Embase, Cochrane, Current Contents Search, Science Citation Index and so on, however results can differ depending on the nature of the health claim and search terms entered.
- b) Start the electronic database search as comprehensively as possible, covering all fields of the search areas for the defined keywords.
- c) It is sensible to search the evidence chronologically, on yearly basis, starting from the present and to organise the results in the reverse chronological order and according the type of the evidence; i.e. systematic reviews, meta-analyses, controlled intervention trials and so on, so results can be compared by study type for consistency.
- d) A systematic approach to searching the evidence should be followed for the entire process, according to an explicit and reproducible methodology and should be recorded for transparency while the search is undertaken.
- e) Applying a systematic approach to search the evidence requires judgment at every step of the process, about the suitability and quality of the evidence and whether it is linked directly to the health claim. Generally the search should focus on primary studies directly related to the health claim.
- f) Selecting only articles in English language is a non-systematic way of excluding articles from the search. However, it may be necessary to do so when articles have not been translated into English.

**Check other sources for relevant evidence**

- g) Hand search the latest issues (the current and past year) of the following periodicals: BMJ, JAMA, Lancet, NEJM and Am J Clin Nutr for the relevant articles. This does not guarantee full coverage of all existing evidence, but provides an idea of the latest articles published in reputable journals, missed by the electronic database search.
- h) Once the full articles have been retrieved, check the reference lists of each article for additional appropriate studies.

**CHECK: Have all appropriate sources of evidence been exhausted? Is it possible that an important piece of evidence remains uncovered?**

**4. Selecting relevant studies from the search results**  
**Set clearly defined inclusion/exclusion criteria**

a) Selection of the studies should be based on an adherence to explicit and pre-defined inclusion and exclusion criteria, which link directly to the health claim. These criteria should be followed meticulously to demonstrate that the included studies were not selected based on personal or biased choice.

b) Common sense should be applied to ensure that relevant studies are not excluded, or studies of poor quality and design are included. It is helpful to question whether the exposure and outcome measurement is directly relevant to the health claim.

c) When undertaking a systematic review, not only must the search for relevant articles be thorough and objective, but the criteria used to reject articles, as flawed or irrelevant, must be explicit and independent of the results of those studies.

d) The methodological quality of included studies must be high and each study should be carefully considered for its validity. Study results are likely to be invalidated by poor study design. Methodological shortcomings are usually generic (they are independent of the subject matter of the study), therefore each study should be judged against a list of minimum quality requirements to help ensure methodological soundness.

**Skim read the abstracts**

e) Assess the search results to identify articles that might be relevant to the health claim and worth reading the abstract for further details. At this stage only skim reading is necessary to select the possibly relevant studies, and consider whether the article is likely to provide an answer to the scientific questions linked to the health claim.

f) Well-written abstracts should provide sufficient information to decide whether the study is relevant to the scientific question based around the health claim. In cases of uncertainty after reading the abstract about the relevance of the article, retrieve the full article to find out.

g) It is for the Expert Committee to make complex judgments about the methodological soundness of the studies, however, it should be possible to weed out studies, which do not meet the basic criteria.

**CHECK: Do all included and excluded studies comply with the inclusion and exclusion criteria? Check that the same objective standard has been applied to each study.**

**Are the criteria appropriate and reproducible? Research quality criteria for different study types.**

**5. Reviewing the evidence and extracting relevant information**

### **Retrieve the full article**

- a) Skim read the retrieved full articles to decide whether the study really answers the scientific question posed by the health claim. Reject those studies that do not fit the inclusion criteria or are poorly designed.
  
- b) Read the full articles in detail and extract the relevant information from all eligible studies, for and against the health claim. Refer to the review protocol for an indication of the information required.

### **Extract and summarise the key relevant points**

- c) Presenting a summary of individual studies in a standardized way, using the review protocol provided, will help determine whether the study is methodologically sound.
  
- d) It is important to provide the Expert Committee with enough information so it can form its overall opinion about whether the claim is substantiated by scientific agreement. It is also important not to detract from the key facts by providing details that are not directly relevant.
  
- e) Supporting information can be provided within the dossier, but it should not be included in the systematic review unless it was included in the search results and complies with the inclusion criteria.

**CHECK: Are the relevant key points extracted in the briefest form possible?**

## **6. Presenting the data**

- a) Data should be grouped according to study type/design and presented accordingly. If it can be demonstrated that different investigators have achieved the same results, using the same study type and quality methodology but with different populations, the results will increase in validity.
  
- b) Ideally the overall results of the review, (i.e. a summary of all individual study results), should be presented in a Forest plot, or odds ratio diagram, to illustrate the weight of scientific opinion.

## **ANNEX 3**

### ***The Source and Nature of Scientific Evidence***

#### **1. INTRODUCTION**

This Annex provides guidance about what is meant by the “totality of the evidence” and “studies which are the most methodologically sound”.

#### **2. THE TOTALITY OF EVIDENCE**

A health claim should be based on a systematic review of the totality of the evidence relevant to the claim. There are now generally recognised ways of ensuring that all the evidence relating to a scientific question is collected and evaluated for its relevance. These methods involve the use of electronic databases, standardised data extraction procedures etc.

The scientific evidence to substantiate a health claim is likely to be drawn from three general types of studies:

1. Human intervention (experimental) studies (sometimes referred to as clinical studies)
2. Observational human studies (sometimes referred to as epidemiological studies)
3. Biochemical, cellular or animal studies.

It is important to note that human studies are always necessary to substantiate a claim but that biochemical, cellular or animal studies are also helpful if the rationale for such studies is clear. Animal studies cannot always be generalised to humans because of differences in metabolism between humans and animals. However it is often convenient to use animals in the early stages of establishing an association between a food or food component and a possible beneficial effect.

#### **3. STUDIES WHICH ARE THE MOST METHODOLOGICALLY SOUND**

##### **3.1 The Hierarchy of Evidence**

A health claim should be based on the studies in humans which are the most methodologically sound. In general intervention studies in humans are more useful when substantiating a claim than observational studies. This is because intervention studies are less susceptible to bias than observational studies i.e. the researcher can be more sure that any observed effect is attributable to the proposed cause and not to other factors. Substantiation of a claim should be based primarily on human intervention data. The design of studies should include the following considerations:

- (a) Study groups that are representative of the target group
- (b) Appropriate controls both for the intervention itself, and for the subject groups

- (c) An adequate duration of exposure and follow up to demonstrate the intended effect
- (d) Characterisation of the target groups' background diet and other relevant elements of lifestyle
- (e) An amount of the food or food component consistent with its intended pattern of consumption
- (f) The effect of the food matrix and dietary context on the bioequivalence of the compound
- (g) Monitoring of compliance with intake of food or ingredient under test
- (h) The statistical power to test the hypothesis
- (i) A scientifically substantiated mechanism, which is valuable but not essential

Some designs for an experimental study are more susceptible to bias than other designs. In intervention studies subjects are purposely allocated to different groups exposed to different conditions (normally an "intervention" group or groups and a "control" group). The most reliable method of allocating subjects to different groups is by random allocation. Ideally this allocation should be concealed from both the investigators and the subjects (double blind).

Similarly some designs for an observational study are more reliable than others. Studies, which are planned in advance and undertaken prospectively, are less likely to be biased than studies, which are carried out retrospectively. Cohort studies are more reliable than case-control studies.

Cohort studies are studies in which groups of individuals who vary their exposure to different conditions are followed to assess what happens to them. Case-control studies are studies in which individuals who have experienced a particular effect are compared with individuals who have not.

Therefore studies, which might substantiate a claim, can be arranged into a hierarchy of evidence as follows:

## SOURCES OF EVIDENCE

<b>TYPE OF EVIDENCE</b>	<b>NO OF IMPORTANCE IN DESCENDING ORDER</b>	<b>TYPE OF STUDY</b>	<b>COMMENTS</b>
<b>HUMAN INTERVENTION</b> (gold standard)	1	Meta analysis of RCT's*	
	2	Single RCT*	
<b>OBSERVATIONAL (Randomised versus non-randomised)</b> (Acceptable in the case of generic type claims)	3 4	Prospective cohort studies Retrospective cohort studies	
	5	Case-control (always retrospective)	
	6	Cross-sectional studies	
<b>OTHER</b>	7	Clinical data	Clinical data for instance could assist in formulating a hypothesis for a potential claim
	8	<i>In vitro</i> cell and molecular studies	
	9	Genetics studies	
		Animal studies	

\* RCT = Randomised control trial

In general claims should be substantiated using studies from the top of the hierarchy. Care should be taken using a hierarchy of evidence since validity not only depends on the type of study but also how well it was designed, carried out and analysed. A badly executed randomised controlled trial may be less valid than a well-conducted case-control study.

### 3.2 The Validity of Studies

With studies used to substantiate health claims (whether these are experimental or observational) validity is

improved if -

**(i) The subjects are representative of the target group for the claim.**

(ii) The subjects consume a reasonable amount of the food or food component in question at a reasonable frequency, consistent with realistic consumption patterns.

(iii) The study is large enough to demonstrate the proposed beneficial effect. The desirable size for a study can be assessed using standard formulae.

(iv) The duration of the study is long enough to justify any implication of the claim that a beneficial effect is a long-term effect rather than a short-term effect.

(v) The outcomes are measured properly according to standard procedures.

(vi) The outcomes are the same or similar to the claimed effect. For example, if the claim refers to a risk factor for a disease then at least some of the studies used to substantiate the claim should involve measuring that risk factor.

(vii) Possible confounding variables are taken into account. In a study of the association between a food or a food component and a beneficial effect, confounding can occur when the study population is exposed to something else (e.g. age), which is associated with the proposed cause and effect.

#### **4. DRAWING CONCLUSIONS FROM THE EVIDENCE**

In drawing conclusions from the totality of the evidence and from the studies, which are the most, methodologically sound the conclusions will be more valid if the results:

(i) **Are consistent.** The observed effects should have been observed more than once by different persons, in different places, under different circumstances and at different times.

(ii) **Are biologically plausible.** An association is more likely to be causal if consistent with other knowledge. A health claim is more likely to be valid if supported by physiology and biochemistry.

(iii) **Show a temporal relationship.** The proposed cause must precede the effect. This is usually self-evident though difficulties may arise in situations (e.g. case-control studies) where measurements of the possible cause and effect are made at the same time.

(iv) Are statistically valid.

***The following essential supplementary information is strongly recommended namely:***

Aggett et al., 2005. Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) – Consensus on criteria. European Journal of Nutrition, in press.

Codex Alimentarius: Recommendations on the scientific basis of Health claims

**REPORT TO BE COMPLETED BY SCIENTIFIC EXPERT GROUP**

Submission of document received on (date).....

(Name) of members participated in this Scientific Expert Panel:

- 1.
- 2.
- 3.

Name and/or description of the foodstuff/nutritional supplement:

	<b>Score</b>  (Allocation of score on a scale of 1 to 4*)	<b>Comments</b>
Systematic review		
An overview of the health issue and benefits of the claim has been provided.		
The proposed health claim and related scientific question have been stated.		
The proposed health claim and related scientific question have been stated.		
Terminology used in the health claim has been clearly defined and is consistent with definitions used in the evidence.		
Broad search terms have been used to capture variations in scientific terminology.		
Inclusion and exclusion criteria has been clearly stated and adhered to (i.e. the criteria explains why evidence has been included or excluded from the review).		
All evidence that meets inclusion criteria has been included, regardless of the outcome.		
All references resulting from the search have been documented and categorised according to the		

Framework for Reviewing Evidence.		
Each reference included in the review has been summarised objectively, without interpretation of the results.		
Summaries of references included in the review have been grouped according to study type (rather than according to outcome).		
A detailed account of the process followed to search and review the evidence has been documented.		
The evidence is of good quality and in accordance with well-established scientific methods.		
Subjects are representative of the general population, or target population as appropriate.		
The proposed efficacy level of each nutrient that is the subject of the claim has been stated per serving/daily serving.		
The evidence relates to intake levels of the dietary component that can be achieved by the average consumer via realistic quantities in food products.		
Feeding patterns and serving sizes reflect consumption patterns that can be achieved by the average consumer.		
Supplementary Information		
The claim been set in the context of the South African diet and has consideration been given to how the claim will impact on the overall diet.		
Potential implications and any possible adverse effects have been considered.		
Information about current intakes in SA has been provided. Recommended consumption patterns, to demonstrate how		

consumers obtain the benefits from the dietary component at the levels as shown to be effective by the evidence, have been included.		
Examples of typical products likely to carry the claim and any alternative wordings of the claim are noted.		
Consideration of the claim against the legal, nutrition and consumer related issues have been documented.		
	<b>Total score:</b>	

- \* 1 = Information incomplete and unacceptable
- 2 = Information complete but unacceptable
- 3 = Information not complete but acceptable
- 4 = Information is complete and acceptable

**Final conclusion and recommendation of the Scientific Expert Group**

<b>Question</b>	<b>Yes?</b>	<b>No?</b>	<b>Comments or alternative proposal</b>
Can the claim be accepted?			
Will the minimum level of the nutrient(s) involved per serving or per day be efficacious to achieve the desired result?			
Was the evidence sufficient to substantiate or support the claim and the recommended level of the food/nutrients?			

<b>Signature of each member of the Scientific Expert Group</b>	<b>Date</b>
1.	
2.	
3.	

**Definitions:**

“**case-control study**” means a study that compares the exposure to a suspected cause of a disease in people with that disease (the cases) to the exposure in those without that disease (controls); exposure is thus assessed retrospectively. See also ‘cross-sectional study’;

“**endpoint**” means a variable or outcome that is relevant in itself, e.g. survival time after medical surgery, time to run a marathon, fewer periods of gastrointestinal discomfort, or a reduced risk of a disease. The level of a surrogate or intermediate endpoint – also referred to as ‘marker’ - is in itself not relevant, but is indirectly relevant because it reflects a relevant endpoint. See also ‘marker’;

“**observational study**” means researchers do not intervene but only observe outcomes of interest and the levels of their suspected causes, e.g. cohort or case-control study. See also ‘cross-sectional study’ and ‘intervention study’. Observational studies are often commonly loosely referred to as epidemiological studies;

## GUIDELINE 14

### **GUIDELINES FOR PREPARING DOSSIERS TO SUBSTANTIATE CLAIMS FOR ENTERAL FOODS FOR THE DIETARY MANAGEMENT OF PERSONS WITH SPECIFIC MEDICAL CONDITIONS FOR PRE-MARKET APPROVAL BY THE DEPARTMENT**

The use of enteral foods for special medical purposes shall have been demonstrated, by scientific research in the form of clinical studies, to be safe and effective in meeting the nutritional requirements of the persons for whom they are intended, and a written submission with a request for approval and a dossier containing the required scientific substantiation according to the format provided in this Annexure, has been submitted to the Directorate: Food Control at least 6 months before the foodstuff appear on the market.

These guidelines relate to the scientific substantiation of the statement “For the dietary management of...”, indicating the specific disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective.

#### **1. INTRODUCTION**

The Guidelines focus on practical steps to prepare a dossier to demonstrate that the weight of evidence supports the statement

An overview of the approach for progressing dossiers can be summarised as follows:

- (a) Interested party prepares and submits dossier of evidence to Directorate: Food Control for validation of the statement “For the dietary management of...”, indicating the specific disease(s), disorder(s) or medical condition(s) for which the product is intended.
- (b) Directorate: Food Control Secretariat undertakes preliminary assessment of dossier to ensure its completeness prior to submission to an *Ad hoc* independent Expert Committee.
- (c) Completed dossier submitted to each expert on the Scientific Expert Committee for assessment of the scientific validity of the health claim.
- (d) Scientific Expert Committee advises Directorate: Food Control of its recommendation about the validity of the statement.
- (e) Directorate: Food Control adopts or rejects the recommendation.
- (f) Directorate: Food Control reports decision to interested party.

The purpose of the dossier is to provide the Scientific Expert Committee with a review of the evidence relevant to the statement so it can make a recommendation based on the totality of the facts. The Committee must first be assured that the dossier has been prepared in a balanced and unbiased way before it can proceed with assessing the validity of the evidence.

The Scientific Expert Committee will be appointed by the Directorate: Food Control of the Department on an *Ad hoc* basis. All members shall sign a confidentiality and non-disclosure agreement before final confirmation of appointment. The members serving on this Scientific Expert Committee will be chosen according to their individual expertise and the subject of the statements under investigation.

The information on the following pages outlines a step-by-step transparent approach to preparing dossiers, which, if undertaken and documented objectively, will enable the Directorate: Food Control to process requests most efficiently.

## **2. OVERVIEW OF DOSSIER CONTENT**

**The dossier should follow the format below:**

### **Introduction**

An overview of the relevant medical condition issue and how the dietary modifications will benefit the target patient population:

(a) Summary which states the following:

- The wording of the proposed, draft statement and information on the nature and purpose of the food;
- Information on the essential characteristic of the foodstuff e.g., a specific modification of the content, or the nature of the proteins, or fats or carbohydrates and a description of the modification and information on the amino acid, fatty acid or carbohydrate profile;
- The summary referred to above shall be accompanied by the following documentation:
  - The draft label, accompanying leaflets and advertisements, complete with information as required by regulation 70.
  - The true, certified copy of the original laboratory analysis report from a laboratory, which has, accreditation for each method used to analyse the nutrients indicated on the report, including a complete reference of the methods.
  - A true, certified copy of the original certificate/letter from the Accreditation Authority to confirm that the laboratory has the required accreditation.
  - At the back, complete copies of the clinical studies as published.
- Full copies of all reference documents concerning adequate precautions, known side effects, contraindications, and nutrient-drug interactions\*, where applicable.
- Inclusion and exclusion criteria
- Tabulated summary of papers included and excluded
- List of references and full copies thereof included in the final review

\* **References for nutrient-drug interactions shall be the latest editions of -**

1. Natural Medicines Comprehensive Database, ISBN, 096761368X, published by the Therapeutic Research Center.
2. The Nutritional Cost of Prescription Drugs by Pelton R. & Lavalley J.B.

## REPORT TO BE COMPLETED BY SCIENTIFIC EXPERT GROUP

Submission of document received on (date).....

(Name) of members participated in this Scientific Expert Panel:

- 1.
- 2.
- 3.

Name of product under review:

	<b>Score</b>  (Allocation of score on a scale of 1 to 4*)	<b>Comments</b>
Systematic review		
Does the wording of the proposed, draft statement and information on the nature and purpose of the food correspond?		
Is the information on the essential characteristic of the foodstuff e.g., a specific modification of the content, or the nature of the proteins, or fats or carbohydrates and a description of the modification and information on the amino acid, fatty acid or carbohydrate profile correct for the specific medical condition?		
Does the draft label, accompanying leaflets and advertisements, have complete information with regards the nutritional content and modification relevant to the medical condition it is intended for?		
Does the draft label, accompanying leaflets and advertisements, carry the statement " USE UNDER MEDICAL SUPERVISION"?		
Is the information on the osmalality or osmolarity correct?		
Does the product provide the full range of known nutrients essential maintaining a healthy nutritional status in cases where the product		

may be used as the sole source of nutrition on a long-term basis?		
-------------------------------------------------------------------	--	--

- \* 1 = Information incomplete and unacceptable
- 2 = Information complete but unacceptable
- 3 = Information not complete but acceptable
- 4 = Information is complete and acceptable

**Final conclusion and recommendation of the Scientific Expert Group**

Question	Yes?	No?	Comments or alternative proposal
Was it possible to validate the statement by the scientific information provided?			
Will the nutrient profile and nutrient modification(s) per serving or per day is efficacious to achieve the desired result for patients with the specific medical condition for which the enteral foodstuff is intended?			
Was the evidence sufficient to substantiate or support the statement and the recommended level of the food/nutrients and/or modifications?			

Signature of each member of the Scientific Expert Group	Date
1.	
2.	
3.	

