health

Department:
Health
REPUBLIC OF SOUTH AFRICA

DRAFT GUIDELINES

THESE DRAFT GUIDELINES ARE APPLICABLE TO THE DRAFT REGULATIONS RELATING THE

LABELLING AND ADVERTISING OF FOODS (R429 OF 29 MAY 2014),

FOR COMPLIANCE PURPOSES

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GUIDELINE 1

PRODUCT INFORMATION IN TERMS OF INGREDIENT/ADDITIVES TRACEABILITY

The following Supplier Ingredient Information File is a guideline, example or template which suppliers/manufacturers can use as a basis document to record the information about every ingredient and additive used in the manufacturing of foods. Suppliers/manufacturers may use their own formats, provided all the relevant information that is required by the Regulations Relating to the Labelling and Advertising of Foodstuffs.

PRODUCT & CONTACT DETAILS

Customer's Product Name		**Customer's** Product Code	
Supplier's Product Name		**Supplier's** Product Code	

Status	☐ Existing Product	☐ New Product

Supplier Information

Company Name	
Trading Name	
Business Address	
Postal Address	
Technical Contact Person	
Position Title	
Phone	
Fax	
Cell phone (mobile)	
Email	

Manufacturer(s) or Producer(s) Information
(Complete only when manufacturer or producer is different to supplier, e.g. bought from distributor or agent. List all alternative sources or suppliers.)

Company Name	**Site of Manufacture or production (City & Country)**

Clarity / explanation
Additive numbers refer to the International Numbering System as per JECFA (Codex)

Checklist
☐ All sections of questionnaire complete
☐ This document has been signed and dated
☐ Supplier Test Results (COA) attached – if applicable
☐ Current Halaal Certificate attached – if applicable
☐ Current Kosher Certificate attached – if applicable
☐ Other associated documents as requested by the customer attached (Refer customer's covering letter or request)

☐ MSC / Other
☐ Organic certification
☐ Hygiene Audit (or equivalent, e.g. FSIS/BRC/M&S/Global GAP)
☐ HACCP / Food Safety Certification
☐ Supplier Declaration and Warranty

The Supplier –

- Certifies that this product complies with all relevant South African legislation;
- Acknowledges that the Customer, and Supply Chain Customers of the Customer, will rely on the accuracy of the Product Information for food quality, safety and labelling purposes, and that errors or omissions in the above information may cause significant loss and damage;
- Certifies that the Product information contained herein is true and accurate to the following degree-
    - That the Product Information in relation to ingredients that it buys in from a third party relies in good faith on Product Information provided by that third party and attached to this declaration;
    - That the information is unconditionally true and accurate in relation to all other substances and processes;
- Agrees that all Product it supplies to the Customer will conform with the Product Information unless otherwise agreed to in writing and in advance by the Customer;
- Will immediately inform the Customer (and confirm in writing as soon as possible) if it becomes aware of any error or omission in the Product Information;
- Will inform the Customer in writing and in advance of any change to the Product Information provided herein; and
- Acknowledges that the Customer may provide the Product Information to third parties.

Insert the following information:

Company Name (Signed for and on behalf of)	
Name (please print)	
Job Title	
Authorised Signature	
Date	

Customer Internal Use Only	
Internal Product Code / Description	
Internal Supplier Code / Description	
Version No.	
Approved	☐ Yes ☐ No
Additional Information Required	
Received and Reviewed by	

Date	
Signature	

PRODUCT INFORMATION & INGREDIENTS

Product Description

Physical and technological description

Legal Description / Suggested Labelling Description

Ingredient Declaration including QUID

(Full list of ingredients including food additives in descending order, including percentage labelling of characterising components or ingredients [QUID declaration], and full break down of compound ingredients. Ensure all relevant information such as additive numbers are included.)

Processing Aids

(Full list of processing aids used in the manufacture of this product and not declared in the ingredient listing – e.g. carriers / anti foam / divider oil / etc.)

Country of Origin

Statement (Select 1 option only)		**Insert Country Below**		**Specify % Imported Ingredients**	**Specify Country / IES of Imported Ingredients**
☐	Product of				
☐	Produced in and/or Packed in		From local and imported ingredients		
☐	Other – specify				

Component country of origin

(List all ingredients in descending order and Indicate all countries from which ingredient can be sourced)

Ingredient	Country of origin

Allergen & compositional information

Mandatory Advisory or Warning Statements and Declarations

(A "Yes" response may trigger an advisory or warning statement.)

Food / Component	**Present Yes / No**
Aspartame	
Glutamates (MSG)	
Tartrazine	
More than 10 % of final product irradiated	
Herbal and botanical extracts *If 'yes' please specify*	
Isomaltulose	
Polyols, Isomalts, Polydextrose (Lactitol, Maltitol, Maltitol syrup, Mannitol, Xylitol, Erythritol, Isomalt, Polydextrose, Sorbitol). *If 'yes' please specify type/s and levels*	

Type	**Level (g/100g)**

Mandatory Declaration of certain substances

*Please insert YES **or** NO to indicate if the product contains any ingredient, additive or processing aid which has been derived from the food source.*

All responses trigger additional information. Ensure Cross Contact Details are complete.

Food	**Yes*/ No**	***If Yes, additional information must be inserted where prompted**	**Cross Contact Details**	
			Present on same line Yes/No	**Present in same Facility Yes/No**
Cereals containing gluten & their products		Specify name of cereal and type of derivative/s:		

namely, wheat, rye, barley, oats, spelt & their hybridised strains		Has the product been rendered gluten free by processing (no detectable gluten)? Yes / No			
		Has the product been rendered free of all wheat proteins by processing? Yes / No			
Crustacea & crustacea products (shrimp, prawn, crab, lobster and crawfish or crayfish)		Specify name (common & scientific) of Crustacea and type of derivative/s:			

Food	**Yes*/ No**	***If Yes, additional information must be inserted where prompted**	**Cross Contact Details**	
			Present on same line Yes/No	**Present in same Facility Yes/No**
Molluscs & mollusc products (abalone or perlemoen, calamari, clams, cockles, mussels, oysters, scallops, whelks, winkles)		Specify name (common & scientific) of Molluscs and type of derivative/s:		
Egg & egg products		Specify type of egg derivative/s:		
Fish & fish products (Including fish oils)		Specify name (common & scientific) of fish and type of derivative/s:		
Milk & milk products		Specify animal specie from which milk has been derived		
		Specify type of milk derivative/s:		
Peanuts & peanut products (including peanut oil)		Specify type of peanut derivative/s:		

Soybeans & their products (including soybean oils)		Specify type of soybean derivative/s:			
Tree nuts & their products (excluding coconut & pine nut)		Specify name/s of tree nuts and type of derivative/s:			
Sulphites		Total level of sulphites in product (mg/kg):			
		Total level of added sulphites in product (mg/kg):			
		Specify type of added sulphite/s and additive number/s			

Allergen Cross Contact

Has your company addressed the issue of cross contact from allergen causing components?

☐ Yes	How is cross contact of allergens avoided? ☐ validated cleaning procedures swabs/visual/Elisa ☐ production scheduling ☐ control of personnel movement in factory ☐ staff training ☐ documented procedures and controls ☐ isolated storage of allergens ☐ other
☐ No	Does your company handle, process or have onsite any allergen causing components? ☐ Yes ☐ No
	If YES by what date do you plan to have addressed the issue of allergen cross contact within your manufacturing premises?

Additional Consumer Information Requirements
Indicate if the product contains or is manufactured from any of the following

Food / Component	**Yes* /No**	***If YES additional information must be inserted where prompted**
Beef (or bovine)		Specify type/s of beef (or bovine) derivative/s:
		Does the cattle feed exclude animal derived products?
		Is growth hormones used?

Food / Component		**Yes* /No**	***If YES additional information must be inserted where prompted**	
			Specify country/ies of origin:	
Chicken			Specify type/s of chicken derivative/s:	
			Does the chicken feed exclude animal derived products?	
			Is routine antibiotics used as a growth promoter during the chicken production?	
			Specify source of chicken products (i.e. country and city):	
Pork			Specify type/s of pork derivative/s:	
			Does the pig feed exclude animal derived products?	
			Specify country/ies of origin:	
Gelatine			Specify name, type & Halaal status:	
Eggs			Liquid egg ☐	Shell egg ☐
			Free range ☐	Barn / cage ☐
			Pasteurised ☐	Other
Fruit and vegetables			Used unpeeled ☐ Waxed ☐	
Milk and milk products			Is rBST used to produce the milk?	
Antioxidants	Added BHA			
	Added BHT			
	Added TBHQ			
	Other Antioxidants		Specify Antioxidant/s:	
Flavour Enhancers			Specify flavour enhancer/s and additive number/s:	
Alcohol (Residual)			Specify level % v/v:	
Added Fats & Oils	Animal		Specify type of fats & oils:	
			If applicable specify the name of any process used to alter the fatty acid composition:	
	Vegetable		Specify types of fats & oils:	
			If applicable specify the name of any process used to alter the fatty acid composition:	
Allium Genus (Onion, garlic, spring onion, leek, chives etc.)			Specify name and type of derivative/s:	
Sweeteners (intense, non-nutritive)			Specify types of intense sweetener/s and additive number/s:	
Preservatives			Specify type/s of preservative/s, additive number/s and level/s in mg/kg:	

Food / Component	**Yes* /No**	***If YES additional information must be inserted where prompted**	
Seeds (sunflower, poppy, cottonseed, etc.)		Specify name and type of derivative/s:	
Yeast & Yeast Products (including yeast extracts)		Specify type of yeast product/s:	
Herbs		Specify name of herb/s:	
		Irradiated ☐	
		☐ Herb	☐ Herb oil / extracts/ oleoresins
Spices		Specify name of spice/s:	
		Irradiated ☐	
		☐ Spice	☐ Spice oil / extracts/ oleoresins
Hydrolysed Vegetable Proteins		Specify type/s of protein sources (e.g. maize or soya):	
Added Flavourants (If the product is a flavour, answer YES)		Specify type of flavour/s:	
		☐ Natural ☐ Artificial	
Added Colourants (If the product is a colour, answer YES)		Specify Type/s	Specify Name and Additive number/s
		☐ Natural	
		☐ Artificial	
		☐ Azo dye	
		☐ Not Defined	
Added Salt (If the product is salt, answer YES)		Specify type of salt (e.g. sea, mined, etc.)	
		Is salt iodated according to SA legal requirements?	
Added Sugar (If the product is sugar, answer YES)		Specify type of sugar	
Honey & Honey products		Specify type/s of honey or honey derivative/s:	
		☐ Badger Friendly ☐ Irradiated ☐ Antibiotics used	
		Country of origin?	

TYPICAL NUTRITION INFORMATION & DIETARY SUITABILITY

Nutrient	**Average Quantity per 100**	☐ mL SG =	☐ g
Energy (kJ)			
Protein (g)			
Total carbohydrates: of which Glycaemic carbohydrates (g) of which total sugar (g) Dietary fibre# (g)			

Nutrient	**Average Quantity per 100**	☐ mL SG =	☐ g
Prebiotics (Novel fibre) (g) Polyols (g)			
Fat: of which Saturated fat (g) Trans fat (g) Monounsaturated fat (g) and/or Polyunsaturated fat (g) and/or of which Omega-3 fatty acids (mg) Cholesterol (mg)			
Total Sodium (mg)			
Vitamins – insert information on additional vitamins	Indicated in milligrams (mg), micrograms (mcg/ µg), or IU (International Unit), as appropriate according to Annexure 3		
Minerals – insert information on additional minerals	Indicated in milligrams (mg), micrograms (mcg/ µg), or IU (International Unit), as appropriate according to Annexure 3		
Insert any other nutrient or biologically active substance	Indicated in milligrams (mg), micrograms (mcg/ µg), or IU (International Unit), as appropriate according to Annexure 3		
GI GL			

Nutrition Information based on – *mark boxes as appropriate*

☐ 100 g Drained Product ☐ 100 g Un-drained Product ☐ 100 g De-glazed weight

☐ Not Applicable

☐ 100 g Uncooked Product ☐ 100 g Product cooked / reconstituted in accordance with directions

☐ Not Applicable

Rehydration Rate:

Carbohydrate has been determined by:

☐ Carbohydrate Calculated by difference	☐ Analysed as Glycaemic Carbohydrate	☐ Analysis of all glycaemic carbohydrate components and the sum thereof summed

Stipulate the method for the determination of dietary fiber and novel fiber(s) where applicable

Data Source

☐ Analysed – i.e. Laboratory Tested Lab Name Accreditation status details
Date Tested

☐ Reference tables – e.g. MRC Food Finder, USDA **Please specify the source**

Dietary Suitability

	Yes* / No	*** If YES, additional information must be inserted where prompted**
Vegan Suitable (NO meat, milk, eggs, honey)		
Lacto Vegetarian Suitable (contains milk)		
Ovo Vegetarian Suitable (contains egg)		
Ovo Lacto Vegetarian Suitable (contains milk and egg)		
Other type vegetarian		
Halaal Suitable		Is this product Halaal certified? ☐ Yes – attach copy of valid certification ☐ No
Kosher Suitable		Is this product Kosher certified? ☐ Yes – attach copy of valid certification ☐ No
Organic Certified		Is this product Organic certified? ☐ Yes – attach copy of valid certification ☐ No
Hindu Suitable (contains NO beef)		Is product certified? ☐ Yes – attach copy of valid certification ☐ No

OTHER

Food Irradiation / Sterilisation / Microbial reduction steps

Has this product or any of its components been treated with:	**Yes* / No**	*** If YES, additional information must be inserted where prompted**
Microbial reduction heating		Specify time and temperature:
Steam Sterilisation		Specify treated ingredient/s:
Ionising Radiation		Specify treated ingredient/s:
Ethylene Oxide		Specify treated ingredient/s:
Other fumigants or sterilants		Specify fumigant/s or sterilant/s:
		Specify treated ingredients:

Contaminants & Residues (Pesticides / Heavy metals / Veterinary residues / Marine biotoxins, etc.)

This product complies with:	**Yes / No**
R.246 of 11 February 1994: *Regulations governing the maximum limits for **pesticide residues** that may be present in foods*	
R.1809 of 3 July 1992: *Regulations governing the maximum limits for **veterinary medicine and stock remedy residues** that may be present in foods*	
R.500 of 30 April 2004: *Regulations relating to Maximum Levels for **Metals** in Foods*	
R.491 of 27 May 2005: *Regulations relating to **Marine Biotoxins***	
R.1145 of 8 October 2004: *Regulations governing tolerances for **fungus-produced toxins** in foods* (**mycotoxins**)	
R.911 of 28 September 2001: *Regulations governing **certain solvents** in foods* (benzene and methanol)	

Food Produced using Gene Technology

Q1 Are there any ingredients in this product (including food additives, processing aids and enzymes) which contain or have been derived form genetically modified material or have been produced using the application either directly or indirectly of genetically modified substrates or genetically modified organisms?

☐ Yes ☐ May contain ☐ No – Go to Section 6

Q2 Does this product require labelling in accordance with R.25 of 16 January 2004: *Regulations relating to the Labelling of Foods obtained through Certain Techniques of Genetic Modification*?

☐ Yes ☐ No

Q3 This product:

☐ Does not contain genetically modified novel DNA and/or novel protein

☐ Contains or ☐ May contain genetically modified novel DNA and/or novel protein exempt from labelling

☐ Contains or ☐ May contain genetically modified novel DNA and/or novel protein which requires labelling

Q4 Do any of the genetically modified components of this product have altered characteristics?

☐ Yes ☐ No

If 'YES' list the GM components and altered characteristics:

GM Component	**Altered Characteristics**

Q5 The genetically modified components of this product are classified as (*select appropriate box):*

☐ Genetically modified food – containing novel DNA and/or novel protein

☐ Genetically modified food – highly refined to remove novel DNA and/or novel protein

☐ Genetically modified food additives or processing aids where novel DNA and/or novel protein is present

☐ Genetically modified food additives or processing aids where novel DNA and/or novel protein is not present

☐ Enzymes originating from genetically modified organisms where no novel DNA and/or novel protein is present

☐ Other – specify

BIOFORTIFICATION

Specify method: Specify nutrient and % difference from conventional crop: Specify required label statement:

PREPARATION, STORAGE PACKAGING & CODING INFORMATION

Storage & Transportation

Recommended Storage Conditions	Unopened	
	Opened	
Shelf Life	Unopened	
	Opened	
Recommended Transportation Requirements		

Packaging

Pack Size – Net Weight or Net Volume	
Target Fill Weight (*If applicable)*	
Drained Weight (*If applicable)*	
Deglazed	

Packaging	**Unit**	**Agent or distributor (*If applicable)***

Pack Type		
Sealing Method		
Tamper Evidence		
General packaging Requirements		

Is product double bagged? ☐
What is the colour and micron of the inner bag?
Are potential foreign objects such as staples avoided in packaging? ☐
Does the packaging indicate recycling symbols? ☐

Coding

General Coding Requirements:		
Coding	Unit	Agent or distributor (*If applicable)*
Barcode	EAN:	TUN:
Type of Code (best before date, use by date, date packed, Julian code, baked on code etc.)		
Method of Coding (sticker, embossed, inkjet, stamped etc.)		
Format of Code (*Insert an example of the product code)*		
Translation of Code		
If in contact with Food, is coding ink Food grade?		

COMMENTS / ADDITONAL INFORMATION

SPECIFICATIONS

Test methods must be quoted completely: Accredited, independent or international methods. Where a supplier's internal test method is quoted, the method must be attached.

Physical Specifications

(*Examples may include particle size, shape, specific gravity, metal detection, foreign matter tolerances, physical defect tolerances etc. as appropriate for the product)*

Test / Parameter	**Specification**	**Test Method**

Chemical Specifications

(*Examples may include Salt, acid, pH, histamine, moisture, brix, Aw, pesticide compliance etc. as appropriate for the product)*

Test / Parameter	**Specification**	**Test Method**

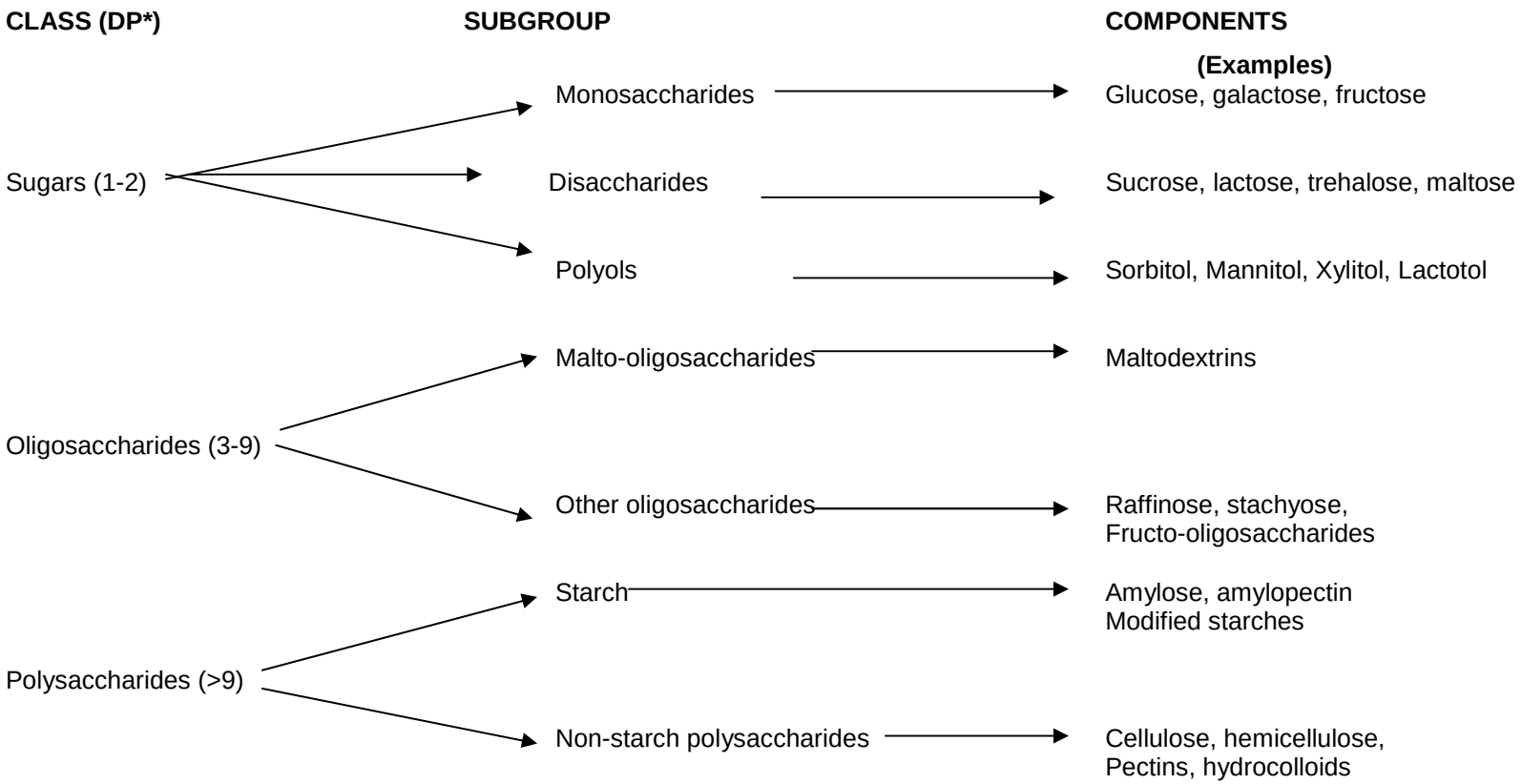
Microbiological Specifications

(*Examples may include standard plate count, yeasts & moulds, coliforms, salmonella, listeria, etc as appropriate for the product)*

Test / Parameter	**Specification**	**Test Method**

GUIDELINE 2

THE MAJOR DIETARY CARBOHYDRATES



DP* = Degree of polymerisation

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

GUIDELINE 2 (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 which is done by calculation rather that analysis. Direct analysis allows separation of individual monosaccharides, disaccharides and starch, which is useful in determination of energy values. Direct analysis is considered the only acceptable method for analysis of carbohydrate in foods, especially when any type of carbohydrate claim or carbohydrate related claim is made.

Glycaemic carbohydrates, namely glucose, fructose, galactose, sucrose, lactose, maltose, trehalose, maltodexrins and starch should be determined by adding together all the analytical values of the individual components.

2. Definition of dietary fiber

The definition of dietary fiber is clearly linked to fruits, vegetables and whole-grain cereals and includes the purified non-starch polysaccharides (NSP) from fruit, vegetables and cereal plant material as well as the food additives, Powdered cellulose (INS 460ii) and Cellulose gum (INS 466). The permitted purified NSP plant material sources are wheat, oat, corn, apple, potato and pea. The established epidemiological support for the health benefits of dietary fiber is based on diets that contain fruits, vegetables and whole-grain cereal foods, which have the characteristic of containing plant cell walls. It is this food component that should form the basis of a dietary fiber 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 fiber. The following labeling practice shall be used to distinguish the presence of the purified, concentrated NSP from the presence of actual fruit, vegetables and whole-grain in the list of ingredients:

Examples:

List of ingredients:

….purified, NSP dietary fiber (from apples)…

Or

…purified, NSP dietary fiber (Powdered cellulose)…

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 of dietary fiber when measured for non starch polysaccharides (NSP).

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 fiber-like ingredients as supplements, and the current epidemiological evidence base for dietary fiber rich foods cannot be extrapolated to diets containing such preparations. To include them within a dietary fiber 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 fiber definition. Instead, resistant starch, oligosaccharides and fiber 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 definition for dietary fiber 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 fiber.

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 fiber as plant cell wall carbohydrate found in whole-grain 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 fiber 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.

This emphasizes that dietary fiber reflects fruits, vegetables and whole-grain 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 fiber reflecting a natural plant-rich, whole food diet. Other sources of non-glycaemic carbohydrates (polyols, oligosaccharides (non-α-glucan), resistant and modified starches, non-starch polysaccharides) would best be served by individual health claims that take into account their specific efficacy and dosage issues.

TABLE: METHODS OF ANALYSIS FOR DIETARY FIBER AND NOVEL FIBERS

Recommended method for measuring dietary fiber as NSP as defined in the Regulations Governing the Advertising and Labelling of Foods.[2]				
Standard	**Component(s) measured**	**Method**	**Principle**	**Type**
All foods containing fruit, vegetables and whole-grain cereals	Non-starch polysaccharides (NSP) [3]	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.	Enzymatic Gas–Liquid Chromatographic method	IV
General methods that do not measure the lower molecular weight fraction (i.e., monomeric units <=9)[2]				
All foods[1]	Method applicable for determining dietary fibers that do not include the lower molecular weight fraction. [4]	AOAC 985.29 AACC Intl 32-05.01 (1991,1999)	Enzymatic gravimetric	I
All foods[1]	Method applicable for determining dietary fibers that do not include the lower molecular weight fraction and also includes determination	AOAC 991.43 AACC Intl 32-07.01 (1999, 1991) NMKL 129, 2003	Enzymatic gravimetric	I

	for soluble and insoluble dietary fibers[4]			
All foods[1]	Method applicable for determining dietary fibers that do not include the lower molecular weight fraction in foods and food products containing more than 10% dietary fibers and less than 2% starch (e.g., fruits)	AOAC 993.21	Gravimetry	I
All foods[1]	Method applicable for determining dietary fibers that do not include the lower molecular weight fraction. Provides sugar residue composition of dietary fiber polysaccharides, as well as content of Klason lignin [4]	AOAC 994.13 AACC Intl 32-25.01 (1999, 1994) NMKL 162, 1998	Enzymatic GC/ colorimetry gravimetry	I
All foods[1]	Insoluble dietary fibers in food and food products [4]	AOAC 991.42 (Specific for insoluble fiber) AACC Intl 32.20.01 (1999, 1982)	Enzymatic gravimetry	I
All foods[1]	Soluble dietary fibers in food and food products [4]	AOAC 993.19 (Specific for soluble fiber)	Enzymatic gravimetry	I
General methods that measure both the higher (monomeric units >9) and the lower molecular weight fraction (monomeric units,<=9)[2]				
All foods[1]		AOAC 2001.03 AACC Intl 32-41.01 (2002)	Enzymatic gravimetry and Liquid	I

			Chromatography	
All foods[1]	Method applicable for determining the content of dietary fibers of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches.	AOAC 2009.01 AACC Intl 32-45.01 (2009)	Enzymatic gravimetry-High-Pressure Liquid Chromatography	I
Methods that measure individual specific components (monomeric units: the whole range for type of components is covered)[2]				
All foods[1]	(1→3)(1→4) *Beta*-D-glucans	AOAC 995.16 AACC Intl 32-23.01 (1999,1995)	Enzymatic	II
All foods[1]	Fructans (oligofructoses, inulin, hydrolyzed inulin, polyfructoses, fructooligosaccharides) (applicable to added fructans)	AOAC 997.08 AACC Intl 32-31.01 (2001)	Enzymatic & HPAEC-PAD	II
All foods[1]	Fructans (oligofructoses, inulin, hydrolyzed inulin, polyfructoses, fructooligosaccharides) (not applicable highly depolymerised fructans)	AOAC 999.03 AACC Intl 32-32.01 (2001)	Enzymatic & colorimetric	III
All foods[1]	Polydextrose	AOAC 2000.11 AACC Intl 32-28.01 (2001)	HPAEC-PAD	II
All foods[1]	Trans-galacto-oligo saccharides	AOAC 2001.02 AACC Intl 32-33.01 (2001)	HPAEC-PAD	II
All foods[1]	Resistant starch (Recommended for RS3)	AOAC 2002.02 AACC Intl 32-40.01 (2002)	Enzymatic	II

Other methods[2] that have not been subjected to interlaboratory evaluation under AOAC international guidelines				
All foods[1]	Insoluble glucans and mannans of yeast cell wall (for yeast cell wall only)	Eurasyp (European association for speciality yeast products) – LM Bonnano. Biospringer- 2004 – online version: http://www.eurasyp.org/public/technique.home.screen	Chemical & HPAEC-PAD	IV
All foods[1]	Fructo-oligosaccharides (monomeric units<5)	Ouarné et al. 1999 in *Complex Carbohydrates in Foods.* Edited by S. Sungsoo, L. Prosky & M. Dreher. Marcel Dekker Inc. New York	HPAEC-PAD	IV

1. Users should consult the description of each method for the food matrices that were the subject of interlaboratory study in the Official methods of analysis of AOAC International.
2. Two issues are left for national authorities to decide: (a) whether to include monomeric units 3-9 or not in the definition of dietary fiber and (b) which isolated or synthetic compound(s) have physiological benefit (Refer to CAC/ GL 2-1985) as revised in 2009.
3. Quantification lost for resistant starch. Refer to specific methods.
4. Quantification lost for inulin, resistant starch, polydextrose and resistant maltodextrins. Refer to specific methods.

Other methods of analysis as referred to in Alinorm10/33/26 (CCNFSDU Report of 2 to 6 November 2009), Appendix II may be used subject to the requirements of the Regulations, particularly Regulation 51(10).

References

1. Codex Alimentarius Report: CCNFSDU 1-5 November 2010, CL 2010/53-NFSDU Appendix VI

2. Codex Alimentarius Report: CCMAS 2012

3. Nshida C, Martinez Nocito F, Mann J (Guest Editors). Joint FAO/WHO Scientific Update on Carbohydrates in Human Nutrition. European Journal of Clinical Nutrition (Supplement 1) 2007, 61: S19-S39

GUIDELINE 3

Guidelines on:

Criteria for evaluation of dossiers containing applications to use certain endorsement logos on foodstuff labels and advertising thereof according to the latest Regulations relating to the Advertising and Labelling of Foods.

The draft Regulations Relating to the Labelling and Advertising of Foodstuffs (No. R429 of 29 May 2014), which were published by the Minister of Health under Section 15 of the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), provides for in Regulation 16(1)(a)(ii), the prohibition of certain information or declarations to be reflected on a label or advertisement of a foodstuffs, including words, pictorial representations, marks, logos or descriptions which create an impression that such a foodstuff is supported, endorsed, complies with or has been manufactured in accordance with recommendations by organizations, associations, foundations and other entities. The regulation also requires that the use of such information or declarations be considered by the Department of Health and approved by the Director-General, based on the evidence provided as verification that your organization is involved in generic health promotion, supported by evidence-based nutrition, as well as that the aims of your organization do not contradict the requirements of these regulations related to nutritional claims, based on the criteria thereof.

It is for this purpose that the Department of Health, Directorate: Food Control compiles these Guidelines to assist in the compilation of applications for endorsement of certain logos as explained below.

1. **Which type endorsements are ***excluded*** from the requirement to obtain permission from the Director-General of Health?**

   Endorsing entities such as:

   - religious certifying entities
   - any Fauna and Flora related certifying and endorsing entities
   - other entities which focus on certifying certain quality aspects of foodstuffs

2. **Which types of endorsements are required to obtain permission from the Director-General of Health through an independent entity?**

   The endorsement logos of endorsing entities which are involved in generic health promotion activities which promote the reduction of risk of developing one or more particular non-communicable disease(s) of lifestyle (e.g. cancer, coronary heart disease, diabetes mellitus, obesity, poor oral hygiene, osteoporosis, et cetera).

3. **What process should be followed to obtain approval from the Director-General of Health?**

- A hard copy of the dossier (in triplicate, unless otherwise indicated) should be delivered to the offices of the Department of Health, addressed to the Director-General. The dossiers shall contain all the information indicated below under point 8.
- The physical address is:
  Department of Health
  Directorate: Food Control
  3rd Floor Civitas Building, South Tower
  Corner of Thabo Sehume and Struben Streets
  Pretoria, 0001
- An electronic copy of the dossier shall be forwarded to:
  Booyza@health.gov.za, copy to PienaE@health.gov.za

4. In which legal document can the requirement to obtain approval be found?

The requirement to obtain approval can be found in Regulation 16(1)(a)(ii) of the current Regulations Relating to the Labelling and Advertising of Foodstuffs, R429 of 29 May 2014.

5. Who serves on the *Ad Hoc* evaluating Committee?

The *Ad Hoc* Evaluating Committee comprises of at least one or more technical/professional staff member(s) from the following Directorates:

- Food Control (Convener of meetings and Chair)
- Nutrition
- Non-communicable diseases
- Oral health (only when the endorsement logo relates to oral health)

6. How often are meetings convened?

The meetings are convened once every 6 months, provided applications were received during that time period:

Period in which applications are received	**Month in which applications received will be evaluated**
February to July	August
August to January	February

7. Are there any financial costs involved?

There are no financial costs involved.

8. What information must be included in each dossier?

8.1 Information regarding the endorsing entity

Proof that-

8.1.1 the endorsing entity is not related to, independent of and free from influence by the supplier/manufacturer of food in relation to which an endorsement is made; and

8.1.2 the supplier/manufacturer of food has no financial interest in the endorsing entity nor receiving any benefits from applying the endorsement except to use the logo on labels of qualifying foodstuffs, has not established the endorsing body either by itself or with others, and exercises no direct or indirect control over the endorsing body.

8.2 General criteria to comply with before an endorsement will be considered

8.2.1 The foodstuff to be endorsed shall be fully compliant with all applicable Regulations published under the Act (Act No. 54 of 1972);

8.2.2 The criteria used by the endorsement entity to determine whether a specific foodstuff is suitable to bear its logo, shall not contradict the requirements of the Regulations Related to the Labelling and Advertising of Foodstuffs in terms of nutrition and health claims and the criteria thereof;

8.2.3 The foodstuff to be endorsed shall be eligible for making a nutrient or health claim according to the Nutrient Profiling Model. Endorsement logos, nutrient or health claims should not ***mask*** certain undesirable nutritional qualities or nutritional content of a food and thus mislead the consumer;

8.2.4 In the case of fruit or vegetable juices being endorsed, the fruit or vegetable juice shall not contain added fructose, shall qualify for the “no sugar added” claim and shall have a dietary fibre content per 100 ml that equals the dietary fibre content of 100 g of the same fresh fruit or vegetable;

8.2.5 Evidence shall be included in the dossier which provides proof that the endorsement entity is actively involved in projects aimed at promoting "**evidence-based nutrition" and "generic health promotion"** (see definitions of these terminology in Regulation 1 in R146/2010) ;

8.2.5.1 Generic health promotion: Examples of what is promoted by the logo as well as examples of how it was done. Any health promotion activities may not be restricted to one category of foodstuffs only, e.g., breakfast cereals, but have to include foodstuffs from as many foods groups or categories as possible:

a) Any brochures, leaflets, posters et cetera;

b) Any media statements, internet information, printed material, advertisements, or any other methods of communication used to communicate to the target group(s);

c) Proof of Projects in which the endorsement entity is involved in to educate the public about the particular health concern(s) the endorsement entity is focusing on;

d) Proof that what the logo promotes, is making a difference to the consumer's health/behaviour to improve their attitudes, proof that consumers really benefit from having this endorsement and how the endorsement campaign changed consumers’ shopping behaviour/patterns et cetera;

e) An indication of the population group(s) which is(are) targeted; and

f) A complete, full size, colour copy of the logo printed on a A4-size paper.

8.2.5.2 Evidence-based nutrition:

a) Which public health considerations are taken into consideration? Public health considerations are those which are identified by the National Department of Health. Any Evidence-based nutrition should be based on generally accepted scientific evidence relative to the relationship between diet, nutrition and health (the scientific rationale);

b) A copy of the endorsement entity's nutritional criteria that are applied to select a particular product for the endorsement logo and the scientific rationale for it; and

c) The food groups/categories which are targeted.

GUIDELINE 4

EXAMPLES TO ILLUSTRATE NEGATIVE CLAIMS IN REGULATION 17

Regulation number	Examples
Regulation 17(1)(a)	Tomatoes naturally contains lycopene
Regulation 17(1)(b)	Vegetable cooking oils are naturally cholesterol free food or Rooibos tea is a naturally caffeine free food
Regulation 17(2)(a)	Colourant free tomato sauce or Preservative free tomato sauce
Regulation 17(2)(b)	A preservative free frozen vegetable, as is the case with all frozen vegetables
Regulation 17(2)(c)	No added colourant guava juice

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. There must be evidence of long traditional usage of such name. A period of 40 years or more is advised.

(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 a mandatory requirement for canned fish and marine products, canned meat, frozen fish and seafood products, agricultural fishery products and agricultural products for which compositional standards or regulations already exist under the National Regulator for Compulsory Specifications Act, 2008 (Act 5 of 2008), and the Agricultural Products Standards Act, 1990 (Act 119 of 1990), and the Liquor Products Act, 1989 (Act No. 60 of 1989), except for:

(i) processed meat products, excluding traditional biltong and dry sausage under SANS 885:2011;

(ii) raw-processed meat products

(iii) fruit juices, excluding fresh, orange juice

(iv) primary dairy products with added ingredient(s)

(v) edible ices

(e) 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.

(f) In the case of mixtures of fruit or vegetables or nuts, etc, referred to in regulations 18, 19 and 20, where no ingredient in the relevant mixture predominates significantly by weight, a QUID declaration would not be required.

(g) A QUID declaration will not be required for vitamins and/or minerals that are added to foods for enrichment or fortification purposes, as their content will be indicated in the nutritional information table.

(h) 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, garlic (in garlic bread) or other herbs and spices.

(i) A QUID declaration should not be confused with nutritional information labelling and does not replace the nutritional information table.

(j) A QUID declaration is not required for single ingredient foods.

(k) A QUID declaration is not required for a food 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**
	"Chicken and mushroom pie", "chicken polony", "olive oil margarine", tomato sauce", "honey and oats biscuits, "banana loaf",

*** 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:

Product	Example of description	QUID for
"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 <u>not</u> 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";

(bb) 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);

(cc) 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;

(dd) in the case of warnings aimed at allergy sufferers (e.g., a warning statement about the presence of nuts in a product); and

(ee) 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.

(d) Calculation of the percentage water and meat in raw-processed meat (poultry or red meat).

The formula to use is: QUID (%) = (declarable weight of ingoing Ingredient / weight of end product) x 100

1 000 g fresh chicken meat

\+ 100 g brine-based mixture (100 g includes both water and soluble solids (additives salt etc)

Equals 1 100 g raw-processed chicken meat end product

Apply formula: QUID (%) = (declarable weight of ingoing Ingredient / weight of end product) x 100

1 00 g brine-based mixture / 1 100 raw-processed chicken meat end product x 100 = 9.09% (rounded off to 9.1%)

Conclusion: QUID % for water* = 9.1% and QUID % for chicken meat = 90.9%

* water in the case of raw-processed poultry and red meat means water plus soluble solids (additives, salt etc), therefore a compound ingredient for the purposes of calculating QUID and complying with the requirements regarding the need for a list of ingredients.

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

EXAMPLES OF FLAVOURINGS MIXTURES CONSIDERED COMPOUND INGREDIENTS

Examples include:

- flavoured emulsions
- sprinkle flavourings
- snack food flavourings
- flavoured coatings etc., all of which incorporate non-flavouring food ingredients and/or additives such as salt, sugar, MSG, colourants, preservatives, cloudifiers, pre-packed additives, including products sold as “Sprinkle” or “Dusting” flavourings intended for use on snack foods or/and other foods

GUIDELINE 7

ALLERGEN RISK ANALYSIS AND ALLERGEN CONTROL POLICY (ACP)

ALLERGEN RISK ANALYSIS

The avoidance of the unintentional presence of allergens in food products requires an assessment of the likelihood of allergen cross-contamination throughout the supply chain, from raw materials through to the final product.

The allergen risk analysis should comprise the following four steps:
1. *Risk assessment*– what is the risk of unintentional presence of an allergen(s) in a food?
2. *Risk management* – can the risk be managed, and how will it be managed?
3. *Risk communication* – how will the risk be communicated?
4. *Risk review* – how is the risk monitored and has the risk changed?

GUIDELINES ON THE IMPLEMENTATION OF 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.

4.1 ALLERGEN RISK ASSESSMENT

An allergen risk assessment should form part of a food manufacturer's HACCP plan, and should assess whether specific food products intentionally contain an allergenic food, and whether there is the potential for allergen cross-contamination of other foods produced on the premises.

The first step in 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. fish gelatin as a nutrient carrier for betacarotene and 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.

4.1.1. IDENTIFICATION OF HIDDEN ALLERGENS IN FOODS

Label terminology that may indicate the presence of egg protein

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

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
* Casein
* Natural flavouring
* Caseinate
* Rennet casein
* Cheese
* Sour cream (or solids)
* Cream curd
* Sour milk solids
* De-lactosed whey
* Whey or whey powder

* Dry milk solids
* Whey protein concentrate
* Milk solids

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

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.

4.2. ALLERGEN RISK MANANGEMENT

4.2.1. Allergen control and pre-requisite programs (PRPs)

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

4.2.2. Processing 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.

4.2.3. Supplier control

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

4.2.4. 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 on ingredients and additives supplied to the company. Do such ingredients contain allergens or additives derived from allergens?
 The allergen content of the raw ingredients/additives the supplier receives/uses.
 Does the supplier have an ACP in place?

 Does the ACP of the supplier consider allergen cross-contamination during:

- o Storage
- o Transport
- o Preparation
- o Cleaning
- o Shared production line or equipment
- o Rework

This is where the product information in terms of ingredients, additives, allergens and traceability, specifically the Supplier Ingredient Information files, as set out in Guideline 6 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 food by the specific company.

4.2.5. 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 should be ensured that allergen containing foods or ingredients are stored separately or in airtight containers.

4.3. ALLERGEN RISK COMMUNICATION

If a risk of allergen contamination is identified in a food manufacturing facility, this risk needs to be communicated. This communication needs to be directed towards employees (in order to reduce the risk), and to consumers (in order to afford protection from a potential allergic reaction).

4.3.1 Employees

All employees (including temporary employees and contractors) that handle ingredients, utensils, equipment, packaging and products should be aware of food allergens, the potential of allergen cross-contamination, and the consequences of ingestion by sensitive individuals.

 Procedures on the management of allergens should be available and/or posted wherever there is a risk for allergen cross-contamination

 Allergen awareness and management should form part of basic employee training, and should at least include :

- o Recognition of which ingredients are allergens of concern,
- o Identification of potential allergen cross-contamination situations,
- o Identification of dedicated equipment for the processing of allergenic ingredients,
- o Movement of equipment around the plant, e.g. maintenance tools, trays and utensils,
- o Effective hand washing,

- o Re-work procedures,
- o Waste management procedures,
- o Cleaning procedures.

4.3.2. Communication to the consumer: Labelling and Packaging

Regulations 44 -47 provide the detail of the labelling regulations with regards to allergen including communication to the consumers.

The reasons for the use of precautionary labelling statements as a risk management tool should be documented by the manufacturer/processor/importer. 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.

4.4. RISK REVIEW

4.4.1. Allergen testing in the ACP

Allergen testing is a useful tool for monitoring the effectiveness of the ACP in reducing the risk of allergen cross-contamination. Where a risk of allergen cross-contamination is identified, allergen testing should be part of the ongoing strategy for monitoring the risk of such contamination.

The risk of the unintentional presence of food allergens in a food product can be assessed using validated Enzyme Linked Immunosorbent Assay (ELISA) methods and/or Polymerase Chain Reaction (PCR) methods with the capacity to detect less than 10 mg/kg of a specific allergenic food.

4.4.2. Sampling

There are currently no guidelines indicating the size of the samples required for allergen testing. If a food manufacturer 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

4.4.3. 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.

4.4.4. The role of allergen thresholds

As individuals with food allergies differ in their degree of sensitivity to specific allergenic foods, attempts have been made to determine threshold doses for the major food allergens. The basic concept of establishing allergen thresholds is that if a Lowest Observed Adverse Effect Level (LOAEL) and No Observed Adverse Effect Level (NOAEL) are identified, then the food industry could target their processes to achieve these levels.
The US FDA Threshold Working Group (2006) has summarised the available threshold data to report the following LOAELs for some of the common allergens (Table 1):

Table 1 Summary of Published LOAELs for some common food allergens

Food	**Range of LOAEL (mg protein)**	**LOAEL expressed as ppm for a 100g serving of food**
Egg	0.13 – 1.0	1.3 – 10
Milk	0.36 – 3.6	3.6 – 36
Peanut	0.25 – 10	2.5 – 100
Tree Nuts	0.02 – 7.5	0.2 – 75
Fish	1 – 100	10 – 100
Soy	88 – 552	880 – 5520

It is important to note, however, that limited data is available on threshold levels for some common allergens, e.g. soy and fish. It is therefore likely that ongoing research may reduce these thresholds.

Please note: Lowest Observed Adverse Effect Levels (LOAELs) should not be confused with allowable levels of allergen contamination in food products. Since LOAEL values do not refer to No Observed Adverse Effect Levels (NOAELs), there is still a risk that individuals may react to lower levels of allergens in food products than the LOAELs. When using LOAELs rather than NOAELS to establish allergen thresholds, the selection of appropriate factors to account for uncertainty and inherent variability is critical.

The Australian/New Zealand Allergen Bureau has developed the VITAL (Voluntary Incidental Trace Allergen labelling) procedure to assist with decisions relating to allergen precautionary labelling. The VITAL grid indicates proposed action levels when assessing allergen risk. This grid is based on established LOAEL for common allergens, but has an added safety margin added to each to account for uncertainty. The levels indicated in the VITAL grid, with their added safety margins, are thus seemingly more appropriate to apply to risk assessment procedures than the FDA levels (LOAELs) in their raw format. Visit http://www.allergenbureau.net/vital/ for more information.

GUIDELINE 8

ADDITIVES AND OTHER INGREDIENTS DERIVED FROM NON-VEGETARIAN ORIGIN

INS = International Numbering System

- Bone phosphate (INS 542)
- Bees wax for use on confectionary and chocolate panning (INS 901);
- Canthaxanthin, a colourant (INS 161g) or may be synthesized
- Gelatine
- Honey
- L-Cysteine may be derived from human hair
- Cochineal (INS 120), or Carmine of Cochineal Carminicago derived from the insect *Dactilopius coccus*
- Glycerine/glycerol, (may be derived from animal fats or from vegetable origin INS 422);
- Lactic acid esters of mono- and di-glycerides of fatty acids prepared from esters of glycerol (INS 472b)
- Mono- and di-glycerides of fatty acids may have a synthetic or animal source (INS 471)
- Quinoline Yellow (INS 104) may be derived from non-vegetarian source;
- Rennet, and pepsin
- Roe or caviar (fish eggs)
- Shellac (INS 904) (a substance obtained from the resin produced by the Lac insect which is mainly found in India; the secretions are dried before use on confectionary, chocolate panning , ice creams and edible ices)
- Sucrose esters of fatty acids prepared from glycerol and sucrose (INS 473)
- Sucroglycerides prepared by reaction of sucrose and natural triglycerides from palm oil lard et cetera (INS 474)
- Polyglycerol esters of fatty acids (INS 475)
- Vitamin D_3 may be derived from lanolin produced from sheep's wool.

GUIDELINE 9

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**[a] 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**[b] sample is taken and the second situation is where a **stratified**[c] sample is used. Other sampling methods, such as those based on **selective**[d] or **convenience**[e] 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 foods, a minimum of 12 samples from various batches according to the specific, relevant sampling plan (e.g., random sampling, stratified sampling or representative sampling) made into 1 composite sample or 3 composite samples made up of each 4 individual samples each, 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. However, where, due to the nature of the product, e.g. selenium enriched eggs where the selenium is delivered through a specific feed for the hens, and it is not possible to store the food appropriately and successfully for a certain length of time until enough samples are collected according to the requirements of the specific sampling plan used, individual samples may be submitted for analysis and the average value of all the test results are then calculated.

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 the required number of samples submitted for analysis by drawing equal portions (minimum portion size is 100g) from each sample, 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 the applicable tolerance value as indicated in (iii) below.

(iii) After analysis of the composite sample in duplicate was done, the mean of the two analysis figures shall be calculated as the final result; Provided that neither result shall deviate by more than the applicable tolerance value as indicated in (aa) to (dd) below.

(aa) **Table** below applies to all prepared foods and dry mixes foods for which no nutrient or health claim provided for in the Regulations is made, but exclude food vehicles in dry mix form, formulated foods for which a claim is made, all foods in liquid form, all infant formula, infant follow-on formula, infant formula for the dietary management of certain medical conditions and foods for the dietary management of certain medical conditions;

TABLE: PERMITTED TOLERANCES FOR NUTRIENT DECLARATION IN NUTRITION LABELLING IN THE CASE OF DRY MIXES AND PREPARED FOODS WHERE NO HEALTH OR NUTRIENT CLAIM IS MADE

For any natural-occuring or indigenous nutrients and bio-active food components, such as carotenoids, flavonoids et cetera	The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label. A food with a label declaration of energy, total sugars, fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under Regulation 51 of the Regulations if the nutrient content of the composite is more than 20 percent in excess of the value for that nutrient declared on the label; Provided that reasonable excesses of a vitamin, mineral, other bio-active food components, protein, Omega-3 fatty acids dietary fiber, novel fibers, polyunsaturated or monounsaturated fat, or potassium over-labeled amounts are acceptable within current good manufacturing practice; Provided that reasonable deficiencies of energy, sugars, fat, saturated fat, cholesterol, or total sodium under labeled amounts are acceptable within current good manufacturing practice.
For any *added* nutrients and bio-active food components	At least equal to the value for that nutrient as declared on the label

(bb) In the case of food vehicles in dry mix form, the final result for added vitamins and minerals that is required to be added to these food vehicles in dry mix form according to the Regulations relating to the fortification of certain foodstuffs and food-grade salt shall not be less than the amounts stipulated by the mentioned Regulations.

(cc) In the case of foods in liquid form, any formulated food in any form to which a nutrient or bio-active substance is added and for which a nutrient or health claim is made, excluding infant formula, infant follow-on formula, infant formula for the dietary management of certain medical conditions and foods for the dietary management of

certain medical conditions (FSMPs), the mean of the two analysis figures in the final result for all nutrients shall correspond to the values as declared on the label.

(dd) In the case of any formulated infant formula, infant follow-on formula, infant formula for the dietary management of certain medical conditions and foods for the dietary management of certain medical conditions for which no nutrient or health claim is permitted, the mean of the two analysis figures in the final result for nutrients in general shall correspond to the values as declared on the label.

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 ten (10) years unless a formulation change was made which will require full analysis again.

(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 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 ten (10) years.

GUIDELINE 10

EXAMPLES OF FOODS WHERE THE USE OF THE FOOD BASED DIETARY GUIDELINES ARE USED CORRECTLY (√) AND INCORRECTLY (X) RESPECTIVELY

Food based dietary guideline	Food example	
	X	√
Make starchy food part of most meals	• Fish fingers • Potato chips	• Whole grain wheat (pearled wheat) • Whole grain barley • Brown rice
Fish, chicken, lean meat or eggs could be eaten daily	• Soya mince • Biltong and dried sausage	• Canned fish • Eggs • Lean or extra lean meat • Chicken without skin
Have milk, maas or yoghurt every day	• Frozen yoghurt • Ice cream • Cream cheese	Plain yoghurt
Eat plenty of vegetables and fruit every day	• Fruit juice except single fruit juice • Fruit nectar • Canned fruit in syrup	Fresh fruits and vegetables
Eat dry beans, split peas, lentils and soya regularly	Flavoured, dehydrated soya mince	• Canned legumes • Uncooked legumes • Unflavoured, dehydrated soya mince
Use salt and food high in salt sparingly	Any food which contains more than 120 mg Sodium per 100 g	Unsalted butter
Use fat sparingly; choose vegetable oils rather than hard fats	Hard margarine	• Soft bread spreads in tubs • Vegetable oils • Nuts • Avocado
Use sugar and food and drinks high in sugar sparingly	• Soft drink sweetened with sugars • Fruit nectars • Jams • Syrups • Sweets	Muesli without added sugar

Food based dietary guideline	Food example	
	X	√
Drink lots of clean safe water	Soft drinks	Packaged water (water and/or CO_2)

GUIDELINE 11

REFERENCE AMOUNTS FOR RECOMMENDED SINGLE SERVING SIZES

Unless otherwise noted, the references in the table below are for the maximum amount for a single serving. If not listed separately, the reference amount for the unprepared form, such as dry mixes, concentrates, dough, batter and fresh and frozen pasta is the amount required to make one reference amount of the prepared form.

Item	Column 1 Food	Column 2 Reference amount
1.	***Bakery Products*** Bread, excluding sweet quick-type rolls and fortified bread	80 to 95 g (2 slices)
2.	Bagels, tea biscuits, scones, rolls, buns, croissants, tortillas, soft bread sticks, soft pretzels and corn bread	55 g
3.	Brownies	40 g
4.	Heavy weight cake: 10 g or more per 2.5 cm cube, such as cheese cake, pineapple upside-down cake, cake with at least 35% of the finished weight as fruit, nuts or vegetables, or any of these combined	125 g
5.	Medium weight cake: 4 g or more per 2.5 cm cube but less than 10 g per 2.5 cm cube, such as cake with or without icing or filling, cake with less than 35% of the finished weight as fruit, nuts or vegetables or any of these combined, light weight cake with icing, cupcakes, éclairs or cream puffs	80g
6.	Light weight cake: less than 4 g per 2.5 cm cube, such as angel food, chiffon or sponge cake, without icing or filling	55 g
7.	Coffee cakes, doughnuts, danishes, sweet rolls, sweet quick-type breads and muffins	55 g
8.	Cookies, with or without coating or filling, and wafers	30 g
9.	Crackers, hard bread sticks and melba toast	20 g
10.	Dry breads, matzo and rusks	30 g
11.	Flaky type pastries, with or without filling or icing	55 g
12.	Toaster pastries	55 g
13.	Ice cream cones	5 g
14.	Croutons	7 g
15.	French toast, pancakes and waffles	75 g
16.	Grain-based bars, with filling or partial or full coating	40 g
17.	Grain-based bars, without filling or coating	30 g
18.	Rice cakes and corn cakes	15 g
19.	Pies, tarts, cobblers, turnovers and other pastries	110 g
20.	Pie crust	1/6 of 20 cm crust or 1/8 of 23 cm crust
21.	Pizza crust	55 g
22.	Taco shell, hard	30 g
23.	***Beverages*** Carbonated and non-carbonated beverages, iced tea and wine coolers	355 ml
24.	Sports drinks and water	500 ml
25.	Coffee: regular, instant and specialty, including espresso café au lait, flavoured and sweetened	175 ml
26.	Tea and herbal tea	

	(a) regular and instant (hot) (b) flavoured and sweetened, prepared from mixes	175 ml 250 ml
27.	Cocoa and chocolate beverages (hot)	175 ml
28.	***Cereals and Other Grain Products*** Hot breakfast cereals, such as oatmeal or cream of wheat, excluding	40 g dry 250 ml prepared
29	Fortified maize porridge or maize pap (dry maize meal)	100 g dry
30.	Ready-to-eat breakfast cereals, puffed and uncoated (less than 20 g per 250 ml)	15 g
31.	Ready-to-eat breakfast cereals, puffed and coated, flaked, extruded, without fruit or nuts (20 g to 42 g per 250 ml), very high Fiber cereals (with 28 g or more Fiber per 100 g)	30 g
32.	Read-to-eat breakfast cereals, fruit and nut type, granola (43 g or more per 250 ml) and biscuit type cereals	55 g
33.	Bran and wheat germ	15 g
34.	Flours, including cornmeal	30 g
35.	Grains, such as rice or barley	45 g dry 140 g cooked
36.	Pastas without sauce	85 g dry 215 g cooked
37.	Pastas, dry and ready-to-eat, such as fried canned chow mien noodles	25 g
38.	Starch, such as cornstarch, potato starch, tapioca starch or wheat starch	10 g
39.	Stuffing	100 g
40.	***Dairy Products and Substitutes*** Cheese, including cream cheese and cheese spread, except those listed as a separate item	30 g
41.	Cottage cheese	125 g
42.	Cheese used as an ingredient, such as dry cottage cheese or ricotta cheese	55 g
43.	Hard cheese, grated, such as parmesan or Romano	15 g
44.	fresh cheese and fresh dairy desserts	100 g
45.	Cream and cream substitute, except those listed as a separate item	15 ml
46.	Cream and cream substitute, powder	2 g
47.	Cream and cream substitute, aerosol or whipped	15 g
48.	Eggnog	125 ml
49.	Milk, evaporated or condensed	15 ml
50.	Plant-based beverages, milk, buttermilk and milk-based drinks, such as chocolate milk	250 ml
51.	Shakes and shake substitutes, such as dairy shake mix	250 ml
52.	Sour cream	30 ml
53.	Yoghurt	100 to 250 ml
54.	Ice cream, ice milk, frozen yoghurt and sherbet	125 ml
55.	Dairy desserts, frozen, such as cakes, bars, sandwiches or cones	125 ml
56.	Non-dairy desserts, frozen, such as flavoured and sweetened ice or pops, or frozen fruit juices in bars or cups	75 ml
57.	Sundaes	250 ml
58.	Custard, gelatine and pudding	125 ml
59.	***Dessert Toppings and Fillings*** Dessert toppings, such as maple butter and marshmallow cream	30 g
60.	Cake frostings and icings	35 g

61.	Pie fillings	75 ml
62.	***Eggs and Egg Substitutes*** Egg mixtures, such as egg foo young, scrambled eggs or omelettes	110 g
63.	Eggs	50 g
64.	Egg substitutes	50 g
65.	***Fats and Oils*** Butter, margarine, shortening and lard	10 g
66.	Vegetable oil	10 ml
67.	Butter replacement, powder	2 g
68.	Dressings for salad	30 ml
69.	Mayonnaise, sandwich spread and mayonnaise-type dressing	15 ml
70.	Oil, spray type	0.5 g
71.	***Marine and Fresh Water Animals*** Canned anchovies, anchovy paste and caviar	15 g
72.	Marine and fresh water animals with sauce, such as fish with cream sauce or shrimp with lobster sauce	140 g cooked
73.	Marine and fresh water animals without sauce, such as plain or fried fish or shellfish, or fish or shellfish cakes, with or without breading or batter	125 g raw 100 g cooked
74.	Marine and fresh water animals, canned	55 g, drained of brine or oil where applicable
75.	Marine and fresh water animals, smoked or pickled, or spreads	55 g
76.	***Fruit and Fruit Juices*** Fruit, fresh, canned or frozen, except those listed as a separate item	140 g 150 ml canned (drained)
77.	Candied or pickled fruit	30 g
78.	Dried fruit, such as raisins, dates or figs	40 g
79	Fruit for garnish or flavour, such as maraschino cherries	4 g
80.	Fruit relishes	60 ml
81.	Avocado, used as an ingredient	30 g
82.	Cranberries, lemons and limes, used as ingredients	55 g
83.	Watermelon, cantaloupe, honeydew and other melons	150 g
84.	Juices, nectars and fruit drinks	200 - 250 ml
85.	Juices, used as ingredients, such as lemon juice or lime juice	5 ml
86.	***Legumes*** Bean curd (tofu) and tempeh	85 g
87.	Beans, peas and lentils, such as white beans, kidney beans, romano beans, soybeans or chick peas	100 g dry 250 ml cooked or canned (drained)
88.	***Meat, Poultry, Their Products and Substitutes[3]*** Pork rinds and bacon	54 g uncooked 15 g cooked
89.	Beef, pork and poultry breakfast strips	30 g uncooked 15 g cooked
90.	Dried meat and poultry, such as jerky, dried beef or parma ham, as well as sausage products with a water activity of 0.90 or less, such as salami, dried thuringer or cervelat	30 g

91.	Luncheon meats, such as polony, liver sausage, ham and cheese loaf; pâté; meat pie fillings	75 g uncooked 55 g cooked
92.	Sausage products, such as linked sausage, Vienna sausage, wieners, breakfast sausage, frankfurters, pork sausage, bratwurst, smoked sausage, pepperoni, knackwurst	75 g uncooked 55 g cooked
93.	Cuts of meat and poultry without sauce, and ready-to-cook cuts, with or without breading or batter, including marinated, tenderized and injected cuts	125 g raw 100 g cooked
94.	Patties, cutlettes, chopettes, steakettes, meatballs, sausage meat and ground meat, with or without breading or batter	100 g raw 60 g cooked
95.	Cured meat products, such as cured ham, dry cured ham, back bacon, cured pork back, corned beef, pastrami, country ham, cured pork shoulder picnic, cured poultry ham products, smoked meat or pickled meat	85 g raw 55 g cooked
96.	Canned meat and poultry	55 g
97.	Meat and poultry with sauce, such as meat in barbecue sauce or turkey with gravy, but excluding combination dishes	140 g
98.	***Miscellaneous*** Baking powder, baking soda and pectin	0.6 g
99.	Baking decorations, such as coloured sugars or sprinkles for cookies	4 g
100.	Bread crumbs and batter mixes	30 g
101.	Cooking wine	30 ml
102.	Cocoa powder	5 g
103.	Non-alcoholic drink mixers, such as pina colada	250 ml
104.	Chewing gum	3 g
105.	Salad and potato toppers, such as salad crunchies, salad crispins or substitutes for bacon bits	7 g
106.	Salt and salt substitutes, as well as seasoned salt, such as garlic salt	1 g
107.	Spices and herbs	0.5 g
108.	***Combination Dishes*** Measurable with a cup, such as casserole, hash, macaroni and cheese with or without meat, pot pie, spaghetti with sauce, stir fry, meat or poultry casserole, baked or refried beans, wieners and beans, meat chilli, chilli with beans, creamed chipped beef, beef or poultry ravioli in sauce, beef stroganoff, poultry à la king, goulash, stew, ragout	250 ml
109.	Not measurable with a cup, such as burritos, egg rolls, enchiladas, pizza, pizza rolls, sausage rolls, pastry rolls, quiche, sandwiches, crackers and meat or poultry lunch-type packages, burger on a bun, tacos, pockets stuffed with meat, lasagne, chicken cordon bleu, stuffed vegetables with meat or poultry, meat pie	140 g without gravy or sauce 195 g with gravy or sauce
110.	Hors d' oeuvres	50 g
111.	***Nuts and Seeds*** Nuts and seeds, not for use as snacks: whole, chopped, sliced, slivered or ground	30 g shelled
112.	Butters, pastes and creams, other than peanut butter	30 g
113.	Peanut butter	15 g
114.	Flours, such as coconut flour	15 g
115.	***Potatoes, Sweet Potatoes and Yams*** French fries, hash browns, skins and pancakes	85 g frozen French

		fries 70 g prepared
116.	Mashed, candied, stuffed or with sauce	140 g
117.	Plain, fresh, canned or frozen	110 g fresh or frozen 125 g vacuum packed 160 g canned (drained)
118.	***Salads*** Salads, such as eggs, fish, shellfish, bean, fruit, vegetable, meat, ham or poultry salad, except those listed as a separate item	100 g
119.	Gelatine salad	120 g
120	Pasta or potato salad	140 g
121.	***Sauces, Dips, Gravies and Condiments*** Sauces for dipping, such as barbecue, hollandaise, tartar, mustard or sweet and sour sauce	30 ml
122.	Dips, such as legume or dairy-based	30 g
123.	Major main entrée sauce, such as spaghetti sauce	125 ml
124.	Minor main entrée sauce, such as pizza sauce, pesto sauce or other sauces used as toppings, such as white sauce, cheese sauce, salsa, cocktail sauce or gravy	60 ml
125.	Major condiments, such as ketchup, steak sauce, soy sauce, vinegar, teriyaki sauce or marinades	15 ml
126.	Minor condiments, such as horseradish, hot sauce, mustard or Worcestershire sauce	5 ml
127.	***Snacks*** Potato chips, pretzels, popcorn, extruded snacks, grain-based snack mixes and fruit-based snacks, such as fruit chips	50 g
128.	Nuts or seeds for use as snacks	50 g shelled
129.	Meat or poultry snack food sticks	20 g
130.	***Soups*** All varieties	250 ml
131.	***Sugars and Sweets*** Candies, including chocolate bars and other chocolate products, except those listed as a separate item	40 g
132	Hard candies, except those listed as a separate item	15 g
133.	Baking candies, such as chocolate chips	15 g
134.	Breath mints	2 g
135.	Roll-type hard candies and mini size hard candies in dispenser packages	5 g
136.	Confectioner's or icing sugar	30 g
137.	Bread spreads, except those listed as a separate item, honey and molasses	20 g
138.	Jams, jellies, marmalades, fruit butters and spreads	15 ml
139.	Marshmallows	30 g
140.	Sugars, except those listed as a separate item	4 g
141.	Sugar substitute	Amount equivalent in sweetness to 5 g of sugar
142.	Syrups, including chocolate, maple and corn syrup	30 ml as ingredient 60 ml other uses

143.	***Vegetables*** Vegetables without sauce, including cream style corn and stewed tomatoes, but not including vegetables without sauce listed as a separate item	85 g fresh or frozen 125 ml canned
144.	Vegetables with sauce	110 g fresh or frozen 125 ml canned
145.	Vegetables without sauce, canned	85 g, canned (drained)
146.	Vegetables primarily used for garnish or flavouring, fresh, canned or frozen, but not dried, such as parsley or garlic	4 g
147.	Chilli pepper and green onion	30 g
148.	Seaweed	15 g
149.	Lettuce and sprouts	65 g
150.	Vegetable juice and vegetable drink	250 ml
151.	Olives	15 g
152.	Pickles	30 g
153.	Relish	15 ml
154.	Vegetable pastes, such as tomato paste	30 ml
153.	Vegetable sauce or purée, such as tomato sauce or tomato purée	60 ml

GUIDELINE 12

1. 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" OR ANY OTHER WORD INDICATIVE OF A COMPARATIVE OR A NUTRIENT CONTENT CLAIM APPEARS, WHICH IS NOT REGARDED AS A COMPARATIVE OR NUTRIENT CONTENT 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
- ***Oil-free*** salad dressing
- ***Light*** tuna (referring to the colour of the meat)
- ***Double cream*** dairy cream

2. CALCULATION OF THE COMPARISON WHICH SHALL BE BASED ON A RELATIVE DIFFERENCE OF AT LEAST 25% IN THE ENERGY VALUE OR NUTRIENT CONTENT OR ALCOHOL CONTENT OF AN EQUIVALENT MASS OR VOLUME.

Example 1:

Regular food contains 5 grams of fat; "Lite" food contains 3.8 grams of fat.

5 g – 3.8 g = 1.2 g

(1.2 g / 5 g) x 100 = 24 % difference

Conclusion: A comparative claim is not permitted.

Example 2:

Regular food contains 150 kilojoules; "Reduced" food contains 100 kilojoules.

150 kJ – 100 kJ = 50 kJ

(50 kJ / 150 kJ) x 100 = 33 % difference

Conclusion: A comparative claim is permitted.

GUIDELINE 13

MISLEADING STATEMENTS

The following source of information is hereby acknowledged and adapted: Abstract from "Criteria for the use of the terms such as fresh; pure; natural; etc. in food labelling" by the Food Standards Agency of the United Kingdom, as revised July 2008 and downloaded from: http://www.food.gov.uk/multimedia/pdfs/markcritguidanance.pdf

1. **GENERAL BEST PRACTICE ADVICE**

It is recommended that before using any term, the following points (which are based on the legal requirements set out in Article 5 of the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act No.54 of 1972) as well as the Regulations Relating to the Labelling and Advertising of Foods, (outlawing false and misleading labelling, advertising and presentation of food) be considered and applied at all times:

- foods should be sold without deceit and therefore should be labelled and advertised so as to enable a prospective purchaser to make a fair and informed choice, based on clear and informative labelling;
- a food must be able to fulfil the claim implied by the statement being made for it and therefore adequate information must be available to show that the claim is justified;
- where the use of the marketing term is potentially ambiguous or imprecise, the likely understanding of the 'average' consumer is a good benchmark;
- the statement should allow fair comparison and competition between products, sectors and traders.

Care should be taken when marketing terms are included in business names, trade marks and fancy names (a fancy name that includes a marketing term could be for example "Original Chicken Dinosaurs", where the true name would be "Formed minced chicken and cereal in breadcrumbs"), as it is possible for these to create a false impression for a consumer.

Pictures and illustrative representations on labels and in advertisements, leaflets and on websites can have a powerful effect on prospective purchasers and, in some product sectors, may have a greater significance than names and other descriptive material. These representations should be subject to the same scrutiny and control as the words used to portray similar images and concepts. Care should be taken to ensure that background illustrations and pictures do not mislead the consumer as to the type, quality or origin of the product. For example, kitchen scenes may lead a consumer to believe a product is hand-made or at least produced in a small-scale operation.

The labelling and presentation of the food as a whole, should be used in assessing whether a particular label or description is likely to be considered misleading. Where a consumer might be misled by pictures, any potential ambiguity must be clarified by labelling that is equally clear and as prominent as the pictures.

It is not appropriate to use any marketing term unless its meaning is clear. For example, the term “seasonal” (not specifically covered in this Guideline) might be applied properly to South African grown strawberries in the Spring months but could be misleading when applied to strawberries that have been either imported or grown in heated greenhouses in other seasons.

When using marketing terms it should always be clear in each case what characteristic of a product is being described. For example if the term “wild” is used (not specifically covered in this Guideline) then it could be helpful to clarify whether all stages in the life of an animal have been wild, or if the term “hand-made” is used then it could be informative to explain further if some stages in processing were not carried out by hand.

Where any qualification or explanation is necessary to understand the meaning of a marketing term this should accompany the term and associated imagery. Legal font sizes shall be respected and at all times shall the font and size thereof be easily legible and sufficiently prominent to help consumers make their choice in full knowledge of the facts.

It is generally not helpful to use “style” or “type” to qualify the terms covered by this advice (e.g. “farmhouse style”). If these qualifications are used then clarification should be provided where reasonable practicable to reveal the level of authenticity or link to the original product, whether by the region of origin, source of ingredients or method of production.

2. RECOMMENDED CRITERIA FOR THE USE OF THE TERM “FRESH”

The description “fresh” can be helpful to consumers where it differentiates produce that is sold within a short time after production or harvesting. However, modern distribution and storage methods can significantly increase the time period before there is loss of quality for a product, and it has become increasingly difficult to decide when the term ”fresh” is being used legitimately.

The term “fresh” can also be helpful when used to identify products that have not been processed.

The use of the term “fresh” in some specific circumstances is defined in law (e.g. fresh fruit juice). This Guideline does not apply in such cases.

“Fresh” is often used in a number of phrases that may have an emotive appeal but no real meaning (e.g. “oven fresh”, “garden fresh”, “ocean fresh”, “kitchen fresh”, etc). These should be avoided.

General:

The terms “fresh” or “freshly” should only be used where they have a clear meaning, whether used alone or qualified by other terms. The description can help consumers differentiate between similar products, for example:

(a) fresh fruit salad that is made only from fresh fruit;

(b) fresh dairy products (such as cream) held under chilled conditions at point of sale, with limited shelf life, even where these have been subjected to a minimal, mild heat treatment such as conventional pasteurisation for safety purposes.

Expressions such as “freshly cooked”, “freshly prepared”, “freshly baked”, “freshly picked” should have no other connotation than the immediacy of the action being described. Where such expressions are used, it is recommended they be accompanied by an indication (e.g. of the date or time or period – “freshly prepared this morning”) of when the action being described took place.

Packaging, storage and other supply chain processes that control “freshness” should not be described in terms that may imply that only a short period after harvesting or preparation has elapsed before sale if this is not the case. For example, a food that has been vacuum packed to retain its freshness should not be described as “freshly packed”.

Fruit and vegetables:

The term “fresh” is now used generically to indicate that fruit and vegetables have not been processed (e.g. canned, pickled, preserved or frozen), rather than that they have been recently harvested. This is acceptable provided it is not used in such a way as to imply the product has been recently harvested (e.g. “fresh from the farm”; “freshly picked”) if this is not the case.

The term “fresh” may be used to describe fruit and vegetables that have been washed and/or trimmed, provided that an indication that they have been washed and/or trimmed is also present. However, in the case of prepared fruit or vegetables, e.g. “fruit salad” that could be described as “fresh”, then if it was obvious from its appearance for that product that fruit for example had been trimmed, peeled and cut then such indication would not be necessary, and it would be assumed that it had been washed.

Chill temperatures and other controlled atmospheres are used in the food production chain for the delayed ripening and/or extended storage of fruit and vegetables. The use of the term “fresh” is acceptable in these circumstances.

Meat:

Virtually all carcase meat is chilled following slaughter, principally as a hygiene measure. The term “fresh” is traditionally used to differentiate raw meat from that which has been (chemically) preserved.

It would serve no purpose to disqualify chilled meat from use of the term “fresh”. Use of the term “fresh” in these circumstances is acceptable.
Meat that has been previously frozen but which is sold thawed would not be considered by the average consumer to be “fresh”. The term “fresh” should not be used in these circumstances.

Fish
Use of the term "fresh" to describe fish that has been kept chilled on ice, but not stored deep frozen, is acceptable.

Fish that has been previously stored deep frozen, but which is sold thawed would not be considered by the average consumer to be "fresh". The term "fresh" should not be used in these circumstances.

Smoked or marinated/salted fish should not be referred to as fresh because it has been preserved/undergone processing.

Fruit juice:
The term “fresh” should not be used, directly or by implication, on juices prepared by dilution of concentrates.

The term “freshly squeezed” should only be used to describe juice obtained direct from the fruit (i.e. not prepared from concentrates) where there has been a short time between extraction and packaging and the “use by” date given on the product is within the time period permitted according to applicable Regulations under the Agricultural Products Standards Act, 1990 (Act 119 of 1990), of juice extraction.

Where fruit juice described as “freshly squeezed” has been pasteurised, the indication of treatment should form part of the claim, e.g. “freshly squeezed pasteurised orange juice” etc.

Milk:
“High temperature pasteurised” milk has a recognised meaning and should not carry the term “fresh”.

Fresh pasta:
Fresh pasta is different to dried pasta in having a much higher moisture content and a shorter cooking time. Fresh pasta is traditionally considered as a short shelf life product (although chilling and vacuum packing may extend the shelf life). The term “fresh” can be used to differentiate a fresh pasta product from dried pasta.

Fresh bread:
Terms such as “freshly baked”, “baked in store” and “oven fresh” may mislead consumers into believing that they are being offered products that have been freshly produced on site from basic raw

materials. Some stores sell bread made from part-baked products that have been packed in an inert atmosphere or frozen off-site then "baked off" at in-store bakeries. Use of terms like "freshly baked", "baked in store" and "oven fresh" on these products could potentially infringe the general legal provisions referred to in paragraph 14 above.

Frozen or processed foods or ingredients:

The term "fresh" should only be used in relation to frozen or processed foods if its use is clear from the context. For example:

- **"frozen from fresh"** should only be used to indicate a food was fresh (i.e. recently made or harvested) when it underwent freezing;
- **"made with fresh ingredients"**

should be used only where the intended meaning is that no processed ingredients (i.e. ingredients that have been dried, freeze-dried, frozen, concentrated, powdered, smoked, canned, etc) were used;

- **"made with fresh X"**

should only be used where X is the name of an ingredient that has not been processed and the food does not also contain processed equivalents of the same ingredient. For example, a food described as "made with fresh tomatoes" should not also contain canned tomatoes.

Fresh taste:

The expression "fresh taste" should not be used where it could mislead the consumer, for example by implying "freshly squeezed", unless it is clear from the context that the reference is to the "tanginess" of the taste and only if the appropriate criteria for "freshness" of the food as set out in this Guidance are met. The use of alternative terms like "clean taste" and "refreshing taste" should be considered.

Terms like "with the taste of fresh X" (e.g. "with the taste of fresh lemons") should only be used if the product contains "fresh X" and the flavour being described comes wholly or mainly from that "fresh X".

Chilled foods:

For chilled convenience foods, unless the product complies with the appropriate criteria for use of the term "fresh" (or it is suggested otherwise in this Guideline), the term should not be used to describe foods when indicating a moderate shelf life under refrigerated conditions (e.g. for such products as chilled soups and sauces).

3. RECOMMENDED CRITERIA FOR THE USE OF THE TERM "NATURAL"

"Natural" means essentially that the product is comprised of natural ingredients, e.g. ingredients produced by nature, not the work of man or interfered with by man10. It is misleading to use the term to describe foods or ingredients that employ chemicals to change their composition or comprise the

products of new technologies, including additives and flavourings that are the product of the chemical industry or extracted by chemical processes.

Dairy products:

The term “natural” has been used on certain dairy products for many years, to signify that the products are manufactured only from milk, using only the necessary, associated fermentation cultures and are free from other ingredients or additives, such as preservatives, flavourings, colours, i.e., they are “plain”, unflavoured products, (e.g. “natural” yogurt, “natural” fromage frais, and “natural” cottage cheese). This usage is well understood, and is therefore acceptable, providing it is clear that the term is indicating that the flavour of the product is that derived solely from the ingredients essential to the manufacture of the product, and that the flavour has not been adjusted by any other means. The ingredients must comply with the requirements outlined of this Guideline.

Bottled water:

The name “natural mineral water” may be used in accordance with the consolidated regulations for Packaged water published under the.

Health and Nutrition Claims:

References to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being must comply with the Regulations Relating to the Labelling and Advertising of Foods (R 429 of 29 May 2014. Where these afore-mentioned regulations also allows the use of “naturally” or “natural” as part of the claim (e,g, negative claims) when the food naturally meets the condition(s) laid down in the regulations for the use of such a nutrition claim. Within the context of the health and nutrition claims legislation it is suggested that “naturally / natural” means that either nothing has been removed or nothing has been added to the food, and additionally that the food has not been subjected to any processes or treatment to render it such that it meets the condition.

General:

The term “natural” without qualification should be used only in the following cases (see table for further explanation):

(a) To describe single foods, of a traditional nature, to which nothing has been added and which have been subjected only to such processing as to render them suitable for human consumption:

  (i) Smoking (without chemicals), traditional cooking processes such as baking, roasting or blanching and traditional methods of dehydration are examples of processes that are acceptable, as are physical sieving and washing with water.

  (ii) Fermentation is itself a natural process but subsequent processes may disqualify the final product from the description “natural” unless appropriately qualified.

  (iii) Processes such as freezing, concentration, pasteurisation, and sterilisation, whilst clearly playing a significant role in both making food safe and preserving it do not

accord with current consumer expectations of “natural” foods. However, the process to which a “natural” product has been subjected can be described using these terms (e.g. “pasteurised natural lemon juice”, “frozen, unsweetened, natural orange juice”).

(iv) (aa) Other processes such as non-traditional enzymatic treatment, production by immobilised micro-organisms or non-traditional fermentation processes, solvent extraction, carbon filtration and ion exchange purification, or acid or alkali treatment (outside of traditional pickling) or non-traditional distillation are also not in line with current consumer expectations of “natural”, and so if used then products should not be referred to as natural foods or ingredients. Bleaching, oxidation (outside of treatment of Natural Mineral Water), smoking (with chemicals), tenderising (with chemicals),

(bb) It is suggested that foods containing flavourings other than natural flavourings as defined by law should not be described as ”made from natural ingredients”.

(cc) Hydrogenation and similar processes also fall outside the meaning of this term.

(dd) The restriction to “foods of a traditional nature” excludes from the concept of “naturalness” foods derived from novel processes, GM or cloning.

(v) For single ingredient foods such as cheese, yogurt, butter, acceptable processing is that which is strictly necessary to produce the final product (as described in (iv) above, and all the following paragraphs below).

(b) To describe food ingredients obtained from recognised food sources and which meet the criteria in (a).

(c) To describe permitted food additives that are obtained from natural sources (e.g. food or plant) by appropriate physical processing (including distillation and solvent extraction) or traditional food preparation processes.

(d) To describe flavourings when in conformity with the Regulations Relating to Flavourings, published under the Act.

Compound foods (i.e. foods made from more than one ingredient) should not themselves be described directly or by implication as “natural”, but it is acceptable to describe such foods as “made from natural ingredients” if all the ingredients meet the criteria in the precious sub-paragraphs (b), (c) and (d)above, as appropriate. All additives and flavourings in ingredients that are used to make the final product must also satisfy the criteria.

A food that does not meet the criteria in outlined in this section should not be claimed to have a “natural” taste, flavour or colour. Certain single ingredient foods/ingredients have the natural ability to colour a food such as red fruit palm oil, tomato paste/puree, cherry juice, blueberry or mulberry juice et cetera. These foods, when used as ingredients in a compound food or used as end product may be called a “natural colouring food/ingredient”, whatever may be appropriate.

“Natural” meaning no more than plain or unflavoured should not be used unless the food meets the criteria outlined in this section as well as in accordance with the relevant regulations related to primary Dairy products published under the Agricultural Products Standards Act, 1990 (Act No. 119 of 1990).

“Natural”, or its derivatives, should not be included in brand or fancy names, nor in coined phrases, in such a way as to imply that a food that does not meet the criteria outlined in this section, is natural or made from natural ingredients.

Claims such as “natural goodness”, “naturally better”, or “nature’s way” are confusing and ambiguous. They should not be used and are very likely to be misleading if applied to products not meeting the ‘natural criteria’.

The principles set out above in this section on “natural” also apply to the use of other words or expressions, such as “real”, “genuine”, “pure” etc with separate and distinctive meanings of their own, when used in place of “natural” in such a way as to imply similar benefits. Guidance on such terms and their synonyms is offered elsewhere in these advice notes.

CRITERIA FOR THE USE OF THE TERM “NATURAL”

	Criteria		
Distinction that applies to natural food or natural ingredient	**Natural**	**vs**	**Non-Natural**
Single ingredient or compound food to which nothing non-natural is added.	Single foods to which nothing is added. Compound* foods where all ingredients are natural may be described as “Made from natural food ingredients”.		Compound foods (not as such but see opposite)*. Compound foods that include non-natural ingredients.
Not interfered with by man by use of chemicals.	Foods or ingredients not altered by use of chemicals		Foods or ingredients that have been chemically changed. Foods or ingredients that have been extracted with solvents.
Not interfered with by man by use of technology or not normally consumed by man.	Foods or ingredients that are as in nature and normally consumed by man.		Foods or ingredients that are novel foods, or made with GM or cloned.
Not interfered with by man in that treated only with processes that are traditionally used in food preparation, Including fermentation	Foods or ingredients that have been treated with traditional food preparation processes such as baking or roasting. Foods or ingredients that employ traditional fermentation processes.		Foods ion ingredients that have been treated with novel processes or processes not in accord with consumers’ expectations of what is natural, such as bleaching, ion exchange chromatography etc. Foods or ingredients that have been synthesised with the use of immobilized microorganisms or non traditional fermentations

	Criteria		
Distinction that applies to natural food or natural ingredient	**Natural**	**vs**	**Non-Natural**
	If foods are treated with processes such as concentration# or pasteurisation, they should not be described as "natural" but may be described for example as "pasteurised natural orange juice"		or non traditional enzyme treatments. Foods that have been concentrated etc (not as such but see opposite)#.
Distinction that applies to natural additive or natural flavourings			
Additives that are made from natural sources using traditional food preparation or appropriate physical processes	Additives that are obtained from natural sources by traditional food preparation or appropriate physical processes including distillation or solvent extraction.		Additives that are not from natural sources or that are made using chemical processed or treatments.
Flavourings that are made from natural flavouring source materials.	Set out in legislation. Natural flavourings, under legislation may be made by processes such as distillation or solvent extraction from natural flavouring source materials		Chemically synthesized flavourings or those made with the use of immobilized microorganisms or non traditional fermentations or non traditional enzyme treatments.

4. RECOMMENDED CRITERIA FOR THE USE OF THE TERM "PURE"

The term "pure" is mostly used on single ingredient foods (e.g. to indicate a single, named variety of rice) or to highlight the quality of ingredients of a food (e.g. "pure butter shortbread" to indicate the butter has not been blended with other fats or is the only fat in the shortbread).

The validity of the use of the term "pure" should be determined by the properties of the food itself, not its storage conditions.

The term "pure" should generally only be used in the following circumstances-

(a) to describe a single ingredient food: or

(b) to which nothing has been added;

(c) that is free from avoidable contamination with similar foods and levels should be as low as practically achievable and significantly below, for example, the thresholds requiring GM labelling.

Compound foods should not generally be described, directly or by implication, as "pure". It is, however, acceptable to describe such foods as "made with pure ingredients" if all the ingredients meet the criteria above, or if a claimed, named ingredient meets these criteria and is the only source of that ingredient. The exception to this general rule is in the case of jams and marmalades where the term "pure fruit" is used to indicate that the fruit has not been preserved by sulphur dioxide, prior to

use in the jam/marmalade. This usage is acceptable that the presence of pectin was readily apparent to the average consumer by virtue of its declaration in the ingredient list; the presence of low levels of naturally-occurring contaminants was unavoidable; and the levels of the pesticide residues were “particularly low” as compared with the levels permitted by legislation.

“Pure” should not be included in any brand or fancy names, nor in coined or meaningless phrases, in such a way as to imply that a food that does not meet the criteria above is pure or made from pure ingredients.

“Pure” meaning no more than plain or unflavoured should not be used except where the food in question meets all the criteria above for the use of “pure”.

The principles set out above in this section on “natural” also apply to the use of other words or expressions, such as “real”, “genuine”, “pure” etc with separate and distinctive meanings of their own, when used in place of “natural” in such a way as to imply similar benefits. Guidance on such terms and their synonyms is offered elsewhere in these advice notes.

5. RECOMMENDED CRITERIA FOR THE USE OF THE TERM “TRADITIONAL”

The term “traditional” is widely used to describe a product or method of preparation when newer alternatives are available on the market. It implies more than “original” or “plain”.

The term “traditional” should demonstrably be used to describe a recipe, fundamental formulation or processing method for a product that has existed for a significant period of at least 40 years or more. The ingredients and process used should have been available, substantially unchanged, for that same period. It is within consumer expectations for the product to have been made in a factory.

It is misleading to use the term “traditional”, without qualification, simply to distinguish an “original” recipe from subsequent variants. Manufacturers and retailers should pay particular attention to the use of ingredients, particularly additives, and to the use of processes that have not been used in food manufacture for the significant period of time indicated above. They must ensure that the term does not imply a composition or production method that would not be regarded as “traditional” by the average consumer and should consider whether the term “original recipe” or similar expression may be more appropriate. There should be evidence to substantiate the use of the word for the particular product.

Recipes of what might be described as “traditional” products may change over time to accommodate consumer demands and expectations (e.g. Christmas puddings and mince pies made with vegetable rather than animal fat/suet; and other foods that are traditionally consumed at certain times of the year). Such foods should not be described as “traditional X”. However, reference may be made to the traditional nature of these products, provided this does not imply that the product itself has been made

traditionally/to a traditional recipe unless this is the case. For example - “Christmas pudding – a rich, steamed fruit pudding traditionally eaten on Christmas day with custard, brandy butter or cream”.

6. RECOMMENDED CRITERIA FOR THE USE OF THE TERM “ORIGINAL”

Unlike “traditional” the term “original” does not imply, necessarily, that a product has remained unchanged for a substantial period of time. It may be applied to newer products on the market. It is used to indicate that a product was the first of its type to be placed on the market, where the original form or flavour has remained essentially unchanged through the passage of time (although this need not be a long period) and hence to differentiate it from new additions to a range. The term is commonly used to convey “plain” or “unflavoured” where other variants are offered (e.g. “original flavour crisps”) or to indicate the first variant in a series of products.

The term “original” should not be used to convey “plain” or “unflavoured” where other variants are offered (e.g. original flavour crisps), or to indicate the first variant in a series of products, unless the product can be shown to meet the criteria in the following two paragraphs below.

The term “original” should only be used to describe a food that is made to a formulation, the origin of which can be traced, and that has remained essentially unchanged over time. It should not contain replacements for major ingredients. It can similarly be used to describe a process, provided it is the process first used in the making of the food, and which has remained essentially unchanged over time, although it may be mass - produced.

To be termed “original”, a product should not have changed to any material degree and should remain available as the ’standard’ product when new variants are introduced. A product re-introduced onto the market after a period of absence should only be described as “original” if it can be shown to meet these criteria.

7. RECOMMENDED CRITERIA FOR THE USE OF THE TERMS “AUTHENTIC”, “REAL” AND “GENUINE”

The term “authentic” has a different meaning to “traditional”. It may imply either that a product has remained unchanged through the passage of time, or that it actually originates from the area implied by its name, when the generic description of the product has passed into wider usage.

The term “authentic” is used:

(a) to indicate the true origin of a product where the description may be in wider, generic use;

(b) to convey to consumers that a product has particular characteristics that have not been adjusted for the British palate (e.g. authentic Indian-recipe curry dishes); or

(c) to indicate single types of rice, where this is important because they have particular characteristics.

The current, widespread use of terms such as “real”, “genuine” etc in relation to individual food ingredients (e.g. “made with real fruit juice”) is usually unjustified and repetitive. Such use may be taken to imply that the food or its ingredients possess higher compositional quality than other similar products. In view of the fact that ingredients and flavourings should already be clearly indicated on the label, it is recommended that this use of these terms should be considered carefully and implemented only where the product is sufficiently different to others in the same range. Care should be taken not to mislead when flavourings are used, for example it may not be helpful to use “real” to emphasise the presence of fruit juice when it is only at a low percentage level and most of the flavour arises from added flavourings.

The term “authentic” and related terms like “real” and “genuine” should only be used in the following circumstances:

(a) to emphasise the geographic origin of a product, for example where it might be confused with other products of the same name that do not originate from that location, e.g. “authentic Devon toffees”, as long as the product has the characteristics traditionally associated with the product from that geographic origin;

(b) to describe the recipe used to make a product, the origin of which is specified, e.g. “authentic Indian recipe curry”; or

(c) to emphasise the purity of single varieties of ingredients where such purity is essential to deliver specific characteristics.

“Authentic” and analogous terms should not otherwise be used, without qualification, to describe either a food or an ingredient.

The principles set out above in this section on “natural” also apply to the use of other words or expressions, such as “real”, “genuine”, “pure” etc with separate and distinctive meanings of their own, when used in place of “natural” in such a way as to imply similar benefits. Guidance on such terms and their synonyms is offered elsewhere in these advice notes.

8. RECOMMENDED CRITERIA FOR THE USE OF THE TERM “HOME-MADE”

“Home-made” is a term defined very simply and specifically in dictionaries:

(a) made or prepared in the home; of domestic manufacture;

(b) made at home using traditional methods rather than by a manufacturer;

(c) made by oneself; or

(d) crudely or simply made.

Consumers understand the term “home-made” to mean food prepared in a domestic kitchen or food home industry, rather than in a factory or a manufacturer’s kitchen. The use of the term, if unqualified, should accordingly be restricted to the broad criteria above.
In order to avoid visual misrepresentation, factory-made foods should not be shown being made in small kitchens, farmhouses etc.

In order to accommodate the production of meals and dishes on commercial catering premises, the term “home-made” should be restricted to the preparation of the recipe on the premises, from primary ingredients, in a way that reflects a typical domestic situation. This should not be achieved simply by the assembly of wholly pre-prepared elements, or simple reconstitution from dry base mixes, but must involve some degree of fundamental culinary preparation. As in domestic preparation, it would be legitimate for caterers to use partly-prepared ingredients that are available for domestic use; typical examples could include the use of pre-prepared raw pastry, bakery bread in desserts or stock cubes in sauces.

9. RECOMMENDED CRITERIA FOR THE USE OF THE TERM “FARMHOUSE”

The use of terms like “country”, “farm” etc or similar visual depictions of typical rural scenes may mislead if the food to which they are applied has not been produced on what the average consumer would understand to be a farm.

“Farm House” or “farmhouse” can only be defined as a house on a farm, and more specifically as the main dwelling of the farmer himself.

The baking industry has long used the term “farmhouse” to describe a style of bread with a split and a rounded crust, and sometimes flour dressed. This use of the term is acceptable.

Where the term “farmhouse” is used in connection with foodstuffs other than bread and pâté (see below), it should refer to products that are produced on a farm. If a product is not produced on a farm but is produced to the same quality as that likely to be produced on a farm, it should be described accordingly, not using the term “farmhouse”, but for example by describing the source of its ingredients.

Given the vagueness of the term when used alone, its use should be avoided in preference of other terms which may be more descriptive and more accurate (e.g. “chunky vegetable soup”). When the term is used, its meaning should be made clear either within the context of sale or by associated wording (e.g. “farmhouse-made soup”).

Simply describing an ingredient as “farmhouse”, e.g. “x with farmhouse vegetables”, is meaningless. The term should not be used in this context.

The similar expression “country style” does not appear to have any specific meaning. This phrase should not be used to describe any food or food ingredient.

10. RECOMMENDED CRITERIA FOR THE USE OF THE TERM “FARMHOUSE PÂTÉ”

“Farmhouse Pâté” may be used to indicate a certain type of pâté with a coarse texture.

11. RECOMMENDED CRITERIA FOR THE USE OF THE TERM “HAND-MADE”

A product endorsed as being “hand-made” should be significantly made by hand rather than just one element of the process being carried out in that way. Terms such as “hand assembled”, “hand carved”, or “hand decorated / finished” may be appropriate alternatives. If “hand crafted” is used then it should be clear as to which part of the process this refers to if it is not entirely produced by hand. It would not however be against public expectation for a “hand-made” product to be produced within an industrial setting.

12. RECOMMENDED CRITERIA FOR THE USE OF THE TERMS “PREMIUM”; “FINEST”; “QUALITY”; AND “BEST”

These terms are each seen as ways in which manufacturers differentiate their ranges of products to indicate the one that is ‘top of the range’. It would be advantageous if manufacturers and retailers could help consumers to understand why a claim of high level of overall quality is justified and why the particular term is used.

GUIDELINE 14

GUIDELINES ON:
CRITERIA FOR THE COMMERCIAL MARKETING OF FOODS AND NON-ALCOHOLIC BEVERAGES TO CHILDREN ACCORDING TO THE LATEST REGULATIONS RELATING TO THE ADVERTISING AND LABELLING OF FOODSTUFFS (NO. R 429 OF 29 MAY 2014).

ACKNOWLEDGEMENT

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The policy aim of the National Department of Health is-

**** to reduce the impact on children of the marketing of unhealthy foods and non-alcoholic beverages, which are high in fat, saturated fats, trans-fatty acids, free sugars, and sodium (salt),***

**** to reduce the risk of developing non-communicable diseases (NCDs) such as cardiovascular disease, diabetes mellitus, some cancers and obesity.***

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KEYWORDS

Advertising

Labelling

Non-communicable diseases

ACRONYMS

ASASA – Advertising Authority of South Africa

FBDG - Food Based Dietary Guidelines

INS - Integrated Nutrition Strategy
NCDs – Non-communicable diseases
WHA – World Health Assembly
WHO – World Health Organisation

1. OBJECTIVE

The objective of this Guideline is to provide a framework for implementing a set of recommendations and regulations to limit children's exposure to the marketing of foods and non-alcoholic beverages (resolution WHA63.14), endorsed by the 63rd World Health Assembly (WHA) in May 2010.[1]

2. PRINCIPLE

This guideline is intended to support the new proposed Regulations relating to the Labelling and Advertising of Foods, which will be published in terms of the Foodstuffs, Cosmetics, and Disinfectants, 1972 (Act 54 of 1972), as amended in 2009. The guideline is applicable to food manufacturers, retailers, restaurants, supermarkets, television and radio stations, public relations and advertising agencies, schools, organizers of sporting or children's events, etc., with the intention to manufacture, sell, market, advertise, or otherwise promote food to children. The guideline is intended to provide criteria for advertising and marketing of food to children in order to reduce the impact on children of marketing of foods high in fat, saturated fat, *trans*-fatty acids, total sugars, or total Sodium in a manner that does not compromise their health.

The Guideline is also intended to provide education and public information in promoting a healthy diet, in response to a resolution WHA63.14)[1] and to implement "a set of recommendations to limit children's exposure to the marketing of foods and non-alcoholic beverages".

3. BACKGROUND

The World Health Organization (WHO) as body responsible for directing and coordinating authority for health within the United Nations system, has as part of its responsibility to provide leadership on global health matters, recognized that there is a growing burden of NCDs, which was recognised by the adoption of a target to reduce non-communicable diseases (NCDs) by 25% by 2025.
In 2010 the WHO Global Status Report on NCDs[2] reported that diseases such as cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes, are major causes of death and illness around the world with an estimated more that 36 million deaths each year occurring due to NCDs. Low- and middle-income countries such as South Africa, now bear nearly 80% of the burden from diseases like cardiovascular disease, diabetes, cancer and chronic respiratory diseases. One of the four main risk factors for NCDs is an unhealthy diet. Although poor diets can contribute to NCDs without leading to obesity, overweight and obesity are among the most visible signs of this crisis. The

dramatic rise in obesity in children and youth worldwide means children are at an increased risk of obesity and related chronic diseases in adulthood. Unhealthy diet is a risk factor for non-communicable diseases. The risks presented by unhealthy diets start in childhood and build up throughout life. In order to reduce future risk of non-communicable diseases children should maintain a healthy weight and consume foods that are low in fat, saturated fat, trans-fatty acids, free sugars, and salt. Unhealthy diets are associated with overweight and obesity, conditions that have increased rapidly in children around the world over recent years. It has been widely reported that many countries, including low- and middle- income countries, are witnessing the fastest rise in overweight and obese young children which are contributed by unhealthy diet and lifestyles and occur both in higher and lower income groups. According to the WHO, deaths are attributed by among other risks physical inactivity (6%) and overweight and obesity (5%).

A new study by researchers at NYU School of Medicines reveals for the first time that metabolic syndrome (MetS) is associated with cognitive and brain impairments in adolescents.[3]

In May 2010, the 63rd World Health Assembly (WHA) endorsed a set of recommendations to limit children's exposure to the marketing of foods and non-alcoholic beverages (resolution WHA63.14).[1] One of the key drivers for the increase in NCDs is the promotion, marketing and advertising by food companies of products that are high in fat, sugar and salt and low in nutritional value. A number of voluntary and self-regulatory codes and pledges have since been introduced by food and beverage companies. South Africa has developed a Nutrient Profiling Model with commitments from the food industry and other stakeholders, from which criteria could be developed to determine which foods could or could not be advertised.

South African Context

As a country, South Africa acknowledges the need to tackle the crisis in childhood obesity and that this requires a number of actions to improve children's diets and promote exercise, hence the need to give attention to foods and beverages which children can be encouraged to consume. In South Africa there is an "Integrated Nutrition Strategy (INS)", which was designed to address under- and over-nutrition and operates as the Integrated Nutrition Program (INP), The Strategy aims to facilitate an inter-sectoral collaboration in order to ensure that nutrition problems are solved. The strategic priorities include the "reduction of diseases of lifestyle related to over-nutrition", and promoting healthy lifestyles. The South African Food Based Dietary Guidelines (FBDG) was developed to specifically deal with this priority as well as the promotion of "Healthy Lifestyles" campaign. This has also prompted the Department of Health to develop, as part of the Labelling Regulations, the regulations on foods and beverages, which may not be marketed or advertised to children.

Self-regulation overview

The Advertising Standards Authority of South Africa (ASASA) is a well-established and accepted body with a code on advertising. The Code has an appendix to the code on food and beverage advertising,

which was specifically intended to address concerns about food advertising to children. It is in line with many other self-regulatory codes, but relatively unusual in including licensed characters and primary schools. In addition to this, a South African Pledge on Marketing to Children was signed on June 11 2009 - an initiative of the Consumer Goods Council of South Africa. It has 23 signatories, including food manufacturers, retailers and fast food chains. Companies have not yet developed individual pledges, but it follows in general the EU Pledge.[4] It applies to children under age 12**,** and to foods that do not meet (as yet unset) nutrient profiles.

The Department of Health believes that action to limit the marketing of energy dense, nutrient poor foods which high in fat, saturated fats, *trans*-fatty, acids, total sugars, or total sodium directly to children, is fundamental to any long-term solution. Several major reviews of the evidence on the impact of food marketing to children show a connection between food marketing and children's food preferences, purchase requests and consumption patterns. [5]

International context

The International Obesity Taskforce (IOTF)[7] estimates that globally up to 200 million school-aged children are either overweight or obese and, of those, 40-50 million are classified as obese.

• Worldwide in 2010, it is estimated that 43 million children under the age of five were overweight and obese. Of those, 35 million lived in developing countries.

• The worldwide prevalence of overweight and obesity in pre-school children is expected to rise from 6.7% in 2010, and reach 9.1% or close to 60 million children under five in 2020.

• The estimated prevalence of childhood overweight and obesity in Africa in 2010 was 8.5%, and is expected to reach 12.7% in 2020.

• The prevalence is lower in Asia (4.9% in 2010) than in Africa (8.5% in 2010), but the number of affected

Globally, measured media spending on food is the third largest category after automotive and personal care. USD11.9 billion was spent on food advertising in 2008.

• In the US, in 2006, 44 of the largest food and beverage marketers spent USD1.6 billion adolescents. Of this, marketers spent USD745 million, or 46% of the 2006 total, on TV advertising.

• According to a 2010 forecast, global advertising spend online will reach USD96.8 billion by 2014, up from USD55.2 billion in 2009. Online advertising spend will make up 17% of total global advertising spending.

• Companies are directing more of their global advertising budgets towards emerging and developing countries; the share of global marketing spending increased in Asia and the Pacific, Latin America and the Middle East between 2007 and 2008.

The WHO Technical Meeting held in Oslo, Norway, on 2-5 May 2006 on Marketing of Food and Non-Alcoholic Beverages to Children, concluded that a strong scientific rationale is available through the

robust science and research that links commercial promotion of foods and beverages to poor diets in children.[6] The evidence shows that:

- there is extensive food and beverage promotion to children
- children are aware of, appreciative of, and engage with this promotion
- this food promotion is overwhelmingly for energy-dense, micronutrient-poor foods and undermines recommendations for a healthy diet
- this food promotion has a deleterious effect on children's food knowledge, attitudes, purchase behaviour and consumption

A systematic review of the extent, nature and effects of food promotion to children commissioned by the WHO[8] also indicates that children are likely to respond to advertising in the same way whichever part of the world they live in. However, it suggests that children in developing countries may be more vulnerable to food promotion because they are in some cases less familiar with advertising; they are a key entry point for developed country firms because they are more flexible and responsive than their parents.

Member States of the World Health Organisation- [7]

- AFFIRMING the importance of a multi-faceted approach to tackle non-communicable diseases as established in the Global Strategy on Diet Physical Activity and Health (Resolutions of the World Health Assembly 57.17 and 60.23);
- CONSCIOUS of the high rates of non-communicable diseases globally and the burden that this presents in both developed and developing countries;
- RECOGNISING that the spread of non-communicable diseases is a global problem with serious consequences for public health that calls for the widest possible international co-operation and the participation of all countries in an effective, appropriate and comprehensive international response;
- CONCERNED about the impact of marketing techniques, including advertising, promotion and sponsorship encouraging children to consume energy-dense, nutrient-poor foods high in fat, sugar or salt;
- ASSERTING that poor diet is an important risk factor for non-communicable diseases;
- ACKNOWLEDGING that the UN Convention on the Rights of the Child affirms the right of children to the highest attainable standard of health, to protection from exploitation and recognising the importance of ensuring that all segments of society, but particularly parents and children are supported in the use of basic knowledge of child health and nutrition;
- CONVINCED of the importance of ensuring that food marketing, particularly to children, does not undermine efforts to meet dietary guidelines and goals as established by the World Health Organization (WHO);
- RECOGNISING the recommendation from the WHO Technical Meeting on Marketing of Food and Non-Alcoholic Beverages to Children that there is now a strong scientific rationale linking commercial promotion of foods and beverages to poor diets in children

and that food promotion is overwhelmingly for energy-dense, micronutrient poor foods and undermines recommendations for a healthy diet;

- AWARE of the wide range of marketing techniques and media that are used to promote foods to children;
- RECOGNISING that national and domestic regulations and standards should ensure that advertising is legal, decent, honest, true, fair and not misleading regardless of the product or audience;
- ACKNOWLEDGING that the WHO's International Code of Marketing of Breast Milk Substitutes and subsequent relevant World Health Assembly recommendations already apply to the marketing of breast milk substitutes including infant formula and these are therefore outside the scope of this Code;
- CONSCIOUS that methods for nutrient profiling are now available that can be used to differentiate healthier and less healthy foods;
- BELIEVING that commercial operators have a responsibility to ensure that their marketing practices do not undermine children's health irrespective of national borders;
- COGNISANT of the need to implement comprehensive multi-sectoral measures to avoid exacerbating health inequalities;"

At the recent Sixty-Six World Health Assembly, in resolution WHA 60.23 on prevention and control on non-communicable diseases: implementation of the global strategy, requested the Director-General "… to promote responsible marketing including the development of a set of recommendations on the marketing of foods and non-alcoholic beverages to children in order to reduce the impact of foods high in saturated fats, trans-fatty acids, free sugars, or salt, in dialogue with all relevant stakeholders, including private-sector parties, while ensuring avoidance of potential conflict of interest".

In recent years the World Health Organisation also published two documents on this. The "Set of recommendations on the marketing of foods and non-alcoholic beverages to children" (WHO, 2010) and Marketing of foods high in fat, salt and sugar to children: update 2012 – 2013" (WHO, 2013).

The WHO Marketing of foods to children read as follows: "The promotion of potentially unhealthy food and beverage products is now widely recognized in Europe as a significant risk factor for child obesity and for the development of diet-related non-communicable diseases. Reviews conducted for WHO, for European parliamentarians and for national agencies in Europe and the United States of America have all concluded that, despite substantial gaps in the evidence, advertising and the promotional marketing of foods and beverages have enough effect on children's diets to merit action" (WHO, Marketing of foods high in fat, salt and sugar to children: update 2012 – 2013).

The obesity problem has industry's attention, and they are doing things, but the question is whether these things are meaningful or are the predictable behavior of an industry under threat and are designed to stop rather than support public health efforts. The food industry has had plenty of time to prove itself trustworthy. It has been in high gear, making promises to behave better, but their minor progress creates an impression of change while larger attempts to subvert the agenda carry on, such as the massive resistance against soda taxes in the United States and the wholesale attack of

marketing standards proposed by the Interagency Working Group. Other examples include tactics such as the soft drink industry giving the Children's Hospital of Philadelphia a US$10 million gift, at a critical time the city of Philadelphia was considering a soda tax. Such public-sector interaction with industry could be predicted to undermine public health goals and protect industry interests. Worst perhaps is the issue of marketing food to children. The industry launched the Children's Food and Beverage Advertising Initiative designed to ".shift the mix of foods advertised to children under 12 to encourage healthier dietary choices and healthy lifestyles". Objective reports, however, have shown a tidal wave of marketing of calorie-dense, nutrient-poor foods to children, and if any change is occurring, marketing is on the increase. Companies boast of introducing healthier options, and at least one report cites this as evidence that market forces (e.g., consumer demand for better foods) will be the best motivator for companies to change.[9]

But introducing healthier processed foods does not mean unhealthy foods will be supplanted, and might simply represent the addition of more calories to the food supply. Furthermore, the companies have not promised to sell less junk food. Quite the contrary; they now offer ever larger burgers and portions, introduce ever more categories of sugared beverages (sports drinks, energy drinks, and vitamin waters), find ever more creative ways of marketing foods to vulnerable populations (e.g., children), and increasingly engage in promotion of unhealthy foods in developing countries. The food industry, like all industries, plays by certain rules - it must defend its core practices against all threats, produce short-term earnings, and in doing so, sell more food. If it distorts science, creates front groups to do its bidding, compromises scientists, professional organizations, and community groups with contributions, blocks needed public health policies in the service of their goals, or engages in other tactics in "the corporate playbook", this is what is takes to protect business as usual. An emerging area in need of scrutiny is the food industry's attempts to create foods engineered in ways that thwart the human body's ability to regulate calorie intake and weight. Whether overconsumption is a consequence simply of hyper-palatability brought about by extreme processing and/or an addictive process, overconsumption is a predictable consequence of the current food environment. The arresting reality is that companies must sell less food if the population is to lose weight, and this pits the fundamental purpose of the food industry against public health goals. Everybody needs food, but the obesity crisis is made worse by the way industry formulates and markets its products. [9]

The food industry, like other industries must be regulated to prevent excesses and to protect the public good. Left to regulate itself, industry has the opportunity, if not the mandate from shareholders, to sell more products irrespective of their impact on consumers. Government, foundations, and other powerful institutions should be working for regulation, not collaboration.

If history is to look back positively on current times, the future must bring several things. Respectful dialogue with industry is desirable, and to the extent industry will make voluntary changes that inch us forward, the public good will be served. But there must be recognition that this will bring small victories only and that to take the obesity problem seriously will require courage, leaders who will not back down in the face of harsh industry tactics, and regulation with purpose."

The impact of industry self-regulation of advertising of fast food to children on Australian television concluded that children's exposure to unhealthy fast-food advertising has not changed following the

introduction of self-regulation, and some fast foods advertised for children's consumption contain excessive energy. The limited impact of self-regulation suggests that governments should define the policy framework for regulating fast-food advertising to children. [10]

The ubiquitous marketing of energy-dense, nutrient-poor food and beverages is a key modifiable influence on childhood dietary patterns and obesity. Much of the research on television food advertising is focused on identifying and quantifying unhealthy food marketing with comparatively few studies examining persuasive marketing techniques to promote unhealthy food to children. This review identifies the most frequently documented persuasive marketing techniques to promote food to children via television. A systematic search of eight online databases using key search terms identified 267 unique articles. Thirty-eight articles met the inclusion criteria. A narrative synthesis of the reviewed studies revealed the most commonly reported persuasive techniques used on television to promote food to children. These were the use of premium offers, promotional characters, nutrition and health-related claims, the theme of taste, and the emotional appeal of fun. Identifying and documenting these commonly reported persuasive marketing techniques to promote food to children on television is critical for the monitoring and evaluation of advertising codes and industry pledges and the development of further regulation in this area. This has a strong potential to curbing the international obesity epidemic besieging children throughout the world. [11]

4. RATIONALE

For the Department of Health to achieve the policy aim of reducing the impact of con-communicable diseases of lifestyle on children, the following should:

- set nutrition standards for the kinds of food that can and cannot be promoted to children of different ages; and
- implement restrictions on the marketing and promotion of any foods that fall below these nutrition standards (energy dense, nutrient poor foods).

5. IMPLICATIONS

Commercial marketing means a multifaceted, integrated mix of marketing communications, campaigns and techniques that focuses on branding and building relationships with consumers and includes but is not limited to-

a) advertising as defined by the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act No. 54 of 1972), through any media in any manner, directly or indirectly (e.g., using the happy, caring family scenario), combining traditional media, digital marketing, packaging, online sweepstakes, outdoor advertising, food companies' websites, search engines, social networking sites and blogs, around or in films and media clips viewed online, around or in online and downloaded games and music, print media, in-school marketing and all other marketing techniques;

b) radio, television, the internet, any other electronic online medium, e-mails and text messages, mobile and viral marketing, digital marketing, packaging, online sweepstakes; and

c) cross promotions (e.g. linking foods with popular children's movies and television characters), product placement, sales promotion, promotional activities such as redemptions, under-the-cap offerings, advergaming, text message/SMS contests, etc offering prizes or rewards, cross-promotions using celebrities including sport stars, brand mascots or characters popular with children.

d) Sponsorship of TV and radio programmes, music videos, celebrity product endorsement, sponsorship of community and school events and contests, corporate gifts of educational materials and equipment, corporate support of health campaigns, sports clubs, school meals.

6. CRITERIA

(1) Any unhealthy food offered for sale, whether prepacked, non-prepacked or ready-to-eat, shall not be permitted to market it commercially in any manner, directly or indirectly-

a) to children during their entire school-going years from grade 0 to 12, including nursery and pre-school ages, using a child actor 18 years or younger; or using any celebrities, sport stars, cartoon-type character, puppet, computer animation or similar strategy; or

b) using, a competition or a token, gift, or collectable items which appeal to children, in order to encourage the use of such unhealthy foodstuffs.

(2) No energy dense, nutrient poor food and non-alcoholic beverage, which are too high in any one of the following; fat, saturated fats, *trans*-fatty acids, total sugar, or total Sodium (hereafter called unhealthy food), shall be marketed commercially to children in any manner, whether prepacked, non-prepacked or ready-to-eat, if the foodstuff –

a) firstly, does not pass the screening criteria of the Nutrient Profiling Model, using the electronic calculator, by clicking on Nutrient Profiling Model Calculator at the bottom of the web page of the Directorate: Food Control on the website of the Department of Health; **http://www.doh.gov.za or http://www.health.gov.za**

b) secondly, contains added fructose, added non-nutritive sweeteners, added fluoride or added aluminium through an additive or ingredient; and

c) thirdly, exceeds the nutrient levels in the food or beverage per 100 g/ml as indicated in the table below, based on the UK Food Standards Agency Criteria (per 100g**/**100ml) (Published January 2007):

Undesirable	**Nutrient levels in food (per 100 g)**	**Nutrient levels in non-alcoholic beverages**

Nutrient		**(per 100 ml)**
Total sugars	5 g	2.5 g
Fat	3 g	1.5 g
Saturated fat	1.5 g	0 75 g
Sodium/salt	120 mg Sodium/0.3 g salt	120 mg Sodium/0.3 g salt

(3) a) Commercial marketing or promotion of unhealthy food shall not be advertised on radio or television, between 6.00 to 21.00.

b) No commercial marketing activities to children shall be permitted between 6.00 to 21.00, especially using new media (such as, but not limited to websites, social networking sites and text messaging).

c) Principles described in this Guideline shall also apply to commercial communications for those products directed at children outside of children's programmes.

(4) Food business operators shall not abuse positive family values such as portraying any happy, caring family scenario, in order to advertise unhealthy foods.

(5) Settings where children gather shall be free from all forms of commercial marketing of unhealthy foods. Such settings include, but are not limited, to nurseries, school premises, pre-school centres, playgrounds, family and child clinics and paediatric services or during any sporting and cultural activities that are held on these premises. Food operators shall not engage in any direct commercial activity in both pre-school, primary and secondary schools and shall not sell any unhealthy food. Suitable beverages such as pure water, 100% fruit juices and milk may be made available in appropriate container sizes* that allow for portion control. All food business operators shall respect the commercial-free character of schools by providing, where directly responsible for final distribution of products, unbranded vending machines, preferably including educational images and messages promoting balanced diets and healthy and active lifestyles. Third-party distributors shall be made aware of these commitments in such cases where a food business operator is not directly responsible for the final distribution of their products to schools. School districts and bottlers are expected to provide only packaged water as regulated under the Act (Act 54 of 1972), 100 percent fruit juice and milk to school students.

*Suitable serving sizes for non-alcoholic beverages are:

Pure packaged water (still or carbonated) as defined under the Regulations Relating to all Packaged Water, R 718/2006 as	250 to 1000ml

amended by R455/2010 and promulgated under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No 54 of 1972) as amended.	
100% Fruit juices	200 to 250 ml
Unflavoured, unsweetened milk	250 ml

(6) Any food and beverage advertisements, at all times-

(a) shall not encourage or condone excess consumption and portion sizes should be appropriate to the setting portrayed. Any promotional activities (e.g. redemptions, under-the-cap offerings, text message/SMS contests, et cetera) offering prizes or rewards which will require consumers to eat and drink excessive quantities of products in order to participate, shall be avoided.

(b) shall, where presented in the context of a meal, show a reasonable variety of foods to reflect generally-accepted good dietary practice.

(c) shall not undermine the promotion of healthy, balanced diets.

(d) shall not encourage or promote an inactive lifestyle; encourage or promote unhealthy eating or drinking habits (immoderate consumption, excessive or compulsive eating) and shall not omit undesirable aspects of a food's nutritional profile, contain any misleading or incorrect information about the nutritional value of the product.

(e) Food and beverage advertisements shall not undermine the promotion of a healthy, active lifestyle in any way.

(7) Food products not intended to be substitutes for meals shall not be represented as such. Commercial advertising to children representing mealtimes shall clearly and adequately depict the role of the product within the framework of a balanced diet.

(8) The same principles which are applicable to general advertising also apply to advertising directed to children. Advertising is a valuable source of information to them as well, but advertisers must take into account the abilities and judgment that children at various stages of development can be expected to bring to the understanding of communications.

(9) Advertisements shall not mislead about potential benefits from the consumption of a food product.

(10) Food product advertisements shall not undermine the role of parents and other appropriate adult role models in providing valuable dietary guidance.

(11) Advertisements shall not include any direct appeal to children to persuade their parents or other adults to buy advertised products for them. Avoid any direct appeal to children to persuade parents or other adults to buy food products for them or to do anything else that goes expressly against the wishes or authority of a parent, guardian or educator.

(12) Commercial marketing in any form directed toward children shall not create a sense of urgency.

(13) Care should be taken in communication with younger as well as older children, not to exploit a child's imagination in a way that can encourage poor dietary habits.

(14) Broadcast or print media personalities (live or animated) shall not be used to sell food products, premiums or services in a way that obscures the distinction between program or editorial content and commercial promotion. For example, commercials or advertisements featuring characters from programs or publications primarily directed to children shall not be adjacent to programs or articles in which the same personality or character appears.

(15) Commercial marketers offering food and beverages to children via electronic media shall respect provisions on marketing and advertising to children in the ICC International Code of Advertising. Practice and other codes mentioned above and in particular observe the following:

- not exploit the inexperience or credulity of children or strain their sense of loyalty towards their parents and guardians;
- refrain from using content which might result in harm to children;
- collect only the information reasonably required to allow the child to engage in the activity;
- encourage parents and/or guardians to participate in and/or supervise their children’s interactive activities;
- encourage children to obtain their parent’s and/or guardian’s permission before they provide information via electronic media, and make reasonable efforts to ensure that parental consent is given;
- refrain from using the data collected from children to advertise and promote products or services other than those designed for/appropriate for children;
- not collect from children data related to the financial situation or to the privacy of other members of the family;
- only disclose identifiable personal information of children to third parties after obtaining parental support for operational purposes of the web site and who do not use or disclose a child’s personal information for any other purpose.

Advertisers/marketers are expected to make available information to parents and/or guardians about ways to protect their children’s privacy when using electronic media.

REFERENCES

[1] Marketing of foods and non-alcoholic beverages to children. Set of recommendations. Geneva, World Health Organisation, 2010. (http://www,who.iny/dietphysicalactivity/marketing-food-to-children/en/)

[2] Global status report on non-communicable diseases, World Health Organisation, 2010 (http://www.who.int/chp/ncd_global_status_report/en/)

[3] Obesity and Metabolic Syndrome associated with Impaired Brain Function in Adoloscents, ScienceDaily (Sep.3,2012), (http://www.sciencedaily.com/releases/2012/09/120903123610.htm?)

[4] The EU Pledge. Brussels, Commission of the European Communities, 2012 (http://www.eu-pledge.eu)

[5] Manual for Monitoring Food Marketing to Children, Consumers International, September 2011

[6] Marketing of Food and Non-alcoholic Beverages to Children, Report of a WHO Forum and Technical Meeting, Oslo, 2-5 May 2006. Geneva, World Health Organisation, 2006. (http://www.who.int/diephysical activity/publications/marketing_forum_2--6/en/index.html)

[7] Recommendations for an International Code on Marketing of Foods and Non-alcoholic beverages to Children , IASO, CI International Obesity Task Force, March 2008

[8] WHO, July 2006, The extent, nature and effects of food promotion to children: A review of the evidence; Professor Gerard Hastings et al.

[9] Brownell Kelly D, Thinking Forward: The Quicksand of Appeasing the Food Industry. PLoS Med 9(7): e1001254. doi:10.1371/journal.pmed.1001254. Published: July 3, 2012
Available at http://www.ploscollections.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001254

[10] Lana A Hebden, Lesley King, Anne Grunseit, Bridget Kelly and Kathy Chapman, Advertising of fast food to children on Australian television: the impact of industry self-regulation, Medical Journal Australia 2011; 195: 20–24, eMJA Rapid Online Publication 27 June 2011

[11] Obesity Reviews, Volume 15, Issue 4, pages 281-293, April 2014

GUIDELINE 15

GUIDANCE DOCUMENT FOR WEIGHT MANAGEMENT CLAIMS

Background

1. Obesity is a multi-factorial problem and dietary strategies to assist weight loss are complex. Dietary strategies do not act in isolation, and individual variation and response, physical activity, diet quantity and quality, behavioural factors and stress all determine weight loss success. Food products promoted to assist in weight reduction / loss need to be evaluated and considered in light of the afore-mentioned factors.

2. Nutrition is a rapidly changing science, with new evidence emerging continuously. Nutrition science recognises the role of genetic and epigenetic phenomena, early life events, and lifestyle choices, which act in concert to modulate the impact of the food we eat on our health status and health outcomes, including weight management.

3. Current evidence suggests that reduced energy diets could result in clinically meaningful weight loss regardless of which macronutrients they emphasize. Therefore macronutrient conditions were *excluded* from the suggested weight management claims on conventional foods. Due to the lack in significant scientific agreement to support other ingredients in weight management, total energy intake was the focus of the proposed weight management claims for foods.

4. To lose weight, energy expenditure, through physical activity, body metabolism and activities of daily living, must exceed energy intake; therefore creating an energy gap. From a dietary perspective, this can be achieved by an overall reduction in food intake, and/or by manipulating the nutrient or macronutrient content of the diet. Weight management can therefore be categorised in two main categories based on basic principles of weight loss:

(a) Energy Intake and/ or Uptake - Reduced Energy Intake and/ or Uptake through for example, manipulation of macronutrient content of a food.

(b) Energy Expenditure – Increased Energy Expenditure re therefore based on the basic principles of energy expenditure vs. energy intake and the contribution of a food product to either of these.

Energy uptake describes the absorption by a tissue of an energy providing substance, such as a macronutrient, and its utilization; while energy intake describes the ingestion of energy providing substances, or quantities thereof.

Substances or ingredients in a food; or a food that have been suggested to play a role in achieving beneficial physiological effects to support these mechanisms have been described in the literature, but very few have been supported by significant scientific agreement to substantiate health claims.

Table 1 : Examples of categories, mechanisms and substances, ingredients in a food; or foods associated with a reduction in energy intake or uptake; or increase in energy expenditure

Category	Mechanism	Food / substance suggested to achieve stated favourable outcome	Sufficient evidence to substantiate claim
Energy Intake and/ or Uptake	Lowering energy consumption	*Conventional food that are:* *Virtually free from / Free from energy* *Low in energy* *Reduced in energy*	*?*
Energy intake	Appetite control or satiety	Protein, Hoodia	No
Energy expenditure	Enhancing thermogenesis	Capsaicin, Citrus aurantium	No

5. Examples of claims evaluated by international bodies (see references): found to carry insufficient / conflicting scientific evidence to substantiate a weight management claims:

Nutrient / Substance / Food or Food category	Claim category	Claimed cause and effect of Nutrient / Substance / Food or Food category and Weight Loss or Maintenance	Sufficient evidence to substantiate claim	Reference / Journal number / Supporting information
Protein	Satiety /weight management	Dietary intake of protein and a sustained increase in satiety leading to a reduction in energy intake	NO	EFSA Journal 2010;8(10):1811
Protein	Satiety/weight management	Dietary intake of protein and contribution to the maintenance or achievement of a normal body weight	NO	EFSA Journal 2010;8(10):1811
Gamma-linolenic acid	Reduces regaining weight	Dietary intake of gamma-linolenic acid and the contribution to weight maintenance after weight loss	NO	EFSA Journal 2010; 8(2):1477 [21 pp.]. doi:10.2903/j.efsa.2010.1477
Phaseolamine	Lower calorie intake	Dietary intake of phaseolamine inhibit α-	NO	EFSA Journal 2011;9(6):2253 [13

Nutrient / Substance / Food or Food category	Claim category	Claimed cause and effect of Nutrient / Substance / Food or Food category and Weight Loss or Maintenance	Sufficient evidence to substantiate claim	Reference / Journal number / Supporting information
		amulase activity, hindering the conversion of complex carbohydrate to simple sugars, which are stored as reservoir fats if not immediately utilised; and results in lower calorie intake and the contribution to weight loss		pp.]. doi:10.2903/j.efsa.2011.2253
Coffee, *Coffea Arabica* L., chlorogenic acids from coffee, and antioxidants in coffee	Maintenance or achievement of a normal body weight	Weight loss and weight control in overweight adults/reduces glucose absorption from gut; promotes weight-loss and weight-control in overweight healthy adults by reducing glucose uptake in the gastrointestinal system/absorbance from the gut (by regulating glucose homeostasis in the liver, thus promoting the use as fat as a source of energy in the body)		

6. Sustained weight loss claims shall only be considered after a scientific assessment of the highest possible standards has been carried out by a panel of experts for the cost of the applicant.

7. The use of sustained weight loss claims shall only be permitted if the following conditions are met:

(a) the presence, absence or reduced content in a food or category of food or a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence; namely a sustained intentional reduction in total body fat or total body weight.

(b) The food or other substance for which the claim is made:

(i) is contained in the final product in a significant quantity that will produce the nutritional or physiological effects claimed as established by generally accepted scientific evidence and validated for that specific food matrix; or

(ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed, as established by generally accepted scientific evidence;

(c) The substance is a food, food ingredient, or component that has been shown to be safe and lawful at levels necessary to justify a claim;

(d) Where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;

(e) The quantity of the product that can reasonably be expected to be consumed, or quantity in which the product will be consumed to fulfil other weight management criteria, provides a significant quantity of the nutrient or substance; or a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence.

Scientific requirements for weight management claims

8. The following information should be provided by applicants in preparing and submitting their applications for the authorization of weight loss claims:

(a) Proof that:

(i) A relationship exist between the food, nutrient, substance or proposed mechanism and weight loss or weight maintenance;

(ii) Sufficient scientific evidence exist to substantiate such a claim

(iii) The evidence is applicable to the food matrix (food)and is not extrapolated

(iv) Evidence was obtained from an independent third party

(v) The substance, nutrient or food is safe and lawful under levels necessary to justify a claim

(vi) Analytical data is available to show the amount of substance that is present in the representative food / product

(b) Summary of Scientific data as described

(c) Proposed model weight management claim;

(d) Scientific data (as described below) supporting the claim;

(e) Copies of computer literature searches;

(f) Copy of all research articles relied upon for support the proposal

(g) Information concerning adverse effect or consequences pertinent to the proposed target

(h) The following documentation in terms of scientific evidence for the substantiation of sustained weight loss claims shall be included in the dossier*:*

(i) Should be obtained from human intervention studies in overweight or obese subjects treated with lifestyle measures only (diet and exercise); extrapolation of results from studies obtained from obese subjects under treatment with weight loss medications could be considered on a case by case basis;

(ii) The scientific evidence for the substantiation of health claims on the *reduction in body fat* should show a significant reduction in total body fat, or abdominal body fat, using methods with appropriate validity and precision;

(iii) Imaging techniques including dual energy x-ray absorptiometry (DEXA), magnetic resonance imaging (MRI) and computed tomography (CT) are general most appropriate to asses changes in body fat in human intervention studies;

(iv) Skinfold thickness, bioelectrical impedance analysis (BIA) and air displacement plethysmography (ADP) are generally not appropriate to assess small changes in body fat when used alone, particularly in obese subjects and/or when significant changes in body water compartments occur;

(v) Surrogate measures of total body fat (e.g. body weight) could be used for the scientific substantiation of these claims if the reduction in body weight is sufficiently large so that it could not be attributed to a reduction in lean body mass/body water;

(vi) The scientific evidence for the substantiation of health claims on the *reduction of body weight* can be obtained from human intervention studies showing a reduction in body weight which could not be attributed to a reduction in lean body mass/body water;

(vii) The scientific evidence for the substantiation of health claims related to the *maintenance of body weight* after (intentional) weight loss can be obtained from human intervention studies showing an effect on (limiting) body weight regain after significant weight loss;

(viii) Evidence for a sustained effect with continuous consumption of the food / constituent over an acceptable period should be provided. Periods described in existing literature for *weight loss* vary from 12 weeks to 6 months; and 6 months to 2 years for weight maintenance;

(ix) Conditions in which the effect on the body fat / weight is achieved need to be specified; and

(x) Other mechanisms relating to the reduction of body fat / body weight – including changes in appetite rating, energy uptake (absorption and utilisation), energy expenditure (thermogenesis) - have been proposed in the context of claims relating to a reduction in body weight / fat. Evidence for a sustained effect of any of these variables with continuous consumption of the proposed food or substance; using appropriate measures (i.e. behavioural assessments for appetite ratings); to substantiate a positive outcome over an appropriate time period (i.e. weight loss over a 12 week period) is needed to substantiate claims.

9. Meal replacement formulas have been shown to assist in effective weight loss, by substituting one or more meals per day. Internationally, meal replacements are governed by different directives and regulations globally, for instance the European Union has included claims on meal replacements and weight management as part of their list of permitted health claims (subject to specifications laid down for COMMISSION DIRECTIVE 96/8/EC), while the Australian New Zealand Food Standard Code and Canadian Food and Drug regulations classifies formulated meal replacements and formulated supplementary foods under 'Special Purposes Food' or 'Foods for Special Dietary Use'. The latter are often accompanied by guidelines for health professionals when 'prescribing' meal replacement supplements, as well as guidelines for use with hospitals and clinics.

10. Acknowledgement is herewith given to the Nutrition Information Centre of the University of Stellenbosch (NICUS) who have been consulted to assist in formulating this Guideline document.

11. The following regulations, guidelines, provisions and standards were used in compiling this Guideline document:

- Codex Alimentarius: Codex Standard For Formula Foods For Use In Weight Control Diets, Codex Stand 181-1991
- EFSA:
  - Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations; EFSA Journal 2012;10(3):2604
  - Scientific Opinion on the substantiation of health claims related to meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/20061; EFSA Journal 2010; 8(2):1466
  -]Scientific Opinion on the substantiation of health claims related to protein and increase in satiety leading to a reduction in energy intake (ID 414, 616, 730), contribution to the maintenance or achievement of a normal body weight (ID 414,

616, 730), maintenance of normal bone (ID 416) and growth or maintenance of muscle mass (ID 415, 417, 593, 594, 595, 715) pursuant to Article 13(1) of Regulation (EC) No 1924/20061; EFSA Journal 2010;8(10):1811

REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 on nutrition and health claims made on foods

- COMMISSION REGULATION (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

- FSNAZ

  Australia New Zealand Food Standards Code - Standard 2.9.3 - Formulated Meal Replacements and Formulated Supplementary Foods

- CANADA

  Food and Drug regulations, CRC 870, of the department of Justice Canada, , current to 4 September 2012

- FDA
  - 'Guidance for Industry - Evidence Based Review System for the Scientific Evaluation of Health Claims' http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm
  - Code of Federal Regulations Title 21 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.14
  - 'Guidance for Industry: A Food Labelling Guide; 12. Appendix D Qualified Health Claims' http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064923.htm
  - 'Calories Count: Report of the Working Group on Obesity' http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081770.htm

GUIDELINE 16

GUIDANCE DOCUMENT IN THE CASE WHERE A DOSSIER IS REQUIRED BY THE REGULATIONS TO BE FOR PREPARED FOR PREMARKET APPROVAL OF A FOOD HEALTH CLAIM

The following information which has been sourced and adapted from the Bureau of Nutritional Sciences, Food Directorate, Health Products and Food Branch, Health Canada is herewith acknowledged.

This guidance document should be used in the preparation of a health claim dossier relating to a weight loss claim together with the guidance information of Guideline 15. Independent evaluation by a panel of experts shall be for the cost of the applicant.

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1.0 BACKGROUND INFORMATION

1.1 Purpose of the Guidance Document

The purpose of this document is to ensure that health claims for foods are substantiated in a systematic, comprehensive, equitable and transparent manner. When petitioners are preparing submissions for the use of new health claims on food products, they are required to follow the format set out in this guidance document. A common submission format among petitioners will ensure a comprehensive and well-organized submission and an improved efficiency in the review process.

A health claim is a statement or representation that states, suggests or implies that a relation exists between a food or component of that food and health (Codex Alimentarius Commission, 1997). Authorization or acceptability of a health claim requires evaluation of evidence on:

- Causality – consumption of the food affects a health outcome;
- Generalisability – the claimed effect is physiologically meaningful and is applicable to the general population or a subgroup of the population (target market); and
- Quality assurance – the food is produced according to quality standards and consistently meets predefined specifications.

The safety of a food must also be assured for health claim authorization. As such, the subject of a health claim application must be for a food approved for safe use; or, if a novel food is the subject of the health claim, a novel food application must be completed and submitted to Directorate Food Control / SAPHRA concurrent with this application. This guidance document is focused on demonstrating causality and generalisability of a health claim. Additionally, key aspects related to quality assurance are addressed.

1.2 Relevant Regulations

The Regulations Relating to the Labelling and Advertising of Foods (R 429 of 29 May 2014) published under Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No.54 of 1972) governs the use of health claims on food products in South Africa. The Act includes definitions and provisions that are relevant to health claims, as well as food labelling and advertising and prohibition of deceptive advertising.

1.3 When to Use this Guidance Document

This guidance document should be used in the preparation of a health claim dossier relating to a weight loss claim together with the guidance of Guideline 14.

The claim must be truthful and not misleading and manufacturers (included imported products) are expected to have evidence substantiating the claim. They are thus advised to follow this guidance document to ensure the health claim is properly substantiated and/or to prepare a voluntary submission to Directorate Food Control.

1.4 Guiding Principles

Substantiation of a food health claim and the assessment of whether it is valid are guided by the following principles:

- **Systematic Approach**: A methodical, consistent approach is applied to substantiate a health claim.

- **Transparency:** Search strategies, literature selection and evaluation, as guided by the document, are fully disclosed, to increase the credibility of the submission and to permit reproducibility.

- **Comprehensiveness:** All original research in humans, pertaining to the health claim, is captured, including evidence in favour and not in favour of the health claim.

- **Human Evidence:** The focus is on original research in humans that measures the food and health effect of interest.

- **High level of Certainty**: The health claim is supported by a high level of certainty. This means that the majority of high quality human studies support a statistically significant favourable effect. Consideration will be given to statistical significance achieved at $p \leq 0.05$.

- **Demonstration of Causality:** Demonstration of causality will consider the quality and quantity of original research in humans that support a beneficial effect of the food (*i.e.*, direction of effect); the strength of the association between the food and health effect (*i.e.*, statistical significance of the favourable effect) and the relationship between the amount of the food and the health effect (*i.e.*, dose- response).

- **Biological Relevance of the Claimed Effect:** The claimed effect of the food is biologically/physiologically relevant and expected to benefit the health of the target population (target market). To ensure biological relevance of the claimed effect, surrogate markers of the claimed effect must have both methodological validity and biological validity. Markers must additionally be part of the causal pathway between the food and the health outcome.

- **Feasibility of Consumption of Effective Dose:** The amount of food to be consumed to achieve a beneficial effect can be incorporated into a healthy, balanced diet by the target population.

- **Health Claim Wording:** The health claim wording communicates the health outcome that is substantiated in the submission, i.e., it is specific to the substantiated health outcome. If, for example, the submission supports a reduced risk of infectious diarrhoea, this does not mean that the product "supports healthy immune function". The correct claim wording would more directly make a statement to the effect that the product "reduces risk of infectious diarrhoea".

- **Substantiation of one food-health relationship in a submission:** One food/health relationship is to be addressed per submission. Multiple formulations/matrices of a food can be proposed by the petitioner, provided the scientific evidence is valid for all proposed formulations/matrices, but only a single health effect can be the object of a submission. However, more than one biomarker of a single health effect may be used – *e.g.*, using total cholesterol and LDL cholesterol as biomarkers of one health effect – heart disease.

1 5 Study Designs and Evidence of Interest

1.5.1 Human Studies

DoH's evaluation of a health claim will be based on human studies – intervention and/or prospective observational studies. As such, the literature search strategy should be established with a focus on retrieving human studies. The scientific uncertainties in extrapolating non-human data to humans limit the usefulness of non- human studies, such as animal and *in vitro* studies. A submission guided by this document should thus be based on the retrieval and evaluation of human studies. If desired, non-human studies may be used to support the discussion on biological plausibility. This is, however, optional.

1.5.2 Validity of Study Designs

The research design of human studies is a critical factor in interpreting the evidence for a health claim. Certain research designs can present biases that skew the interpretation of the evidence in an erroneous fashion and/or are not useful in inferring causality. Characteristics of research designs that limit the interpretation of the validity of the evidence are, for intervention studies, the absence of randomization and/or a control group. For observational studies, the use of retrospective studies (retrospective cohort, case-control), cross-sectional, and descriptive studies (ecologic, time series, demographic) does not allow determination of a causal relationship.

This document provides guidance on how human studies with different research designs should be dealt with. For intervention studies, non-randomized studies may be included during literature filtering; however, their subsequent quality rating will affect their contribution to supporting consistency. For observational studies, only those with a prospective design (*i.e.*, prospective cohort and nested case-control studies) should be included; all other observational studies should be excluded.

Finally, if the subject of a health claim is a food constituent (*i.e.*, not a food or a food category), the submission must at least include intervention studies; relevant observational studies would also be included, if available. Observational studies may be of greatest relevance for substantiation of health effects related to foods or food categories, but without intervention studies, observational studies alone generally do not allow for a causal inference to be made on the relationship between a food constituent and a health effect.

1.6 Definitions

Definitions for commonly used terms in the guidance document are provided below.

- The term “food” or “food”, as defined in the Foods, cosmetics and disinfectants Act 54 of 1972, hereafter means any article or substance [except a drug as defined in the Drugs Control Act, 1965 (Act 101 of 1965)] ordinarily eaten or drunk by man or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part of ingredient of any such article or substance.

- “Food exposure” and “food intake” are used interchangeably in this document. In both experimental and epidemiological studies, the assessment of food intake may be supported by a biomarker of exposure (*e.g.*, intake of lutein from foods may be supported by measurement of blood lutein levels).

- A “bioactive substance” is a substance that is demonstrated or purported to have a

favourable effect on health. In the context of food, bioactive substances include nutrients (*e.g.*, vitamins and mineral nutrients) and non-nutrients (*e.g.*, lycopene, live microbes) that may be inherent in or added to food.

- The term "health effect" refers to a body function, health condition or disease risk, or mental or physical performance. With regard to disease risk, it refers to an effect on a true disease endpoint, such as heart disease mortality, or to an effect on a recognized surrogate marker of disease or a disease risk factor, such as blood LDL cholesterol. With regard to normal physiological function, or mental or physical performance, it refers to an effect associated with the maintenance or enhancement of health (*e.g.*, promotes regularity, builds and repairs muscles), and not to a therapeutic effect (*e.g.*, relieves constipation, restores mental alertness).

- The terms "health effect" and "health outcome" are used interchangeably in the document.

- The term "submission" means a stand-alone dossier containing all the required information for substantiation of a food/health relationship (*i.e.*, a health claim).

- The term "food/health relationship" refers to a biologically plausible association between a food and a health outcome.

1.7 Organisation of Submission

The submission should meet the requirements below:

- The submission should include all components outlined in the checklist (Table 16).
- Pagination must be sequential for the entire submission.
- Paper copies must be bound or organised in a binder.
- The applicant's identification (*e.g.*, company name) should be included on all pages of the submission.
- Submissions must be in English. Relevant submission material in other languages must be translated into English.
- Applicants are responsible for clearly indicating parts of the application that contain proprietary or confidential data (*e.g.*, results from an unpublished clinical trial, details on manufacturing, *etc.*).
- Applicants are responsible for the accuracy of all cited references, published or unpublished. An established style for citing references must be used.

- The application must be signed by the person responsible for the submission. The submission must be signed by the petitioner or by his/her attorney or agent, or, if a corporation, by an authorized official.
- Five hard copies of the submission must be forwarded by mail to the address below (unless otherwise stipulated by DFC). (Electronic copies will be allowed)

All submissions will be screened for completeness. The petitioner will be informed of deficiencies regarding completeness. In cases where deficiencies are major, the file will be rejected and a new application submitted.

1.8 Submission to Directorate Food Control

Five hard copies of the submission must be forwarded by mail to the address below (unless otherwise stipulated by DFC).

Directorate Food Control
Department of Health
Private Bag X828
Pretoria

An electronic submission may be forwarded to the following e-mail address in addition to, but not in place of hard copies: booyza@health.gov.za

1.9 Review Process Following a Submission

Within 30 days of receipt of the submission, Directorate Food Control will notify the petitioner in writing that the submission has been received.

1.10 Re-Evaluation of a Health Claim

Directorate Food Control may re-evaluate an approved health claim in response to a petitioner or on its own initiative due to new scientific evidence that brings into question the certainty of the claim or the conditions for its use.

2 SUBMISSION REQUIREMENTS

2.1 Contact Information

Objective: To identify the organisation submitting the health claim and to provide the coordinates of a person that can be contacted for scientific and/or regulatory issues/concerns/questions.

Procedure:

Complete Table 1 – Applicant Information.

Table 1. Applicant information

Applicant information	Applicant (Organisation/Company)	Contact person
Name		
Affiliation		
Position		
Address		
Telephone Number		
Fax Number		
E-mail		
Website		

If information requested is not applicable, please indicate NA.

2.2 Details Pertaining to Proposed Health Claim

Objective: To communicate important aspects related to the health claim up front.

Procedure:

Complete Table 2.

Table 2 – Details pertaining to the proposed health claim.

Item	Details (State N/A where necessary)			
Food/bioactive substance of interest				
Health outcome of interest (include surrogate markers if used):	Intervention Studies		Prospective Observational Studies	
	Yes	No	Yes	No
Proposed health claim wording:				
Minimum effective intake of the food/bioactive substance to obtain the claimed effect				
Proposed daily intake of the food				
Proposed qualifying criteria for foods to carry a health claim (*e.g.*, minimum or maximum allowable levels of nutrients)				
Target population for the proposed claim				

Rationale for the target population	
Potential adverse effects related to food intake (from human studies)	
Proposed restrictions on use of food (*e.g.*, a subgroup of population, mode of consumption of food)	
Proposed risk management strategies to address adverse effects and/or restrictions on use of food (*e.g.*, indicate wording of recommended warning statements)	

Abbreviations: N/A, not applicable.

2.3 Regulatory Status of the Health Claim in Other Jurisdictions

Objective: To understand the regulatory status of the health claim in other jurisdictions in addition to the claim wording and conditions for use of approved claims.

Procedure:

Complete Table 3 – Regulatory status of the health claim in other jurisdictions.

Country	**Regulatory Body**	**Date of Submission (day/month/year)**	**Status of Health Claim Application** [1]	**Details for Approved Claims**		
				Wording of approved claim	**Conditions for use of the claim**	**Date of claim authorization**

[1] State “under review”, “withdrawn”, or “rejected”

3.0 CHARACTERIZATION OF THE FOOD

Objective: To understand the composition and manufacturing of the food/bioactive substance and to ensure it meets quality standards and pre-defined specifications.

Background

The nature of the food that is the subject of the proposed health claim will guide the type and extent of information required to be provided in this section. More information will be required if the subject of the health claim is a food containing a bioactive substance (added to or inherent in the food) *versus* a

food category or a whole food.

Procedure:

Fulfil the information requirements outlined in Table 4 – Information requirements for characterization of the food. Note that the requirements differ depending on the subject of the claim.

Table 4:

Food containing an added bioactive substance[2]	<u>End Product (Food with added bioactive substance)</u> • Describe the common or usual name of the food. • State the amount of kiloJoules and levels of macronutrients and micronutrients, and added bioactive substance per 100 g, per single serving and per minimum effective intake (the minimum quantity of food shown to be effective in the human studies).[1] • State the ingredients, and their amounts, that comprise the food (including the added bioactive substance). • Summarize the specifications for the food (*e.g.*, chemical, physical, microbiological characteristics) and include a certification of this data in an Appendix. • Summarize the manufacturing process of the food and indicate whether it follows a quality system (*e.g.*, Good manufacturing practices). • Describe the tests, and their results, used to ensure the food meets pre-defined specifications (*e.g.*, batch to batch variability tests). • Describe the studies, and their results, used to ensure stability of the added bioactive substance during the shelf-life of the food and under the recommended storage conditions. <u>Bioactive substance (added to the food)</u> • Summarize the specifications (*e.g.*, chemical, physical, microbiological characteristics) for the bioactive substance and include a certification of this data in an Appendix. • Summarize the manufacturing process of the bioactive substance and indicate whether it follows a quality system (*e.g.*, Good manufacturing practices). • Describe the tests, and their results, used to ensure the bioactive substance meets pre- defined specifications (*e.g.*, batch to batch variability tests). • Describe the studies, and their results, used to ensure stability of the bioactive substance under the recommended storage conditions of the bioactive substance.

[1] The South African Nutrient File is the preferred source for this information. Alternatively, the USDA National Nutrient Database may be used.

[2] Information is required for the end product (with the added bioactive substance) and for the added bioactive substance, individually. Requirements for each are separately outlined.

4.0 CHARACTERIZATION OF THE HEALTH EFFECT

Objective: The purpose of this section is to provide information on the health effect, the validity of biomarkers used, and the relevance of the health effect to the South African population (or Target Market).

Procedure:

4.1 Describe the health effect and all relevant biomarkers of the health effect with a rationale for the selection of biomarkers to be used. Discuss the methodological and biological validity of the health effect/its biomarkers.

4.2 Discuss data on the prevalence of the health effect/its biomarkers in the South African population/ Target Market and provide a rationale on the cause for concern about the health effects/its biomarkers.

5.0 EVALUATION OF CLAIM VALIDITY

The purpose of this section is to guide the retrieval and evaluation of the totality of relevant evidence on the food/health relationship, to allow for an assessment of causality (*i.e.*, whether intake of the food causes the health effect of interest) and generalizability (*i.e.*, applicability of the food/health relationship to the target group), as well as the biological relevance of the health effect and the feasibility of consuming an effective intake of the food. See Figure 1 for an outline of the steps to be completed. The remainder of this document describes the requirements for each step in detail.

Figure 1. Required Steps to Address Claim Validity
Step 1. Describe the search strategy for literature retrieval
Step 2. Implement the search strategy for literature retrieval
Step 3. Develop inclusion and exclusion criteria to filter the literature retrieved
Step 4. Filter the literature
Step 5. Generate reference lists of included and excluded studies
Step 6. Tabulate studies
Step 7. Evaluate study quality
Step 8. Tabulate study findings per health outcome
Step 9. Assess causality
Step 9a. Rate consistency
Step 9b. Rate the strength of the association
Step 9c. Discuss the relationship between the food exposure and the health effect
Step 10. Discuss generalizability of the data to the target population
Step 11. Discuss the physiological meaningfulness of the effect of the food exposure
Step 12. Discuss the feasibility of consuming an effective amount of the food
Step 13. Make conclusions

5.1 Details of the Steps

5.1.1 Step 1. Describe the Search Strategy for Literature Retrieval

Objective: To develop a relevant, comprehensive (*i.e.*, minimizing exclusion of relevant evidence), and reproducible strategy that will be used to retrieve the totality of evidence from human studies on the food/health relationship.

Procedure:

It is highly recommended to seek the assistance of a librarian to develop a relevant and comprehensive search strategy.

Brainstorm relevant keywords related to the food and health effect that will be used to retrieve the literature. Consider alternate terminologies/synonyms (*e.g.*, scientific/technical terms and/or Latin terms) and alternate spellings of common terms. Electronic databases may be a helpful reference to learn of alternate terminologies of common terms.

- Literature retrieval will <u>not</u> be limited at this point to the target population in order to maintain a broad evidence base on the food/health relationship as much as possible and to address applicability of the relationship to a population group. Therefore, keywords related to the target population do not require brainstorming.
- Decide on relevant keywords to be used to retrieve the literature and how they will be

combined to search the literature within electronic databases.

- Decide on relevant electronic databases that will be used to search the literature. Examples include: MEDLINE, Cochrane Library, EMBASE, CINAHL, Food Science and Technology Abstracts, Current Contents, Scopus, Cab health (Global Health), Web of Science, Scholars Portal Search, PsycInfo, AGRICOLA, Science Citation Index. The use of at least MEDLINE and two additional electronic databases is recommended.
- Decide on whether you will consider non-electronic methods to retrieve relevant literature – *e.g.*, unpublished literature; hand-searching (systematic reviews, meta-analyses or other relevant articles).
- Decide on your search limitations, such as the date range; languages; whether you will limit the search to publications in humans; etc.
- Complete Table 5 – Identification of databases and search parameters used for literature retrieval.
- Complete Table 6 – Keywords and their combinations used to retrieve literature on the food/health relationship from electronic databases.

Table 5. Identification of databases and search parameters used for literature retrieval	
A. Electronic Databases • List electronic databases used and identify fields searched within each database	
Database	**Fields searched in database (*e.g.*, title, abstract, subject headings, descriptors)**
B. Non-Electronic Methods/Sources • State whether the below were conducted/considered	
Hand Searching	Yes No
Unpublished Studies	Yes No
C. Humans • State whether a search parameter was used to limit retrieval to human studies	
Yes No	If yes, search parameter used:
D. Publication Years State the publication years considered for your electronic/non-electronic searches and justify the start date	

Table 5. Identification of databases and search parameters used for literature retrieval
Start date (*i.e.*, year):
End date (*i.e.*, year):
Justification for start date (*i.e.*, year), and if necessary, for end date if different from the current year:
E. Languages • State the languages considered for your electronic/non-electronic searches.
Languages considered for search:

Table 6. Keywords and their combinations used to retrieve literature on the food/health relationship from electronic databases[1]	
A. Food	
Indicate keywords used (*e.g.*, Oat, oats, beta-glucan, beta glucan, Avena sativa):	
B. Health effect(s)	
1. Final health effect	**2. Biomarker/Surrogate marker of health effect**
Indicate keywords used (*e.g.*, heart disease, coronary heart disease, cardiovascular death):	**Indicate keywords used** (*e.g.*, myocardial infarction, ischemia, atherosclerosis, total cholesterol, LDL cholesterol):
C. Combinations of keywords used	
Indicate combinations of keywords used – *e.g.*, A and B1; A and B2; [(A and B1) or (A and B2)], *etc.*:	
D. Justification for exclusion of potentially relevant terms	
Please specify and justify the disuse of relevant terms as keywords – *e.g.*, Opting to only use keywords related to the surrogate marker of a health effect, rather than using keywords related to both the health effect and its surrogate marker:	

[1] State N/A if not applicable.

5.1.2 Step 2. Implement the Search Strategy for Literature Retrieval

Objective: To implement the search strategy consistently across all electronic databases, to maintain a record of all literature retrieved prior to literature filtering and to organize the retrieval of the literature in a systematic way.

Procedure:

- Implement the search strategy outlined in Step 1 in each electronic database.
- Include a copy of the 'search history' in an Appendix (the record of the keywords used, their combinations, and the limitations imposed on the search) by printing it directly from

the electronic database.

- Include a copy of the entire literature search in an Appendix by printing it directly from the electronic database.
- Complete Table 7 – Number of references retrieved from electronic and non-electronic sources.

Table 7. Number of references retrieved from electronic and non-electronic sources	
Source	**# of References**
A. Retrieved from Electronic Databases	
B. Retrieved from Non-Electronic Databases (*e.g.*, unpublished literature; hand-searched)	
C. Duplicates	
TOTAL (A+B-C):	

5.1.3 Step 3. Develop Inclusion and Exclusion Criteria to Filter the Literature Retrieved

Objective: To develop inclusion/exclusion criteria that will be applied to all references retrieved from electronic and non-electronic databases so that not relevant/non-useful references can be excluded.

Procedure:

- Specify your inclusion and exclusion criteria in Table 8a using Table 8b as a guide. You can simply re-state what is written in Table 8b in Table 8a if similar criteria were used (where examples are included in Table 8b, you can substitute the example with information relevant to the health claim in Table 8a).

Table 8a. Inclusion and exclusion criteria used for literature filtering		
Factor	**Inclusion Criteria**	**Exclusion Criteria**
Source		
Report type		
Language		
Publication Year		
Duplicate		
Treatment (Food)		
Control (if used)		
Route of exposure		
Health effect		
Population health status/study setting		
Ages		
Statistical significance		

Table 8b: Guidance on appropriate inclusion and exclusion criteria for literature filtering		
Factor	**Inclusion Criteria**	**Exclusion Criteria**
Source	Published or in press in a peer-reviewed journal, or unpublished	Published in a non peer-reviewed source (magazine, website *etc*,)

Report type	• Full length article/study report of original research in humans:
	  • Human intervention studies
	  • Prospective observational studies (cohort and nested case-control studies)
	• Systematic reviews, or meta/pooled analysis of original research in humans
	• Authoritative statement (position papers by a credible scientific body, such as the Institute of Medicine, the World Health Organization, *etc.*)
		• Animal and *in vitro* studies
		• Published abstract, short communication, opinion letter, consumer letter, testimonials
		• Abbreviated unpublished study report
		• Retrospective studies (retrospective cohort, case-control, cross-sectional, ecological, time-series, or demographic studies)

Language	e.g., English	e.g., all but English
Publication year	*e.g.*, Start date of database (*e.g.*, 1967) to date of search (*e.g.*, January 31, 2009)	*e.g.*, N/A
Duplicate	• N/A	• Publication is a duplicate

Table 8b. Guidance on appropriate inclusion and exclusion criteria for literature filtering		
Factor	**Inclusion Criteria**	**Exclusion Criteria**
Treatment (Food)[1]	• Food of interest quantified: dose of food known (intervention studies); amount of food consumed calculated (prospective observational studies). • For intervention studies, food of interest administered independently of other nutritional and/or pharmacological interventions • Biomarker of food biologically/methodologically relevant	• Food of interest not quantified: dose of food not known (intervention studies); amount of food consumed not calculated (observational studies). • For intervention studies, food of interest not administered independently of other nutritional and/or pharmacological interventions • Biomarker of food not biologically/ methodologically relevant
Control	• Control group included and use of a control/placebo appropriate to design	• No control or comparison group or inappropriate control used
Route of exposure	• Oral	• Non-oral (*e.g.*, intravenous)
Health effect[1]	• Health effect of interest measured • Biomarker(s) of health effect biologically and methodologically relevant	• Health effect of interest not measured • Biomarker(s) of health effect not biologically/methodologically relevant
Population health status/study setting	• Representative of target population – *e.g.*, free-living, generally healthy adults	• Not representative of target population – *e.g.*, hospitalized or free- living sick or diseased individuals
Ages	• Representative of target population – *e.g.*, Adults ≥18 years	• Not representative of target population – *e.g.*, Individuals <18 years
Statistical significance	• Reported	• Not reported

Abbreviations: N/A, not applicable

[1] You may find it helpful to articulate terminologies (in a footer to the table) that could be used in publication titles and that could indicate a relevant publication – *e.g.*, a publication title may reference "cholesterol-lowering foods" rather than "oats", or "dyslipidemia" rather than "cholesterol-lowering".

5.1.4 Step 4. Filter the Literature

Objective: To exclude references that based on their title, abstract, or full-text, meet the exclusion criteria/do not meet the inclusion criteria specified in Table 8a.

Procedure:

Title-Filtering

5.1.4.1 Apply the inclusion/exclusion criteria to the titles of all retrieved references.*

5.1.4.2 Count the number of references excluded at the title filtering stage and complete the applicable section of Table 9 – Results of literature filtering.

* **It is highly recommended that two people independently apply the inclusion/exclusion criteria.** Their results can be compared and disagreements can be resolved through discussion. **It is recommended to err on the side of over- inclusion at the title-filtering stage to minimize the likelihood of excluding relevant/useful literature early on.** When deciding on inclusion/exclusion at the title- filtering stage, in addition to using the reference title to determine relevance/usefulness, the name of the journal may be helpful. For example, if the food/health relationship of interest is oats and cholesterol-lowering, a correct inference would be that a reference appearing in the "International Journal of Cancer" is not relevant/useful.

Abstract-filtering:

5.1.4.3 Apply the inclusion/exclusion criteria to the abstracts of references which were not excluded during title filtering.

5.1.4.4 Count the number of references excluded at the abstract-filtering stage and complete the applicable section of Table 9 – Results of literature filtering.

Full-text filtering:

5.1.4.5 Apply the inclusion/exclusion criteria to the full text of references which were not excluded during abstract filtering.

5.1.4.6 Count the number of references excluded at the full text-filtering stage, noting the reason for exclusion of each reference (Table 11).

5.1.4.7 Complete the applicable section of Table 9 – Results of literature filtering.

Table 9. Results of literature filtering

Factor	Number of References
References prior to applying inclusion/exclusion criteria	
References excluded at title-filtering stage	
References excluded at abstract-filtering stage	
References excluded at full-text filtering stage	
TOTAL References Excluded (after applying inclusion/exclusion criteria):	
TOTAL References Included (after applying inclusion/exclusion criteria):	

5.1.5 Step 5. Generate Reference Lists of Included and Excluded Studies

Objective: To indicate the references that met the inclusion criteria and those that met the exclusion criteria at the full-text filtering stage.

Procedure:

5.1.5.1 Produce a reference list of all studies that met the inclusion criteria at the full-text filtering stage and include it in Table 10 – List of references that met the inclusion criteria at the full-text filtering stage.

5.1.5.2 Produce a reference list of all studies that were excluded on the basis of the exclusion criteria at the full-text filtering stage and include it in Table 11 – References excluded at the full-text filtering stage and reason(s) for exclusion. Note the reason for exclusion for each reference. Count the total number of excluded studies per reason for exclusion and include the tally in Table 11.

5.1.5.3 Ensure you have the full-text copy of all publications that have met the inclusion criteria at the full-text filtering stage. Full-text copies of all included publications should be included with your submission in an Appendix. If studies in languages other than English were included, then translations of the studies in English must be provided.

Note: Only original research will be evaluated in the remaining steps. Systematic reviews and meta-analyses lack sufficient detail on individual studies to be used in these steps. Systematic reviews, meta-analyses and authoritative statements may, however, be used in the last step of the systematic approach to support concluding statements.

Table 10. List of references that met the inclusion criteria at the full-text filtering stage

Table 11. List of references excluded at the full-text filtering stage and reason(s) for exclusion	
Reference (Full citation)	**Reason(s) for Exclusion[1]**
Total number of excluded studies per reason	*e.g.*, Source (n=2); Report type (n=5), *etc.*

[1] Reason(s) for exclusion include: Source, report type, language, publication year, duplicate, treatment, control, route of exposure, health effect, population health status/study setting, age, statistical significance, or other (specify).

5.1.6 Step 6. Tabulate Studies

Objective: To provide a synopsis of the relevant information from intervention and observational studies in a standardized and objective manner.

Procedure:

5.1.6.1 Group the included studies according to publication type as follows:

(a) Intervention/Experimental studies

(b) Observational studies

(i) Prospective cohort studies

(ii) Nested case-control studies (case-control within a cohort)

5.1.6.2 Summarize relevant information from each of the intervention and observational studies

that met the inclusion criteria at the full-text filtering stage using Table 12a (for intervention studies) and 12b (for observational studies) as templates.

Table 12a: Summary of intervention studies addressing the food/health relationship (e.g., oats beta glucan fibre and heart disease risk)

Reference and Quality Rating (Author, year)	Aim of study	Design • R (Randomised) • NR (Non-randomised • C (Control group) • SB (Single-blind) • DB (Double-blind) • P (Parallel) • CO (Crossover)	Sample Characteristics • Country • Health Status • Setting(Metabolic unit, free-living subjects) • Age range • Gender (M,F) • No. recruited • No. randomized • No in final sample	Exposure and Duration • Food Matrix • Food dose; method and frequency of consumption • Duration of intervention • Design and/or duration of stabilization period, washouts, follow-ups	Background Diet & Assessment Tool	Results & Statistics • Changes in health effect • Adverse effects	Relevant Author's Conclusions
Biorklund et al., 2005 Quality:	• To investigate whether Cholesterol-lowering effect of a beverage enriched with 10 g beta-glucans is more pronounced compared to a beverage providing half that amount (5 g). • To compare the effect of products enriched with beta-glucan from oats and barley on the serum lipoprotein profile and Postprandial	R, C, SB, P	• Netherlans and Sweden • BMJ: 20 – 30; No history of CAD or heart failure; No diabetes; Hypercholesterolemia: Total Chol 5.5-8.0 mmol/L, LDL Chol 4.1-5.7mmol/L • Free-living • 18-70 yrs • M & F • 100 recruited and randomized • 89 in final sample	• Fruit beverage • Oat Dose high 10 g beta-glucan from oats/day; Two 250 ml beverages, to be consumed with two main meals (breakfast, lunch or dinner) • Oat Dose low 5 g beta-glucan from oats/day; Two 250 ml beverages, to be consumed with two main meals (breakfast, lunch or dinner) • Control Dose 0 g beta-	• Usual diet • 3-day food record or food frequency lists	Mean ± SD of lipid outcomes (mmol/L) at end of run-in and intervention, and change from run-in. Oat -5 (n=19) | Oat -10 (n=15) | Control (n=20) **Total Chol** Run-in: 6.64 ± 1.06 | 6.33 ± 1.05 | 6.54 ± 0.81 Intervention: 6.33 ± 0.92 | 6.21 ± 0.77 | 6.71 ± 1.02 Change: -0.32 ± 0.39[a] | -0.12 ± 0.54 | 0.17 ± 0.49 **LDL Chol** Run-in: 4.32 ± 0.87 | 4.02 ± 0.82 | 4.43 ± 0.76 Intervention: 4.07 ± 0.81 | 3.91 ± 0.67 | 4.48 ± 0.93 Change: -0.24 ± 0.35[b] | -0.11 ± 0.54 | 0.05 ± 0.38 **HDL Chol**	A daily consumption of 5 g of oat beta-glucans in a beverage improved lipid metabolism Compared to control, LDL Chol was non-significantly lowered by 5 g (6.7%) and 10 g (3.7%) beta-glucan oat beverages. Compared to control, Total Chol was significantly lowered by 5 g beta-glucans oat beverage (7.4%) but not by the 10 g

Reference and Quality Rating (Author, year)	Aim of study	Design • R (Randomised) • NR (Non-randomised • C (Control group) • SB (Single-blind) • DB (Double-blind) • P (Parallel) • CO (Crossover)	Sample Characteristics • Country • Health Status • Setting(Metabolic unit, free-living subjects) • Age range • Gender (M,F) • No. recruited • No. randomized • No in final sample	Exposure and Duration • Food Matrix • Food dose; method and frequency of consumption • Duration of intervention • Design and/or duration of stabilization period, washouts, follow-ups	Background Diet & Assessment Tool	Results & Statistics • Changes in health effect • Adverse effects	Relevant Author's Conclusions
	concentrations of glucose and insulin.			glucan from oats/day; 22.5 g rice starch per dayfrom two 250 ml beverages, to be consumed with two main meals (breakfast, lunch or dinner) • 3-wk run-in period with control (rice-starch beverage) • 5-wk treatment in one of 5 grps: 1. 10 g beta-glucans from oat (Oat-10) + usual diet 2. 5 g beta-glucans from oat (Oat-5) + usual diet		Run-in: 1.60 ± 0.50 / 1.45 ± 0.41 / 1.42 ± 0.30 Intervention: 1.59 ± 0.44 / 1.52 ± 0.42 / 1.49 ± 0.36 Change: -0.01 ± 0.15 / 0.06 ± 0.10[b] / 0.07 ± 0.14[b] **TAG** Run-in: 1.59 ± 0.78 / 1.87 ± 1.13 / 1.53 ± 0.53 Intervention: 1.45 ± 0.67 / 1.73 ± 0.98 / 1.63 ± 0.67 Change: -0.14 ± 0.37 / 0.14 ± 0.45 / 0.10 ± 0.40 [a]ANOVA and Tukey's post hoc test: significant change compared to control ($p<0.01$). [b]Paired samples t-test: significant change between run-in and intervention period, $p<0.05$. **Adverse effects**: Subjects recorded AE in a diary. Some subjects reported GI discomfort during study. Major complaint included bloating, flatulence, diarrhea reported for both control and oat grps. GI problems were more frequent in oat (10 g) grp (11 complaints) compared to other grps (7-8 complaints) but the problems decreased gradually for all subjects after 1-2 wks of consumption.	beta-glucan oat beverage (4.5%). The study was unable to show a dose-response effect of 5 g compared with 10 g of beta-glucans from oats and barley. The amount of beta-0glucan does not necessarily predict its effect on serum Chol concentrations.

Reference and Quality Rating (Author, year)	Aim of study	Design • R (Randomised) • NR (Non-randomised • C (Control group) • SB (Single-blind) • DB (Double-blind) • P (Parallel) • CO (Crossover)	Sample Characteristics • Country • Health Status • Setting(Metabolic unit, free-living subjects) • Age range • Gender (M,F) • No. recruited • No. randomized • No in final sample	Exposure and Duration • Food Matrix • Food dose; method and frequency of consumption • Duration of intervention • Design and/or duration of stabilization period, washouts, follow-ups	Background Diet & Assessment Tool	Results & Statistics • Changes in health effect • Adverse effects	Relevant Author's Conclusions
				3. 10 g beta-glucans from barley (Barley -10) + usual diet 4. 5 g beta-glucans from barley (Barley 5-10) + usual diet 5. Control beverage + usual diet			

Table 12b: Summary of observational studies addressing the food/health relationship (e.g., dietary fibre and heart disease risk)

Reference and Quality Rating (Author, year)	Aim of study	Design • PROS (Prospective cohort) • Nested Case-control within a cohort	Sample Characteristics • Country • Health Status • Setting(free-living subjects) • Age range • Gender (M,F) • No in final sample	Exposure and Duration • Food exposure • Duration of follow-up (for measurement of health effects)	Diet assessment Tool	Results & Statistics • Changes in health effect							Relevant Author's Conclusions
Wolk et al., 1999 Quality:	To examine the association between long term intake of total dietary fibre as well as fibre from different sources and risk of CHD in women	PROS	• USA • Mean BMI at baseline: 24; At baseline no previous diagnosis of angina, myocardial infarction, stroke, cancer, hypercholesterolemia, diabetes • Free-living • 37-64 yrs • F • 68782 in final sample	• Mean energy adjusted daily intake of total dietary fibre was: Year:0: 16.2 (4.8) g Year 2: 17.5 (5.3) g Year 6: 18.0 (5.5) g • 10 year follow-up on health effect	Semi-quantitative food frequency questionaire		Quintiles of Energy-Adjusted Long-term Total Dietary Fibre Intake, 1984-1990						A significant inverse association between intake of dietary fibre and risk of CHD found. This association confined to fibre from cereal sources. In age adjusted analysis, women in the highest quintile of long-term total dietary fibre intake had a 43% lower risk of nonfatal MI and a 59% lower risk of fatal coronary disease
							1	2	3	4	5	p-value for trend	
						Median fibre intake for 1984 to 1990, g/d	11.5	14.3	16.4	18.8	22.9		
						Age-adjusted RR (95% CI for Non-Fatal MI)	1.0 (Referent)	0.80 (0.61-1.06)	0.68 (0.51-.90)	0.57 (0.42-0.77)	0.57 (0.42-0.77	<0.001	
						Age-adjusted RR (95% CI for Fatal CHD)	1.0 (Referent)	0.83 (0.52-1.31)	0.74 (0.46-1.18)	0.73 (0.46-1.16)	0.41 (0.23-0.70)	0.002	

Reference and Quality Rating (Author, year)	Aim of study	Design • PROS (Prospective cohort) • Nested Case-control within a cohort	Sample Characteristics • Country • Health Status • Setting(free-living subjects) • Age range • Gender (M,F) • No in final sample	Exposure and Duration • Food exposure • Duration of follow-up (for measurement of health effects)	Diet assessment Tool	Results & Statistics • Changes in health effect							Relevant Author's Conclusions
						Age-adjusted RR (95% CI for Total CHD	1.0 (Referent)	0.81 (0.64-1.02)	0.69 (0.54-0.89)	0.61 (0.47-0.79)	0.53 (0.40 -0.69)	<0.001	compared with the lowest quintile (Table 1). Cigarette smoking accounted for most of the difference between the age-adjusted and multivariate analysis. In multivariate analysis, women in the highest quintile of cereal fibre intake has a 34% lower risk of total CHD compared with those in the lowest quintile. Intakes of fibre from vegetables and fruits
						Multivariate RR (95% CI) for Total CHD[a]	1.0 (Referent)	0.98 (0.77-1.24)	0.92 (0.71-1.18)	0.87 (0.66-1.15)	0.77 (0.57-1.14)	0.07	
						[a] Multivariate model controlled for age, study period, BMI, smoking, menopausal status, hormone use, aspirin use, multivitamin supplement use, vitamin E supplement use, exercise, hypertension,parental history of MI, alcohol nintake, energy intake, saturated fat intake, carbohydrate intake.							

Reference and Quality Rating (Author, year)	Aim of study	Design • PROS (Prospective cohort) • Nested Case-control within a cohort	Sample Characteristics • Country • Health Status • Setting(free-living subjects) • Age range • Gender (M,F) • No in final sample	Exposure and Duration • Food exposure • Duration of follow-up (for measurement of health effects)	Diet assessment Tool	Results & Statistics • Changes in health effect	Relevant Author's Conclusions
							were not appreciable associated with risk of total CHD.

5.1.7 Step 7. Evaluate Study Quality

Objective: To discriminate between studies that have a high or low internal validity and risk of bias. A quality appraisal tool can help in the critical appraisal of individual studies and help identify studies that are more likely to generate unbiased results (*i.e.*, higher quality studies). Bias may occur in the selection of subjects (bias affected by study design; subject inclusion/exclusion criteria), the measurement of the exposure (the food) and health outcomes (bias affected by study design; identification and analysis of food and health effect), and in data analysis (bias affected by confounding variables; inappropriate group comparisons). While both higher and lower quality studies are considered in the following sections, substantiation for claim validity should be largely based on higher quality studies.

Procedure:

5.1.7.1 It is highly recommended that two independent experts appraise the quality of each study. If scores are different, the source of the differences should be discussed, and disagreements resolved through discussion, to result in a single score.

5.1.7.2 Apply the quality appraisal tool outlined in Table 13a to each of the intervention studies that met the inclusion criteria during full-text filtering.

5.1.7.3 Apply the quality appraisal tool outlined in Table 13b to each of the observational studies that met the inclusion criteria during full-text filtering.

5.1.7.4 Rate the quality as “higher quality” or “lower quality” where indicated based on the quality score.

5.1.7.5 Add the quality score for each study to the “Reference and Quality Rating” column in corresponding Tables 12a or 12b.

5.1.7.6 Attach a copy of the completed quality appraisal to the full-text copy of the article in the Appendix. If two evaluators rated the quality of each study, then attach a consensus quality appraisal.

Table 13a: Quality appraisal tool for intervention studies **Assign a score of 1 for each "Yes", and a score of 0 for each "No/NR".**			
Reference (Author, year):			
Item	**Question**	**Score**	
		Yes	**No/NR**
1. Inclusion/ Exclusion Criteria	Were the inclusion and/or exclusion criteria for study participation reported (*e.g.*, age greater than 50 years, no history of heart disease)?		
2. Group Allocation[1]	Was the study described as randomized?		
	Was the randomization method reported?		
	Was the randomization method appropriate?[2]		
	Was allocation concealed?[3]		
3. Blinding	Were the study subjects blinded to the intervention received?		
	Were the research personnel blinded to the intervention received by the subjects?		
4. Attrition	Was attrition numerically reported?		
	Were the reasons for withdrawals and dropouts provided?[4]		
5. Exposure / Intervention	Was the type of food described (e.g., composition, matrix)?		
	Was the amount of food described (i.e., dose)?		
6. Health Effect	Was the methodology used to measure the health effect reported?		
7. Statistical Analysis	Was a between-group statistical analysis of the health effect conducted (*i.e.*, control vs. intervention)?		
	Was an intention-to-treat analysis conducted?[5]		
8. Potential Confounders	Were potential confounders of the food/health relationship considered?[6]		
TOTAL SCORE (maximum of 15):			
Higher quality (Score ≥ 8) Lower quality (Score ≤ 7)			

Abbreviation: NR, not reported

[1] Studies without an appropriate control group would be excluded at Step 3, page 19.

[2] Examples of appropriate randomization include the use of computer-generated random number table, while date of birth and alternate allocation are examples of inappropriate methods of randomization.

[3] Allocation concealment is not the same as blinding. Allocation concealment refers to the method used to implement the random allocation sequence, *e.g.*, numbered envelopes containing the assignment. It protects the assignment sequence before and until allocation. Blinding protects the sequence after subjects have been allocated.

[4] If the study reported no attrition, (*i.e.*, no subjects were lost to follow-up, withdrew or were

excluded) then reasons for withdrawals/dropouts is a “non-applicable” factor. In such a circumstance, please check “yes” so as to not unfairly lose a point.

[5] If there was no subject attrition, a per-protocol analysis is appropriate and an intention-to-treat analysis not applicable. In such a circumstance, please check “yes” so as to not unfairly lose a point.

[6] Specify the confounders considered in a footer to this table. Confounding could have occurred during subject selection (*e.g.,* inclusion/exclusion criteria), study conduct *(e.g.,* specific dietary/physical activity restrictions), or data analysis *(e.g.,* use of covariates). If randomization is successful (*i.e.*, no difference in baseline characteristics between the intervention and control groups) and between-group differences that may have occurred during study conduct *(i.e.,* post-randomization between-group differences) are considered during statistical analysis, then confounders were “considered”. See the Appendix for more information on confounders.

Table 13b. Quality appraisal tool for prospective observational studies **Assign a score of 1 for each "Yes", and a score of 0 for each "No/NR".** **Reference (Author, year):**			
Item	**Question**	**Score**	
		Yes	No / NR
1. Inclusion/ Exclusion Criteria	Were the inclusion and/or exclusion criteria for study participation reported (*e.g.*, age greater than 50 years, no history of heart disease)?		
2. Attrition	Was attrition numerically reported?		
	Were the reasons for withdrawals and dropouts provided?[1]		
3. Exposure	Was the methodology used to measure the exposure reported?		
	Was the exposure assessed more than once?		
4. Health Outcome	Was the methodology used to measure the health outcome reported?		
	Was the health outcome verified (e.g., through assessment of medical records, confirmation by a health professional)?		
5. Blinding	Were the outcome assessors blinded to the exposure status?		
6. Baseline Comparability of groups	Were the subjects in the different exposure levels compared at baseline?		
7. Statistical Analysis	Was the statistical significance of the trend reported?		
8. Potential Confounders	Were key confounders related to subjects' demographics accounted for in the statistical analysis?[2,3]		
	Were key confounders related to other risk factors of the health outcome accounted for in the statistical analysis?[2,4]		
TOTAL SCORE (maximum of 12):			
Higher quality (Score ≥ 7) Lower quality (Score ≤ 6)			

Abbreviation: NR, not reported

[1] If the study reported no attrition, (*i.e.*, no subjects were lost to follow-up, withdrew or were excluded) then reasons for withdrawals/dropouts is a "non-applicable" factor. In such a circumstance, please check "yes" so as to not unfairly lose a point.

[2] Specify the confounders considered in a footer to this table. Confounding could have occurred during subject selection (*e.g.,* inclusion/exclusion criteria), study conduct, or data

analysis.

[3] Confounders related to subjects' demographics include age, sex and ethnicity.

[4] Confounders related to other risk factors of the health outcome include, but are not limited to, diet, physical activity, smoking, alcohol intake, body mass index (BMI), weight loss, health status, family history and medication/supplement use.

5.1.8 Step 8. Tabulate Study Findings per Health Outcome

Objective: To report the effect of the food exposure, per health outcome, in a consistent way across the studies and to summarize important elements of the studies.

Procedure:

5.1.8.1 Complete Table 14a for intervention studies and Table 14b for prospective observational studies per health outcome.

5.1.8.2 Refer to Excel spread sheet (available upon request) to assist with the calculations of the magnitude of effect for intervention studies. Include the Excel spread sheet of the calculations in an Appendix.

5.1.8.3 *If possible*, provide a visual representation, or carry out a meta-analysis, of the findings by considering the quantity of exposure (*e.g.*, daily exposure) and the magnitude of effect. Include the visual plot and/or the methodology and results of the meta-analysis in an Appendix.

Table 14a. Summary of study findings from intervention studies per health outcome

Reference and Quality Score	Design	Sample Size	Outcome for which study was powered[1]	Study Duration	Food Matrix	Exposure (Food/Bioactive substance Intake Per Day)	Magnitude of Effect[2]		P- value[6]
							Number[3,4]	Percent[3,5]	
HEALTH OUTCOME – TOTAL CHOLESTEROL (mmol/L)									
Biorklund *et al.*, 2005 Quality:	R, C, SB, P	89	LDL cholesterol (6% decrease)	5 weeks	Beverage	5 or 10g beta-glucans from oats	5g: *-0.49* 10g: *-0.29*	5g: *-7.4%* 10g: *-4.5%*	p<0.01 (5g vs. control) p>0.05 (10g vs. control)

[1] If the study did not indicate an outcome for which it was powered, state N/A.

[2] Use Appendix B as a guide and include the Excel spreadsheet used to derive these calculations in an Appendix.

[3] Reporting the magnitude of effect as a number and as a percentage may require computations by the petitioner.

Use a system to differentiate the computed values *versus* those taken directly from the study – *e.g.*, italicize all computed values.

[4] For studies with a control/comparison group, report the effect as: (Mean end-of-treatment – Mean baseline)treatment group – (Mean end-of-treatment – Mean baseline) control group. For studies with a control/comparison group that do not report baseline values, report the effect as: Mean end-of-

treatmenttreatment group – Mean end-of-treatment control group.

[5] For studies with a control/comparison group, report the effect as: [(Mean end-of-treatment – Mean baseline)/Mean baseline]*100%treatment group – [(Mean end-of-treatment – Mean baseline)/Mean baseline] *100%control group. For studies with a control/comparison group that do not report baseline values, report the effect as: [(Mean end-of-treatmenttreatment group – Mean end-of-treatment control group)/Mean end-of-treatment control group]*100%.

[6] Report between-group p-values. If between-group p-values are not reported in the study, report within-group values and indicate that values apply to within-group analyses.

Table 14b. Summary of study findings from prospective observational studies per health outcome									
Reference and Quality Score	**Design** **•Prospective cohort** **•Nested case-control**	**Study Population and Final Sample Size**	**Centile**	**Exposure (Dietary Intake/ Circulating Levels)**	**Incidence of Health Outcome**	**Multivariate Adjusted Risk Ratios Between Different Centiles**			
						Hazards Ratio	**Relative Risk**	**95% CI**	**P_{trend}**
HEALTH OUTCOME – TOTAL CHD									
Wolk *et al.*, 1999 Quality	Prospective cohort; the Nurses' Health Study (10-year follow-up), FFQ administered at baseline and at 0, 2, and 6 years of follow-up	68 782 females ages 37 to 64 years at baseline (1984)	1st quintile of fibre intake	11.5 (median g fibre/day, energy-adjusted)	N/R	N/A	1	N/A	0.07
			2nd quintile of fibre intake	14.3	N/R	N/A	0.98	0.77, 1.24	
			3rd quintile of fibre intake	16.4	N/R	N/A	0.92	0.71, 1.18	
			4th quintile of fibre intake)	18.8	N/R	N/A	0.87	0.66, 1.15	
			5th quintile of fibre intake	22.9	N/R	N/A	0.77	0.57, 1.04	

Abbreviations: CHD, coronary heart disease; N/A, Not applicable; N/R, Not reported

5.1.9 Step 9. Assess Causality

5.1.9 Step 9a. Rate Consistency

Objective: To rate the consistency of findings across studies, per health outcome with regard to the direction of effect of the food on the health outcome with consideration given to study quality.

Procedure:

- Complete Table 15a for intervention studies for each health outcome. This table requires you to consider all studies with regard to statistical significance, based on cut off of $p<0.05$, direction of effect (whether favourable, unfavourable or neutral), and study quality. Calculate the consistency rating according to direction of effect, alone [(C1 + C3) / A] and with regard to study quality [(D1 + D5) / (D1 + D3 + D5 + D7)].
- Complete Table 15b for observational studies for each health outcome. This table requires you to consider whether the trend was statistically significant ($p<0.05$) in each study, as well as the direction of effect (whether there was increased, decreased or no risk), and study quality.
- As indicated in Tables 15a and 15b, calculate the consistency ratings according to a favourable direction of effect alone, and with regard to a favourable direction of effect and study quality. Suggest plausible explanations for moderate or low consistency.
- Comment on the evidence related to study design; *e.g.*, do observational study designs tend to show an effect whereas intervention studies do not?

Table 15a. Rating of consistency in direction of effect for intervention studies, considering study qu						
HEALTH OUTCOME 1 **A. Total number studies included: ____**						
Statistical Significance (SS)						
B1. # studies with a SS effect of exposure (p<0.05): _____			**B2.** # studies with a non-SS effect of exposure (p>			
Direction of Effect[1]						
C1. # studies from B1 with a SS favourable effect of the exposure: _	**C2.** # studies from B1 with a SS unfavourable effect of the exposure: _		**C3.** # studies from B2 with a non-SS favourable effect of the exposure: _		**C4.** # stud showing e unfavoura distinguish exposure:	
Study Quality						
D1. # higher quality studies from C1:_	**D2.** # lower quality studies from C1: _	**D3.** # higher quality studies from C2:_	**D4.** # lower quality studies from C2:_	**D5.** # higher quality studies from C3: _	**D6.** # lower quality studies from C3:_	**D7.** # higher quality studies from C4:_
Consistency Rating on Direction of Favourable Effect						
(C1 + C3) / A1 x 100 % =				High (≥ 75%) □ Moderate (60-74%) □ Low (< 60%) □		
Consistency Rating on Direction of Favourable Effect in Higher Quality Studies						
(D1 + D5) / (D1 + D3 + D5 + D7) x 100% =				High (≥ 75%) Moderate (60-74%) Low (< 60%)		

[1] Direction of effect assesses whether the health outcome is changing in a favourable (*i.e.*, beneficial) direction with exposure to the food,

or in an unfavourable (non-beneficial) direction, without regard to statistical significance.

Table 15b. Rating of consistency in direction of effect for prospective observational studies, considering study quality					
HEALTH OUTCOME 1					
A. Total Number of Studies Considered: _____					
Direction of Effect					
B1. # studies from A showing trend for risk reduction (p < 0.05)[1]: _	**B2.** # studies from A showing a trend for increase in risk (p < 0.05): _____		**B3.** # studies from A showing no effect (p > 0.05): _____		
Study Quality					
C1. # higher quality studies from B1: _____	**C2.** # lower quality studies from B1: ____	**C3.** # higher quality studies from B2: _____	**C4.** # lower quality studies from B2: _____	**C5.** # higher quality studies from B3: _____	**C6.** # lower quality studies from B3: ____

Consistency Rating on Direction of Favourable Effect (Risk Reduction)		**Consistency Rating on Direction of Unfavourable Effect**		**Consistency Rating on No Effect**	
B1 x 100% = A	High (≥ 75%) Moderate(60-74%) Low (< 60%)	**B2 x 100% = A**	High (≥ 75%) Moderate (60-74%) Low (< 60%)	**B3 x 100% = A**	High (≥ 75%) Moderate (60-74%) Low (< 60%)
Consistency Rating on Direction of Favourable Effect in Higher Quality Studies					
C1 / (C1 + C3 + C5) x 100% =		High (≥ 75%) Moderate (60-74%) Low (< 60%)□			

[1] Statistically significant associations may not be limited to trends. A rationale may be provided in a footer to this table that logically supports the consideration of statistically significant associations between the highest versus the lowest centiles of intake, or between intermediate centiles *versus* lowest centiles. In cohort studies, intakes distributions are normally grouped by tertiles, quartiles, quintiles or centiles of intake.

5.1.9 Step 9b. Rate the Strength of the Association

Objective: To assess the strength of the association between the food and health outcome by considering the proportion of studies that showed statistical significance at $p<0.05$ among all included studies.

Procedure:

- Consider studies of higher and lower quality from Table 15a [(D1 + D2) / A] and comment on whether all or most of the studies show a statistically significant favourable effect. Consider study features and discuss factors that may have contributed to statistical significance not being reached (e.g., power calculations, sample size, duration, etc.).

- Consider studies of higher quality from Table 15a [D1 / (D1 + D3 + D5 + D7)] and comment on whether all or most of the higher quality studies show a statistically significant favourable effect.

- Consider studies of higher and lower quality from Table 15b [B1/A] and comment on whether all or most of the studies show a statistically significant favourable effect. Consider study features and discuss factors that may have contributed to statistical significance not being reached (e.g., power calculations, sample size, duration, etc.).

- Consider studies of higher quality from Table 15b [C1 / (C1 + C3 + C5)] and comment on whether all or most of the higher quality studies showed a statistically

significant favourable effect.

5.1.10 Step 9c. Discuss the Relationship between the Food Exposure and the Health Effect

Objective: To understand whether a dose-response relationship exists and /or the minimum effective dose.

Procedure:

- For intervention studies using Table 14a as a guide and visual plots (if conducted), discuss the range of effect sizes observed (number and percent) with different food exposures (doses). Discuss the relationship that exists between the food exposure and its effect: whether a greater effect is observed with a greater food exposure (dose-response), and/or whether the evidence indicates a minimum effective food dose/food intake.
- For the observational studies, using Table 14b and Table 15b (specifically B1/A) as guides, comment on whether a dose response relationship exists. Include discussion of whether statistical significance was achieved between the highest and lowest dietary intake groups, where a trend was also statistically significant.

5.1.11 Step 10. Discuss Generalizability of the Data to the Target Population

Objective: To demonstrate that the food/health relationship is relevant to the target population.

Procedure:

- Using all studies that support a favourable direction of effect, discuss the health status of the sample populations studied in the intervention/experimental and observational studies and whether the baseline health status of sample populations was a factor in the effect of the food (*e.g.*, was a cholesterol-lowering effect only seen in hyperlipidaemics?)

- Discuss whether the target population for the health claim was represented in the higher quality studies used to rate consistency with respect to background diets, health status, age, gender, study setting.

5.1.12 Step 11. Discuss the Physiological Meaningfulness of the Effect of the Food Exposure

Objective: To understand the impact of the food exposure on human health.

Procedure:

- Using Tables 14a and 14b as guides, discuss whether the effects (range of effects and/or a specific effect) observed with food exposure (range of exposures and/or a specific exposure) are physiologically meaningful/relevant to human health. Provide reasons to support your response. Based on the study durations, include discussion on the sustainability of the beneficial effect.

5.1.13 Step 12. Discuss the Feasibility of Consuming an Effective Amount of the Food

Objective: To discuss whether the food exposure required for a meaningful effect can be feasibly consumed as part of a healthy diet.

Procedure:

- Provide information on the feasibility of incorporating this effective amount of food into a healthy diet. Include information on the current intakes of the food in the target population (from Table 4).
- Provide information on the expected* intakes of the food/bioactive substance from all sources, if added to one or more foods, in the target population using South African intake data where possible.
- Estimate changes* in usual dietary patterns (*i.e.*, substitution or elimination of existing foods) with potential approval of the food for a health claim.
- State the subgroups of the population expected to have the greatest exposure to the food and subgroups at risk of exposure to the food.

*Clearly communicate the assumptions (and the evidence on which they were based) and statistical simulations used for these estimations

5.1.14 Step 13. Make Conclusions

Objective: To justify a health claim for a food based on the totality of evidence.

Procedure:

- Provide relevant information from the totality of evidence reviewed focusing on the outcome of Steps 9-12, and any other supporting evidence such as meta-analyses, systematic reviews and authoritative statements, to make concluding remarks on the food/health relationship and its relevance to public health.
- Propose claim wording.
- Propose and justify conditions for a food to qualify for the health claim such as:
    - The minimum amount of the food eligible to carry the claim, *e.g.*, minimum 1 g beta-glucan per reference amount, minimum 3 servings per day required;
    - The maximum levels of food to be consumed, *e.g.*, no more than 3 grams plant sterols per day;
    - The proposed food matrix, *e.g.*, a fermented dairy matrix;
    - The minimum, maximum levels of nutrients in the food that are not the subject of the claim, *e.g.*, meets criterion for low in saturated fat.
- Comment on any adverse effects (*i.e.*, adverse direction of effect) observed in the evaluated human studies, and subgroups at risk of excessive intakes of the food.
- Propose risk management strategies (if necessary) to address adverse effect and/or

restrictions on use of the food (*e.g.*, indicate wording of recommended warning statements).

6.0 CHECKLIST FOR SUBMISSION

Objective: To ensure that all requested information is included in the submission. Directorate Food Control will use this same checklist when evaluating submissions for completeness. If deficiencies exist, petitioners may be asked to address them before the full evaluation can proceed.

Procedure:

Please complete and submit the following checklist. If any items do not meet the requirements, please revise the application to include it before submitting it to Directorate Food Control.

Table 16. Checklist for submission			
	Yes	**No**	**N/A**
Organisation and Presentation of the Submission			
All required sections completed and properly identified			
Pagination sequential throughout submission			
Submission bound or organized in a binder			
Applicant identified on every page			
Language of submission in English or French			
References accurate and formatted			
Application signed by person responsible for it			
Two hardcopies of application provided			
All confidential/proprietary data is identified			
Content of the Submission			
Applicant information (Table 1)			
Details pertaining to proposed health claim (Table 2)			
Regulatory status of health claim in other jurisdictions (Table 3)			
Information requirements for characterization of the food (requirements in Table 4 met)			
Lab-certified specifications for the food/bioactive substance (added or inherent) included in an Appendix			
Characterization of biomarkers of the health effect			
Identification of databases and search parameters used for literature retrieval (Table 5)			
Keywords and their combinations used to retrieve literature on the food/health relationship from electronic databases (Table 6)			
Number of references retrieved from electronic and non-electronic sources (Table 7)			
A copy of the entire literature search, including the literature search strategy and the literature search results, by printing it directly from the electronic database in an Appendix			
Inclusion and exclusion criteria used for literature filtering (Table 8a)			
Results of literature filtering (Table 9)			
List of references that met the inclusion criteria at the full-text filtering stage (Table 10)			
List of references excluded at the full-text filtering stage and reason(s) for exclusion (Table 11)			
Full-text copies of all publications that met the inclusion criteria at full- text filtering in an Appendix. If studies in languages other than English or French were included, then translations of the studies in either English or French provided.			
Tabulation of intervention studies (Table 12a) and/or prospective observational studies (Table 12b) grouped according to their research design			
Tabulation of study findings per health outcome for intervention studies (Table 14a) and/or prospective observational studies (Table 14b)			
A copy of each completed quality appraisal in an Appendix (Table 13a for intervention studies; Table 13b for prospective observational studies)			
Excel spread sheet of calculations used to determine magnitude of effect of the food/bioactive substance for intervention studies in an Appendix			

Table 16. Checklist for submission			
	Yes	**No**	**N/A**
A visual representation or a meta-analysis of the findings by considering the daily exposure and the magnitude of effect, in an Appendix (optional)			
Rating of consistency for intervention studies (Table 15a) and prospective observational studies (Table 15b)			
Discussion on whether a cause-and-effect relationship between the food and the health effect is supported (data requirements in Steps 9a, 9b, 9c complied with)			
Discussion on generalizability of the evidence to the target population (data requirements in Step 10 met)			
Discussion on physiological meaningfulness (data requirements in Step 11 complied with)			
Discussion on feasibility (data requirements in Step 12 complied with)			
Conclusions made (data requirements in Step 13 complied with)			
Appendices included			

7.0 REFERENCES

Aggett PJ, Antoine J-M, Asp N-G, Bellisle F, Contor L, Cummings JH, Howlett J, Müller DJG, Persin C, Pijls LTJ, Rechkemmer G, Tuijtelaars S, Vergen H. (2005). PASSCLAIM. Consensus on Criteria. *European Journal of Nutrition* 44 (Supplement 1): 1-30.

Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, Gotzsche PC, Lang T. (2001). The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 134: 663-694.

Biörklund, M, van Rees, A, Mensink, RP, Onning, G. (2005). Changes in serum lipids and postprandial glucose and insulin concentrations after consumption of beverages with beta-glucans from oats or barley: a randomised dose-controlled trial. *Eur J Clin Nutr* 59 (11):1272-1281.

Briss PA, Zaza S, Pappaioanou M, Fielding J, Wright-De Agüero L, Truman BI, Hopkins DP, Mullen PD, Thompson RS, Woolf SH, Carande-Kulis VG, Anderson L, Hinman AR, McQueen DV, Teutsch SM, Harris JR. (2000). Developing and Evidence-Based Guide to Community Preventive Services – Methods. *American Journal of Preventative Medicine* 18 (1S): 35-43.

Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.0 [updated February 2008] www.cochrane-handbook org 2008; (4).

Codex Alimentarius Commission. (2008). *Proposed Draft Annex to the Codex Guidelines for Use of Nutrition and Health Claims: Recommendations on the Scientific Basis of Health Claims*. CX/NFSDU 06/28/7. Available at: ftp://ftp.fao.org/codex/ccnfsdu28/nf28_07e.pdf.

Codex Alimentarius Commission (1997) Guidelines for Use of Nutrition and Health Claims CAC/GL 23-1997. Available at: http://www.codexalimentarius.net/download/standards/351/CXG_023e_u.pdf

Downs SH, Black N. (1998). The feasibility of creating a checklist for the assessment of the methodological quality both of randomized and non-randomized studies of healthcare interventions. *Journal of Epidemiology Community Health* 52: 377- 384.

EFSA (European Food Safety Authority). (2007). *Scientific and Technical Guidance for the Preparation of the Application for Authorization of a Health Claim*. Available at: http://www.efsa.europa.eu/en/science/nda/nda_consultation/health_claim.html

FDA (US Food and Drug Administration). (2007, July). *Guidance for Industry. Evidence-Based Review System for the Scientific Evaluation of Health Claims*. Available at: http://www.cfsan.fda.gov/~dms/hclmgui5.html.

FDA (US Food and Drug Administration). (1999, November 2). *Guidance for Industry Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*. Rockville, MD: Center for Food Safety and Applied Nutrition (CFSAN), Office of Special Nutritionals. Available at: http://www.cfsan.fda.gov/~dms/ssaguide.html.

FSANZ (Food Standards Australia New Zealand). (2008, April 11). *Proposal P293 – Nutrition, Health and Related Claims. Final Assessment Report*. Available at: http://www.foodstandards.gov.au/_srcfiles/P293%20Health%20Claims%20FAR%20and%20Att%201%20&%202%20FINAL.pdf.

Harris RP, Helfand M, Woolf SH, Lohr K.N., Mulrow CD, Teutsch SM, Atkins D, Methods Work Group, Third US Preventive Services Task Force. (2001). Current Methods of the U.S. Preventive Services Task Force: A Review of the Process. *American Journal of Preventative Medicine* 20 (Supplement 3): 21-35. (AHRQ [Agency for Healthcare Research and Quality])

Directorate Food Control. (2002). *Interim Guidance Document – Preparing a Submission for Foods with Health Claims Incorporating Standards of Evidence for Evaluating Foods with Health Claims.* Available at: http://www.hc-sc.gc.ca/fn- an/alt_formats/hpfb-dgpsa/pdf/label-etiquet/abstract_guidance- orientation_resume-eng.pdf.

Higgins JPT, Green S, editors. (2008, February). *Cochrane Handbook for Systematic Reviews of Interventions 5.0.0.* Available at: http://www.cochrane- handbook.org/.

Hill, AB. (1965). The environment and disease: association or causation? *J R Soc Med* 58(5):295-300.

Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, McQuay HJ. (1996). Assessing the Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary? *Controlled Clinical Trials* 17: 1-12.

Katrak P, Bialocerkowski AE, Massy-Westropp N, Kumar S, Grimmer KA. (2004). A systematic review of the content of critical appraisal tools. *BioMed Central Medical Research Methodology* 4: 22.

Moher D, Schultz KF, Altman D, for the CONSORT group (2001). The CONSORT statement:

revised recommendations for improving the quality of report of parallet-group randomized trials. *Lancet* 351: 1191.

Wolk A, Manson JE, Stampfer MJ, Colditz GA, HU FB, Speizer FE, Hennekens CH, Willett WC. (1999). Long term intake of dietary fiber and decreased risk of coronary heart disease among women. *JAMA* 21: 1998-2004.

APPENDIX: Additional Definitions

- **Allocation Concealment:** A process to prevent selection bias by concealing the allocation sequence from those assigning participants to intervention and control groups (Altman *et al.*, 2001). The use of a third party is desirable; the third party assigns the participants without knowledge of which assignment is treatment or control. The allocation is concealed before random assignment takes place.

- **Biomarker/surrogate marker of a health effect:** Whenever possible, a claimed health benefit should measure the true endpoint. However, when it is not possible to measure in a practical way, a more easily measured surrogate, or biomarker, of the true endpoint may be used. Biomarkers can relate to health effect or to food intake. A biomarker of a health outcome is a proxy measure (an intermediate measure) of a true endpoint. It predicts development of a final health effect because it lies on the causal pathway between exposure to the food and development of the final health effect. For example, LDL cholesterol is a well-accepted biomarker for heart disease because it can reasonably predict that individuals who have higher LDL cholesterol levels will have a higher probability of developing heart disease. A biomarker of intake or exposure to a food is a measure that supports that the food was consumed by study participants.

- **Blinding:** This refers to keeping study participants, health care providers and sometimes those collecting and analysing clinical data unaware of the assigned intervention. This prevents bias at several stages in a controlled trial (Altman *et al.*, 2001).

- **Prospective Cohort Study:** This is a study design that follows a group of healthy/disease-free people for a period of time after which it can be assessed whether the development of a disease in this group is related to the presence of specific causes. The incidence of a health effect in those people who had a specific exposure (*e.g.*, to a food constituent such as long chain omega-3 fatty acids) is compared to those who did not receive the exposure. Cohort studies can yield relative estimates of risk. They are the most reliable observational study design since intake of the food of interest precedes development of the health effect; as such, temporality is supported.

- **Confounding:** This is a situation where the estimated effect of the intervention is biased because of some difference between the comparison groups apart from the planned interventions, such as baseline characteristics or concomitant intervention. For a factor to be a confounder, it must differ between the comparison groups and affect/predict the outcome of interest (Altman *et al.*, 2001).

- **Control group:** A control group is a group that has not received the exposure of interest and is being compared to the treatment or intervention group in the randomized trial. In a cross-over design, subjects serve as their own controls.

- **Intention-to-treat analysis:** A strategy for analysing data in which all participants are included in the group to which they were assigned, regardless of whether they completed the intervention given to the group. This analysis prevents bias caused by loss of participants which may disrupt the baseline equivalence established by random assignment and may reflect non-adherence to the protocol (Altman *et al.*, 2001).

- **Intervention Studies:** In an intervention study, human subjects are administered the food of interest (intervention group) and the health outcome is subsequently measured. The gold standard intervention study includes randomization, a control group and double blinding. The composition and quantity of the food should be controlled for the intervention group and for the control group. Randomized, controlled studies offer the best assessment of cause and effect since a temporal relationship between the food and health effect – *i.e.*, administration of the food precedes observation of the effect – can be demonstrated. Randomized, controlled intervention studies have either a parallel or cross-over design. Parallel studies involve two groups of subjects, the test group and the control group, which simultaneously receive the test food or the control, respectively. In cross-over studies subjects from the intervention group cross over to the control group and vice versa.

- **Meta-Analysis:** A meta-analysis involves applying statistical methods that combine the quantitative research findings of several studies together allowing for their analysis and summary as if they were one unit.

- **Observational Studies:** Observational studies measure associations between a food and a health effect. These studies lack the controlled setting of intervention studies and are thus often susceptible to confounders. They are most reflective of free-living populations. Because the subjects are not randomized at the beginning of the study, known confounders of the health effect need to be collected and adjusted for to minimize bias. Evaluating the method of dietary assessment is critical to ensure the food of interest is reliably measured. Observational studies may be prospective or retrospective. In prospective studies, investigators recruit subjects and observe them prior to occurrence of a health effect. Prospective observational studies measure incidence of a health effect, and relative risk of

developing the health effect associated with food or other risk factors of interest. In retrospective studies, investigators interview subjects after the health effect has occurred. Retrospective studies are vulnerable to measurement error and recall bias because they rely on subjects' recollections of what they consumed in the past.

- **Per Protocol Analysis:** This refers to a strategy for analysing the set of data generated by the subset of subjects who complied with the protocol sufficiently to ensure that the data would be likely to exhibit the effects of the treatment according to the underlying scientific model. Compliance covers such considerations as exposure to treatment, availability of measurement and the absence of major protocol violations (European Medicines Agency, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Used (ICH) Topic E9, *Statistical Principles for Clinical Trials*, September 1998) Codification as per November 2005.

- **Randomization:** The process of assigning participants to groups such that each participant has known and usually an equal chance of being assigned to a given group (Altman *et al.*, 2001). The random assignment of subjects to intervention and control groups avoids selection bias – that is the possibility that those subjects most likely to have a favourable effect, independent of the intervention, are preferentially selected to receive the intervention. Randomization also helps control for known and potential confounders (*e.g.*, factors that could affect risk of developing health effect).

- **Systematic Reviews:** Systematic reviews consist of a clearly formulated question and use systematic and explicit methods to identify, select, critically appraise, and extract and analyse data from relevant research (Cochrane Handbook, 2008).

GUIDELINE 17

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 Department of Health considers the definition of medical foods to narrowly constrain the types of products that fit within this category of food. Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims, by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition, and all foods fed to sick patients are not medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring food used in a natural/manufactured state for the ordinary public) for a patient who is seriously ill or who requires use of the product as a major component of a disease or condition's specific dietary management.

Criteria

1. The following criteria will clarify the definition of a medical food:
    a. It is a specially formulated and processed product (as opposed to a naturally occurring food used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
    b. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foods or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
    c. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
    d. It is intended to be used under medical supervision; and
    e. It is intended only for a patient receiving active and on-going medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

Scientific basis of an FSMP

2. 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 Guideline, has been submitted to the Directorate: Food Control at least 12 months before the food appears on the market.

Dossier

3. 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.

The Guideline focuses 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:
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.

The dossier content should follow the format below:

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:

(a) The wording of the proposed, draft statement and information on the nature and purpose of the food;

(b) Information on the essential characteristic of the food 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;

(c) The summary referred to above shall be accompanied by the following documentation:

(i) The draft label, accompanying leaflets and advertisements, complete with information as required by regulation 66;

(ii) 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;

(iii) A true, certified copy of the original certificate/letter from the Accreditation Authority to confirm that the laboratory has the required accreditation;

(iv) An original letter by at least 5 other National Authorities (of which the EU is counted as one Government Authority) which indicates that the particular FSMP has been evaluated and approved for sale in the specific country.

(v) At the back, complete copies of the clinical studies as published;

(d) Full copies of all reference documents concerning adequate precautions, known side effects, contraindications, and nutrient-drug interactions***,** where applicable;

(e) Inclusion and exclusion criteria;

(f) Tabulated summary of papers included and excluded; and

(g) List of references and full copies thereof included in the dossier.

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

1. Natural Medicines Comprehensive Database, ISBN, 096761368X, published by the Therapeutic Research Centre.

2. The Nutritional Cost of Prescription Drugs by Pelton R. & Lavalle J.B.

3. Krauses's Food and the Nutrition Care Process by L.K Mahan,S Escott- Stump and J. L. Raymond, 13 th Edition or latest version, http:// evolve.elsevier.com