South Africa - ZAF / 66

Back to search result

Date arrival : 08 August 2007.

Final date for comments : **04 October 2007.**

Title es Propuesta de reglamento relativo al etiquetado y la publicidad de los productos alimenticios – 76 páginas, disponible en inglés

Description of content es La propuesta de reglamento notificada establece los criterios de etiquetado y publicidad de los productos alimenticios preenvasados, que fiscaliza el Departamento de Salud con arreglo a la Ley de productos alimenticios, cosméticos y desinfectantes, 1972 (Ley Nº 54 de 1972).

Objectives Consumer Information, Labelling
Protection of Human Health or Safety

Fields of activity PACKAGING AND DISTRIBUTION OF GOODS
Food products in general

To consult the full text of the notification form, please click on one of the following language New **:** ES

To consult the full text of the announced text or any other relevant text, please click on one of the following language :

Files with a green border can take some time to be extracted from the database (size > 2 Mo).

- **Draft Text 1** New
  EN
- **Draft Text 2** New
  EN
- **Draft Text 3** New
  EN
- **Draft Text 4** New
  EN
- **Draft Text 5** New
  EN
- **Draft Text 6** New
  EN
- **Draft Text 7** New
  EN
- **Draft Text 8** New
  EN

GOVERNMENT GAZETTE NO 30075

DEPARTMENT OF HEALTH

No. R 642 **20 July 2007**

FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT 54 OF 1972)

REGULATIONS RELATING TO THE LABELLING AND ADVERTISING OF FOODSTUFFS

The Minister of Health intends, under section 15 (1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), to make the regulations set out in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Food Control), within 3 months from the date of publication of this notice.

TABLE OF CONTENTS

SCHEDULE

1. DEFINITIONS

In these regulations, any expression to which a meaning has been assigned in the Act shall bear such meaning and, unless inconsistent with the context –

"address" means an address in the Republic of South Africa and includes the street or road number or name and the name of the town, village or suburb and, in the case of a farm, the name or number of the farm and of the magisterial district in which it is situated;

"allergen" means any substance that causes an allergic or other adverse immune response;

"annexure" means an annexure to these regulations;

"antioxidant" means an additive that prolongs the shelf life of foods by protecting against rancidity or colour changes or other deterioration caused by oxidation or a nutrient that protects cells against free radical oxidation;

"approve" in terms of certification means the procedure by which the certifying organisation evaluates and gives a formal recognition that the inspection and certification programme complies with the requirements of appropriate regulations or standards;

"audit" in terms of certification means a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives;

"batch" means a definite quantity of a commodity produced essentially under the same conditions;

"**Best before**" or "**Best before end**" or "**Best consumed before**" or **"BB"** means the date indicating the end of the period under the stated storage conditions as specified on the label by the manufacturer, until which the product will retain any specific qualities for which tacit or express claims have been made;

"bleaching" in terms of oil manufacturing means the use of filters, "Fuller's earth", and/or acid-treated activated clays to bleach oils by removing pigments (such as chlorophyll and beta-carotene), natural polycylic and aromatic substances and remaining traces of soap at a temperature of 110°C (230°F) for 15 to 30 minutes, during which trans fats and/or toxic peroxides are formed from essential fatty acids present in the oil;

“bulk stock” means either a container that is used to display several individual units suitable for sale by itself, or several units, which are pre-packed or wrapped for the purpose of bulk sales or foodstuffs, which are offered for sale to consumers in quantities of their own choice from a large-scale container;

“carbohydrate” means the sum of all glycaemic carbohydrates that are carbohydrates, which are available for metabolism;

“catering establishment” means any establishment including a vehicle or a fixed or mobile stall where, in the course of business, foodstuffs are prepared for direct sale to the consumer for consumption;

“cereal” means a product derived from the fruit of any cultivated grasses of the family *Poaceae;*

“certification” means the procedure by which approved certifying organisations provide written or equivalent assurance that a product, process or service is in conformity with certain standards;

"certification programme" means an approved system of rules, procedures and management for carrying out certification;

"certifying organisation" means an organisation performing certification through an audit process;

“chemically extracted” in terms of oil manufacturing means using one or more of the following processes degumming, refining, bleaching and deodorizing and the oil contains no traces of chemical solvents;

“chilled” or “refrigerated” means stored at any temperature ranging from 0°C to 7°C, as appropriate for the specific type of product;

“chocolate confectionary” means any foodstuff that contains chocolate as it is described in *Codex* and which is meant to be consumed as a sweet snack;

“claim” in relation to a foodstuff or nutritional supplement, means any written, pictorial, visual or other descriptive matter or verbal statement, communication, representation or reference brought to the attention of the public in any manner including a trade name or brand name and referring to the characteristics of a product, in particular to its nature, identity, nutritional properties, composition, quality, durability, origin or method of manufacture or production;

“clean, safe and sound” in relation to a foodstuff, means that the foodstuff or ingredient is fit for human consumption;

"Codex" means the latest version of the relevant Codex Standard or Guideline issued by the Codex Alimentarius Commission of the Joint FAO/WHO Food Standards Programme;

"colourant" means any substance described as such in the Regulations Relating to Food Colourants published under the Act;

"common allergens" means an ingredient derived from egg, milk, crustaceans and molluscs, fish, peanuts, soybeans, tree nuts, natural flavourants and an ingredient, which is derived from cereals of all *Triticum* species such as kamut and spelt, wheat, durum wheat, rye, barley, oats, or their crossbred varieties or the products thereof;

"comparative claim" means a claim that compares the nutrient level(s) and/or energy value and/or alcohol level and/or synthetic colourant level of two or more similar foodstuffs;

"compound ingredient" means any ingredient, which is itself composed of two or more ingredients;

"container" means any packaging of foodstuffs for sale at retail level or for catering purposes for delivery as a single item, whether by completely or partially enclosing the foodstuff and includes wrappers for individual and multiple-unit-packs;

"contaminant" means any substance not intentionally added to foodstuffs, which is present in such foodstuff as a result of the production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such foodstuff or as a result of environmental contamination;

"cold-pressed" in terms of oil manufacturing, has the same meaning as mechanically pressed;

"cross-sectional study" means a study design that relates the rates of a certain exposure to the levels of an outcome of interest in a number of individuals or populations. Key feature is that exposure and outcome are measured at the same point in time and in different groups of individuals;

"daily serving" means the average daily intake of a food vehicle;

"dairy product" means milk or a product obtained or manufactured exclusively or mainly from milk;

"date of manufacturing" means the date on which the food becomes the product as described;

"deflavour" means the intentional removal of the bulk of volatile and non-volatile natural flavourants from fruit juices or fruit juice concentrates;

“degumming” in terms of oil manufacturing means the removal of phospholipids including lecithin, true gums, protein-like compounds, polysaccharides, chlorophyll, calcium, magnesium, iron, copper and other nutrients and biologically active substances from unrefined oils through external heat of about 60°C (140°F) with water and phosphoric acid;

“deionise” in terms of fruit juices or fruit juice concentrates means the intentional removal of the bulk of mineral salts from fruit juices or fruit juice concentrates;

“deodorise” in terms of oil manufacturing means the process during which the oil is steam-distilled under pressure at a high temperature of between 240 to 270°C (464 to 518°F) for 30 to 60 minutes in the absence of air and during which the aromatic oils, nutrients, free fatty acids, and molecules that impart pungent odors and unpleasant tastes (peroxides), which were not present in the natural oils before refining and bleaching, are removed and during which, from the temperature of 150°C (302°F), unsaturated fatty acids become mutagenic and from 160°C (320°F), trans fatty acids are formed;

“dietary fiber” or “fiber” means intrinsic plant cell wall polysaccharides;

“drained weight” means the remaining solid part of the foodstuff that is ordinarily used for culinary purposes or consumption after excess liquid has been drained under normal culinary practices;

“endorse “ means to confirm or convey or declare an approval of a particular foodstuff in any manner but exclude certification**;**

“enhanced function claim” means claims which concern specific beneficial effects of consumption of foods or their constituents in the context of the total diet on normal functions or biological activities of the body (nutrient function claims) beyond their established role in growth, development and other normal functions of the body and relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health;

“enrichment” means the voluntary addition by a manufacturer of one or more nutrient(s) to a foodstuff, excluding foodstuffs not regarded as essential for a healthy diet as listed in Annexure 6, whether or not it is normally contained in the food, with the sole purpose of adding nutritional value to the food;

“evidence-based nutrition” means the application of the best available systematically assembled evidence in setting nutrition policy and practice;

“fat” or “lipid” means the total amount of chemically extractable fat, including phospholipids, determined according to the appropriate extraction method for animal and plant fats as described in Guideline 2;

"flavourant" means a natural, nature-identical or artificial flavouring substance or preparation in concentrated form with or without solvents or carriers which is not intended to be consumed directly, but which is used in foodstuffs to impart a particular taste or aroma;

"flavour enhancer" means a substance that enhances, intensifies or supplements the existing taste and/or odour of a foodstuff;

"flour confectionery" means any cooked foodstuff ready for consumption without further preparation (other than reheating) having as its characteristic ingredients ground cereal and sweeteners and/or other ingredients, and includes uncooked pastry casings but does not include pizzas, samoosas, sausage rolls, meat pies and dry biscuits;

"food additive" means any substance not normally consumed as a foodstuff by itself and not normally used as a typical ingredient of the foodstuff, whether or not such substance has nutritive value, the intentional addition of which to a foodstuff for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or storage of such foodstuff results, or may reasonably be expected to result, (directly or indirectly) in such substance or its by-products becoming a component of or otherwise affecting the characteristics of such foodstuff, excluding any substance added to foodstuffs for maintaining or improving nutritional qualities or any contaminants;

"food constituent" means any biologically active substance other than a nutrient, which is naturally present in certain foodstuffs and with which health effects are associated;

"foodstuffs for catering purposes" means those foodstuffs intended for use in the hospitality services, schools, hospitals and similar institutions;

"food vehicle" means dry, uncooked wheat flour, dry, uncooked maize meal and bread prepared with and containing at least 90% fortified wheat flour and/or maize meal, but excludes water;

"food vending machine" means any mechanical device, whether attended or not, by means of which foodstuffs are sold;

"fortification" means the addition of one or more micronutrient(s) to a foodstuff identified by Regulations Relating to the Fortification of Certain Foodstuffs and the Regulations Relating to Salt under the Act, whether or not the micronutrient is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the general population of and/or persons in South Africa as determined by the Department;

“fresh processed meats” means raw meat products from all species of meat animals and birds that have undergone a process of the addition of marinades, sauces or basting solutions containing water, either by injection, massaging, tumbling or soaking, but no further processing except packaging;

“frozen” means stored at any appropriate temperature colder than 0°C which will maintain a specific product in its hard, cold condition or state;

“function claim” means a claim that describes the physiological role of the nutrient or substance in growth, development and normal functions of the body;

“gluten” means the protein fraction from wheat, rye, barley, oats or other cereals of all *Triticum* species and their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0,5M NaCl and of which the method of analysis is stipulated in these regulations and the Guidelines;

“Glycaemic Index (GI)” means the blood glucose responses of carbohydrate foods under certain conditions as specified in the Guidelines;

“Glycaemic load (GL)” means a numerical expression of how much impact a specific carbohydrate food will have in affecting blood glucose levels and which is calculated according to the formula in the Guidelines;

“good manufacturing practice” means that combination of manufacturing and quality control procedures aimed at ensuring that food products are consistently manufactured to their specifications;

“Guidelines” means guidelines as determined from time to time by the Director-General in terms of these regulations;

“health claim” means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health, and include but is not limited to nutrient function claims, enhanced function claims, reduction of disease risk claims, prebiotic claims, probiotic claims and slimming claims;

“health practitioner” means any medical or dental practitioner, psychologists or other person who carry on a supplementary health service referred to in the Health Professions Act, 1974 (Act 56 of 1974) or The Allied Health Professions Act, 1982 (Act 63 of 1982);

“honey” means the sweet foodstuff derived from the nectar of flowers, sugary excretions of insects, plant juices or sugary secretions of living plant parts other than flowers after it has been gathered, partially converted and stored in the comb by honeybees or stingless bees;

“ingredient” means any substance, including any food additive and any constituent of a compound ingredient, which is used in the manufacture or preparation of a foodstuff and which is present in the final product, although possibly in a modified form;

“irradiation” means deliberate exposure to ionising radiation;

“intervention study” means a trial, an experimental study in which investigators intervene by allocating and establishing an intervention or different interventions to and in certain subjects. See also ´observational study´ and ´randomised controlled trial´;

“label” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed upon, or permanently attached to a container of a foodstuff, including labelling for the purpose of promoting its sale or disposal;

“liquid medium” means water, or aqueous solutions of sugar or salt, or fruit and vegetable juices in canned fruits and vegetables only, or alcohol beverages in the case of typical traditional South African dishes, or vinegar, or oil, either singly or in combination;

“main ingredient” means the ingredient(s) in a foodstuff that have the greatest mass, excluding water;

“main panel” means that part of the label that bears the brand or trade name of the product in greatest prominence or any other part of the label that bears the brand or trade name in equal prominence;

“meat” means the safe, clean and sound skeletal musculature of any healthy food animal, including game or bird species, with or without fat, connective tissue, lymphatic and nervous tissue, bone and cartilage, blood vessels and residual blood, scraped skin (pigs) and defeater skin (poultry) that are naturally associated with such musculature *in situ* of the dressed carcass and head, excluding the musculature of the lips, tongue, snout, scalp and ears, offal, and mechanically recovered meat;

“mechanically pressed” in terms of oil manufacturing means the oil that has been obtained by applying mechanical pressure in the absence of light and air and has reached temperatures not exceeding 50°C (122°F) without applying any external heat during the entire journey from seed to bottle to shelf and which has not been degummed, refined, bleached or deodorised;

“mechanically recovered meat” means the residual muscular tissue, collagen, marrow and fat which has been recovered, using mechanical equipment, from animal bones or poultry carcasses

from which the bulk of meat has been previously manually removed, and shall have a maximum Calcium content of 0,2%;

"MDR" means the minimum dietary requirement of essential nutrients for nearly all healthy individuals ~~in a particular life stage and gender group~~ to maintain health and which is suitable for labelling purposes;

"meta-analysis" means a quantitative summary (pooled analysis) of several individual studies of a similar type. Both intervention and observational studies can be meta-analysed;

"naked bread" means bread, bread rolls and bread buns displayed for sale without being prepacked;

"name" means a word or words giving a true description of the nature of the food product concerned, sufficiently precise to avoid misleading or confusing the consumer in regard to the true nature, physical condition, type of packing medium, style, condition and type of treatment it has undergone to enable such product to be distinguished from products which it could be confused with;

"non-nutritive sweetener" means a sweetener listed in Regulations Relating to the Use of Sweeteners in Foodstuffs under the Act, or a mixture of such non-nutritive sweeteners, of which an amount with the sweetening equivalent of 5g of sucrose does not have an energy value of more than 8kJ;

"nutrient" means any natural or synthetic substance consumed as a constituent of a foodstuff, which provides energy or which is needed for growth, development and maintenance of life or of which a deficit will cause characteristic biochemical or physiological changes to occur;

"nutrient content claim" means a claim that describes the level of a nutrient contained in a foodstuff;

"nutrition claim" means any representation that refers to a specific nutrient content of a particular foodstuff namely a nutrient content claim or a comparative claim;

"observational study" means a study wherein researchers do not intervene but only observe outcomes of interest and the levels of their suspected causes;

"offal" means any edible part, including blood and its products, of any animal or bird that is not included in the definition of meat or mechanically recovered meat;

"omega-3 fatty acids" means the sum of alpha-linolenic acid (ALA) and the omega-3 derivatives, docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA);

"poultry" means any chicken, duck, goose, guinea fowl, ostrich, partridge, pheasant, pigeon, quail, turkey and the chicks thereof;

"prebiotics" means a non-digestible food component or ingredient with a degree of polimerisation (DP) between 2 to 60 which has a proven beneficial effect on the host's health by selectively stimulating the growth and metabolic activities of one or a limited number of beneficial, indigenous, intestinal bacteria, thus improving the host's intestinal balance;

"prepacked", means the packaging of a foodstuff in packaging material ready for sale to the consumer or to a catering establishment, so that such foodstuff cannot be altered without opening or changing the packaging but does not include individually wrapped one-bite sugar confectionary or chocolate confectionery which is not enclosed in any further packaging material and is not intended for sale as individual items, and does not include the outer containers of bulk stock;

"preservative" means an additive that prolongs the shelf life of a food by protecting against deterioration caused by microorganisms;

"pressurised container" means a container of metal, glass or plastic, or a composite of these materials, containing liquids or pastes and a propellant which discharges the contents under pressure through a valve system;

"prevention of disease" means hindrance of the onset of disease. This hindrance may reduce the probability or risk of a disease to zero, but it usually reduces the risk to a lesser degree;

"probiotic" means live bacteria indigenous to the human intestinal tract, which, when consumed in adequate numbers, beneficially affect the health and functioning of the host's intestinal tract by modulating mucosal and systemic immunity as well as improving the nutritional and microbial balance and are therefore considered a dietary adjuvant and are added to foodstuffs for their prophylactic and health enhancing properties;

"probiotic bacteria" means bacterial strains selected mainly from the genera *Lactobacillus* and *Bifidobacterium* for which no drug or antibiotic resistance has been reported in independent studies published in credible, acceptable, peer-reviewed scientific journals, and these strains can be used in biotherapeutics for therapeutic purposes or added to foodstuffs for their prophylactic and health enhancing properties;

"probiotic properties" means that the probiotic bacteria that are able to survive passage through the digestive tract without being destroyed by the action of hydrochloric acid, bile and pancreatic enzymes and that can adhere to the intestinal epithelium, colonise the intestinal tract and that are capable of proliferating in the gut, where they produce anti-microbial substances which control and destroy

pathogenic bacteria, viruses, yeasts and fungi and in addition, play an important part in the maturation and stimulation of the human immune system;

"processed" means a foodstuff that has been subjected to any process which alters its original state, excluding harvesting or slaughtering and preparing by cleaning; decapitating; defeathering; dehairing; eviscerating; portioning; removing of fish scales, blemishes, fruit and vegetable foliage or shells; fermentation of tea; sectioning; mincing; deboning; removing the skin of fruits, vegetables and animals; washing; chilling, freezing, freeze-drying, drying of legumes and irradiation;

"prolamins" means the fraction from gluten, which can be extracted by 40 to 70% of ethanol; the prolamin from wheat being gliadin, from rye secalin, from barley hordein and from oats avenin and of which the method of analysis is referred to in the Guidelines;

"protein" means the protein content calculated using the formula: protein = total Kjeldahl nitrogen x the appropriate factor as listed in the Guidelines;

"randomised controlled trial (RCT)" means a study design in which subjects are randomly allocated to study groups. As a result the groups will expectedly not differ systematically, except with regard to an intervention that one group will undergo and the other will not. As a result, the effects observed can principally be ascribed to the intervention;

"rare allergen" means any food allergen not classified as a common allergen and rubber protein from latex;

"reduction of disease risk claim" means a claim that relates the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition;

"refining" in terms of oils means oils that are mixed with a corrosive base such as sodium hydroxide (NaOH), (caustic soda) or with a mixture of NaOH and Sodium carbonate (Na_2CO_3) to remove any free fatty acids at a temperature of about 75° C (167°F) after the degumming process, resulting in the removal of more phospholipids, protein-like substances and minerals. The oil may still contain pigments, usually red or yellow at this stage;

"reputable laboratory" means a laboratory which has the required accreditation for each method used for the purpose of nutritional and microbiological information on labels of foodstuffs or nutritional supplements by the South African National Accreditation Services (SANAS) or another recognised international accreditation authority who is a member of the International Laboratory Accreditation Cooperation (ILAC) and part of the International Laboratory Accreditation Arrangement;

"resistant starch (RS)" means the fraction of starch not absorbed in the small intestine and consists of physically enclosed starch (RS1), certain types of raw granules (RS2) and retrograded amylose (RS3). Modified starches used as food additives may also be partially resistant (RS4);

"SANAS" means the South African National Accreditation Services, a non-profit organisation registered in terms of section 21 of the Companies Act, 1973 (Act 61 of 1963) registration No.199600354/08;

"sell by" or "display until" means the last date of offer for sale to the consumer after which there remains a reasonable storage period at home during which the product is still safe and edible;

"sell by retail" means sell to a person buying other than for the purpose of resale, but does not include selling to a caterer for the purposes of his catering business, or to a manufacturer for the purposes of his manufacturing business;

"serving" or "portion" in relation to a foodstuff, means the mass, volume or number, as the case may be, of a foodstuff which is typically consumed as a single serving by most people and listed in Annexure 7;

"single ingredient agricultural commodities" means individual fresh fruit and vegetables, single ingredient frozen vegetables, single ingredient dehydrated vegetables without any added additive or ingredient, single ingredient dried fruit without any added additive or ingredient, eggs (hens' and ostrich), fresh or frozen unprocessed fish and marine products, unprocessed meat of poultry, bovines, goats, sheep, and pigs, black and green tea, honeybush tea, rooibos tea, vinegar, honey, single ingredient whole grain cereal kernels, single ingredient rice, single ingredient raw oil seeds, raw soya beans, raw groundnuts without any added ingredient or additive, single ingredient dry legumes, milk, dairy cream, raw fresh tree nuts without any added additive or ingredient, and fresh or dried coconut flesh;

"soy protein" means a soy protein product with a Protein Digestibility Corrected Amino Acid (PDCAAS) value of at least 91;

"starch" means edible starch as listed in Guidelines 3 and exclude chemically modified starches;

"strict vegetarian diet" means a diet which includes ingredients of multi-cellular plant, fungal, algal and bacterial origin, but which excludes all ingredients and additives derived from animal origin; and the expression "vegan diet" may be used instead of "strict vegetarian diet";

"substance" means a collective term for any chemical, microbiological or physical component present in or added to a foodstuff;

"substantial transformation" means such a fundamental change in form, appearance or nature that the goods existing after the change are new and different goods from those existing before the change;

"sugar confectionery" means any foodstuff which is ready for consumption without further preparation and of which carbohydrate sweetening matter is a characteristic ingredient, and includes sweetened liquorice, chewing gum and meringues, but does not include any chocolate or flour confectionery, edible ice, table jellies or sugar, and which may contain non-nutritive sweetening agents;

"sugar(s)" mean(s) any one or any combination of the following sugars such as xylose and mono- and disaccharides such as corn syrup, deionised, deflavoured fruit concentrates and juices, dextrose, dextrose syrup, fructose, fructose syrup, glucose, glucose syrup, invert sugar, lactose, maltose, maltose syrup, sucrose, and sucrose syrup;

"synbiotic" means a combination of a prebiotic and an approved probiotic in a food product;

"the Act" means the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972);

"total carbohydrates" means the sum of all the sugars, oligosaccharides and polysaccharides as indicated in the Guidelines;

"total lean meat content", per cent, means the result after the mass percentage of nitrogen, represented by the non-meat proteinaceous material present in the product, multiplied by a factor of 30, has been deducted from the lean meat content per cent;

"trace" in the case of tests that have a limit of quantification and a limit of detection, means that the amount of the analytical result of a substance is below the limit of quantification; and in the case of tests that only have a limit of detection, means that the amount of the analytical result of a substance is below the limit of detection;

"traceable/traceability/product tracing" means the ability to follow the movement of a food through specified stage(s) of production, processing and distribution;

"trans-fat" means the sum of all the trans fatty acids of all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration as derived from partial hydrogenation of vegetable oils, but exludes trans-fat naturally occurring in meat and dairy products;

"tree nuts" means almonds (*Amygdalus communis L.*), brazil nuts (*Bertholletia excelsa*), cashew nuts (*Anacardium occidentale*), hazel nuts (*Corylus avellana*), macadamia nuts (*Macadamia ternifolia*), pecan nuts (*Carya illinoiesis[Wangenh] K. Koch*), pistachio nuts (*Pistachia vera*) and walnuts (*Juglans regia*);

"typical values" means the real, typical, representative, nutritional or microbiological values of a foodstuff which is sampled according to the relevant criteria stipulated in the Guideline and which is analysed in accordance with the methods described in these regulations and the Guidelines, and which has the required accreditation by the South African National Accreditation Services (SANAS) or other recognised international accreditation authority which are part of the ILAC arrangement;

"vegetarian" means the ingredients are of multi-cellular plant, fungal, algal and bacterial origin to the exclusion of all animal flesh and products obtained from the slaughter of an animal, such as gelatine, animal fats, caviar and roe, and may include honey, dairy foods produced without any slaughter by-products, and/or unfertilised eggs obtained from live animals;

"Use by" means the date which signifies the end of the period of durability under the stated storage conditions as specified on the label by the manufacturer, after which the product probably will not have the quality attributes normally expected by consumers and after which date the food should not be regarded as safe for human consumption;

"water" means a, transparent, colourless, tasteless, odourless compound of one oxygen and two hydrogen molecules in a liquid or frozen state with no energy value to which no additive or nutrient or any other substance, except carbon dioxide has been added;

"whole grains" means grains from cereals, which, after milling, contain all the components of the original whole kernel, namely germ, fiber and endosperm in the same amounts and ratio as the original whole kernel.

GENERAL PROVISIONS

2. No person shall -

(a) manufacture, import, pack, supply, distribute, sell, display or offer any pre-packaged foodstuff for sale, unless the foodstuff container, or the bulk stock from which it is taken is labelled in accordance with these regulations;

(b) advertise a foodstuff in any manner, which contains any information, claim, reference or declaration not permitted on the label in accordance with these regulations; and

(c) offer for sale a foodstuff of which the portion size exceeds the portion size indicated in Annexure 7.

3. A non-prepacked foodstuff that is displayed for sale shall have the particulars with which it is required to be labelled in terms of these regulations appearing on display in its immediate proximity.

Nutritional information

4. (1) A nutrition or health claim that is made on the label shall be accompanied by the appropriate nutritional information i.e., the real, typical values as determined by chemical or microbiological analysis in accordance with the methods recommended in these regulations and Guidelines or Codex, and where nothing is recommended an accredited method by SANAS and/or ILAC.

(2) Where voluntary nutritional information is provided on the label but no nutrition, Glycaemic Index or health claim is made, the nutritional information from the latest edition of the National Food Composition Tables by the South African Medical Research Council (MRC) may be used as the source of information in the case of single ingredient agricultural commodities: Provided that in cases where no suitable information is available from the above-mentioned Food Composition Tables, other recognised Food Composition Tables or in-house analytical data may be used and an indication of the source of the information shall be indicated as a footnote under the table with nutritional information.

(3) Where voluntary nutritional information is provided in the absence of any nutrition, Glycaemic Index, or health claim for foodstuffs other than single ingredient agricultural commodities, the source of the nutritional information shall be the real, typical values as determined by chemical or microbiological analysis in accordance with the methods recommended in these regulations and Guidelines or Codex.

5. Subject to the provisions of regulation 6, information required to appear on any label shall be -

(a) in at least one official language of the Republic of South Africa; and

(b) clearly visible, legible and indelible and the labels of pre-packaged foodstuffs shall be applied in such a manner that they do not separate from the container.

Letter sizes

6. The name of a foodstuff of which the main panel exceeds 12 000mm^2 shall be at least 4mm in height for the smallest letter and words which qualify the name of such foodstuff or which are an essential part of the description thereof shall be in prominent, distinctive, legible letters of the same size, font, colour, prominence and legibility not less than one third of the letter size of the biggest letter of the name, except in cases -

(a) where specific requirements for the letter size of the name are stipulated in the provisions of the Agricultural Products Standards Act, 1990 (Act 119 of 1990); and

(b) where the area of the main panel of the label is less than 12 000mm^2, in which case the letter size of the name and description thereof as described in this regulation may be proportionally smaller in accordance with the directions in the table below, provided that the minimum height to which the letters may be reduced shall not be less than 1mm:

Area of main panel in mm^2	**Percentage (%) of prescribed height**
8 000mm^2 to 12 000mm^2	85
5 000mm^2 to 8 000mm^2	70
3 000mm^2 to 5 000mm^2	50
2 000mm to 3 000mm^2	25

7. The listing of ingredients and proportions of ingredients shall be in a letter type of uniform size, colour, font and prominence throughout and the first letter may be a capital letter.

Identification

8. The label of a foodstuff shall contain -

(a) on the main panel, the name of the particular foodstuff, provided that where the name is not a proper description of the foodstuff, the name shall be accompanied by a appropriate description and where a name or names have been established for a food in a Codex Alimentarius Standard, at least one of these names shall be used;

(b) the name and address of the manufacturer, packer, seller or person on whose behalf the foodstuff is prepacked, provided that in the case of imported foodstuffs, the name and address of the importer or distributor shall appear on the label as well;

(c) instructions for use of a foodstuff, where it would be difficult to make appropriate use of such foodstuff without such instructions;

(d) the list of ingredients required by regulations 19 to 27**,** where applicable;

(e) special storage conditions, where applicable, in capital (upper-case) letters not less than 3,0mm in height; and

(f) the net contents of the container.

9. The net contents shall be declared in the metric system in accordance with the requirements of the Trade Metrology Act, 1973 (Act 77 of 1973).

Country of origin

10. Unless otherwise required by the provisions of the Agricultural Products Standards Act, 1990 (Act 119 of 1990), the country of origin of a foodstuff shall be declared on the label as follows:

(a) "Product of (name of country)" if all the ingredients, excluding additives, nutrients and microbiological cultures designated for use in foodstuffs are from one specific country; or

(b) "Produced in (name of country)", "Manufactured in (name of country)" or "Packed in" where not all the ingredients, excluding additives, nutrients and microbiological cultures designated for use in foodstuffs are from the country producing or packing the final product.

Batch identification

11. A container of a foodstuff shall be clearly marked in such a way that the producing factory where a final product is produced as well as the details regarding the specific batch is easily identifiable and traceable.

Date of durability

12. (1) No person shall import or manufacture or sell a foodstuff unless a date of durability is clearly indicated on the label or container of such foodstuff, except those foodstuffs indicated in point 1 of Annexure 4.

(2) The date of durability shall be indicated by the manufacturer as either a "best before" or "use by" date, depending on the nature of the product as indicated in Annexure 4; Provided the "best before" may be abbreviated as "BB" but the "use by" shall be written out in full.

(3) A "use by" date shall be mandatory for all foodstuffs listed under point 2 of Annexure 4.

(4) The date of durability may not be removed or altered by any person.

(5) In cases where several items are included in an outer wrapper or sleeve, which might be discarded, the date mark shall appear on the packaging that will be retained by the consumer until consumption.

(6) The date of durability shall be indicated in the order, Day-Month-Year, when numbers only are used to indicate the date of durability and in the case where the month is indicated in letters, either written out in full or abbreviated, and the year is written out in full, the sequence of the day, month and year can be in any order.

(7) The date shall be preceded by appropriate words, either "best before" or "use by" or similar words as defined in regulation1.

(8) A "sell-by" date may be added in addition to the "best before" and/or "use by" date.

13. No person may offer for sale, donate, re-label or re-use any foodstuff after the “use-by” date has expired.

Prohibited statements

14. The following information or declarations shall not be reflected on a label or advertisement of a foodstuff:

(a) words, pictorial representations, marks or descriptions which create an impression that such a foodstuff is supported by, endorsed by, complies with or has been manufactured in accordance with recommendations by-

(i) medical or dental practitioners, psychologists or other persons who carry on a supplementary health service referred to in the Health Professions Act, 1974 (Act 56 of 1974) or The Allied Health Professions Act, 1982 (Act 63 of 1982), individually or through any professional or consumer advisory organisation consisting of one or more health practitioners;

(ii) organisations, associations, foundations and other entities, unless approved by the Director-General and can provide proof of the fact that they are involved in generic health promotion which will improve the nutritional status of people and the directions of the organisation, association or foundation do not contradict the requirements of these regulations;

(b) an individual’s endorsement or testimonial in the form of a picture, written or verbal statement or in any other form, unless it is based on an evidence-based nutrition motivation and submitted for pre-market approval to the Director-General;

(c) a manufacturer’s or seller’s endorsement in the form of a logo, mark, symbol, written or verbal statement or any other manner of communication with regard the nutritional, health or safety properties of the foodstuff brought to the attention of the public, unless it is valid according to the provisions of these regulations and appropriate substantiation can be provided to an inspector within 24 hours;

(d) the words "health" or “healthy" or other words or symbols implying that the foodstuff in and of itself has health-giving properties in any manner including the name or trade name , except in the case of the fortification logo for food vehicles as determined by regulations made under the Act and regulation 53;

(e) the words "wholesome" or "nutritious" or any other words with a similar meaning in any manner including the name and trade name;

(f) a claim that a foodstuff provides complete or balanced nutrition in any manner including the name and trade name;

g) notwithstanding the provisions of regulation 58(e)(ii and iii), a claim that the foodstuff, is suitable for diabetics

(h) a claim that a foodstuff contains or was manufactured with live AB cultures (bacterial strains from the genera *Lactobacillus* and *Bifidobacterium* or other typical yoghurt bacteria) or

similar words when it does not comply with the qualifying conditions for a probiotic as specified in regulations 63;

(i) a claim that a foodstuff provides "sustained energy" or words, similar unless the foodstuff qualifies as a low Glycaemic Index category foodstuff as specified in regulation 58 (a to c), and was tested according to the method described in the Guidelines and the Glycaemic Index category is indicated in the table with nutritional information;

(j) a claim that implies that a foodstuff with a low carbohydrate content may have any health or slimming benefits;

(k) subject to the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the word "cure" or any other medicinal claim, except those health claims permitted in terms of these regulations;

(l) a claim "Not made from concentrate" in the case of a fruit or vegetable juice or blend thereof unless the juice is freshly squeezed from the fresh fruit or vegetable and sold within 24 hours;

(m) a claim that implies that a foodstuff may have any detoxification or any similar benefits unless the claim has been evaluated and approved according to the requirements of Regulations 61.

Negative claims

(15) (1) No claim, declaration or implication shall be made on the label of a foodstuff that such foodstuff –

(a) alone possesses a particular characteristic, property or substance when in fact similar foodstuffs in the same class or category also possess the same characteristic, property or substance; unless –

(i) the characteristic, property or substance is often found or commonly present in the referred-to class or category of foodstuffs; and

(ii) the claim, declaration or implication is worded in a generic manner as follows: "(generic or category name of foodstuff but no brand name) naturally contains (name of characteristic, property or substance)";

(b) is free from a particular characteristic, property or substance when in fact similar foodstuffs in the same class or category are also free from the same characteristic, property or substance; unless –

(i) the characteristic, property or substance is often or commonly absent in the referred-to class or category of foodstuffs;

(ii) the claim, declaration or implication is worded in a generic manner as follows:

i. "A naturally (name of characteristic, property or substance) free food"; or

ii. "(generic or category name of food but no brand name) is a naturally (name of characteristic, property or substance) free food" so as not to

reflect negatively on other similar foodstuffs in the same class or category.

(2) Notwithstanding the provisions of regulation 15(1),-

(a) where an additive, which is permitted for a particular class or category of ffoodstuffs under specific regulations under the Act, is absent in the foodstuff under foodstuffs under specific regulations under the Act, is absent from the particular brand name foodstuff, the claim, declaration or implication, when used, shall be worded as follows: "(name of additive) free"; and

(b) where a claim, declaration or implication about a particular additive, which is not permitted for a particular class or category of foodstuffs under specific regulations under the Act, is made for information purposes, the claim, declaration or implication shall be is worded in a generic manner as follows: "A (name of additive) free (name of category or class of food) as is the case with all (name of category or class of food)";

(3) No declaration referred to in regulations 15(1 to 2) shall be made in relation to foodstuffs listed in Annexure 6.

16. A label of a foodstuff shall not refer to the Act, the Department of Health or any Provincial or Local Government, or any official of the said Department or Provincial or Local Government.

Mandatory warning on certain foodstuffs

17. The label of a foodstuff packaged in a pressurised container shall contain the following statement in capital (uppercase) letters of not less than 3,0mm in height:
"WARNING - PRESSURISED - DO NOT PUNCTURE OR STORE ABOVE 50^0C".

SPECIAL PROVISIONS

Seasonal ingredients

18. Where, owing to the climatic or seasonal contingencies, it is not possible to comply with a list of ingredients as indicated on the label, the names of ingredients other than the main ingredient that might be present shall appear consecutively but not necessarily in descending order of mass or volume in the list of ingredients, preceded by the expression "and/or".

Order of list of ingredients

19. Ingredients of a blended, compounded or mixed foodstuff, including mixtures of herbs and spices sold as such, shall be listed on any label in descending order of mass at the time of manufacture under the heading "Ingredients".

20. Subject to regulation 31, added water shall be declared in the list of ingredients in the appropriate order.

21. Where an ingoing concentrated or dehydrated ingredient is reconstituted or partially reconstituted for use in the manufacturing of a foodstuff, the ingredient shall be preceded by the appropriate descriptive words such as “reconstituted (name of ingredient) concentrate” or “reconstituted, dried (name of ingredient)” or whatever is applicable, in the list of ingredients.

22. Where a foodstuff consists of or contains mixed fruit, nuts or vegetables and no particular fruit, nut or vegetable predominates significantly with respect to mass, those ingredients may be listed in any order of mass if -

(a) in the case of a foodstuff which consists entirely of such mixture, the heading of the list of ingredients includes or is accompanied by the words "in variable proportions" or other words indicating the nature of the order in which the ingredients are listed; and

(b) in the case of a foodstuff, which contains such mixture, that part of the list where the names of the said ingredients appear is accompanied by the words "in variable proportions" or other words indicating the nature of the order in which those ingredients are listed.

23. The following ingredients of a foodstuff, may be shown in any order at the end of the list of ingredients:

(a) Herbs or spices not exceeding 2% by mass either singly or in combination

(b) Vitamins; and

(c) Minerals, subject to sub regulation 57(6).

Naming of ingredients

24. The name used for an ingredient in a foodstuff in a list of ingredients on any label shall -

(a) be the name used for such ingredient when independently sold as a foodstuff; and

(b) in the case of a microbiological culture, indicated according to its purpose, such as butter culture or cheese culture or yoghurt culture or lactic acid producing culture or starter culture, or whatever the case may be.

25. Subject to the provisions of regulations 40 to 45, any additive which is added to or used in a foodstuff to perform the function of one of the categories of ingredients listed in Annexure 1, shall be indicated in the list of ingredients and may be indicated by the name of the category and if an additive is added to or used in a foodstuff to serve more than one such function, it shall be indicated by the name of the category that represents the principal function performed in that foodstuff, provided that flavourants shall be indicated as natural or artificial flavourant.

26. Pectin-containing foodstuffs such as jelly and fruit jelly containing less than 0,6% added pectin or pectinaceous material and jams containing less than 0,3% of added pectin are exempted

from the requirement to declare the presence of thickeners in the list of ingredients provided no other thickeners than pectin were used in the product.

27. Names such as “salt” or “sodium chloride”, “vinegar” or “acetic acid”, “brine”, or “syrup” may be used in the list of ingredients.

Quantitative Ingredient Declarations (QUID)

28. (1) Where, in the case of a foodstuff, the labelling places special emphasis on the presence of one or more valuable or characterising ingredients, or where the description has the same effect, the ingoing percentage of this ingredient at the time of manufacture, shall be declared -

(a) in accordance with the Guidelines;

(b) next to the name, or in the name or claim in which the ingredient is mentioned, emphasised or implied, or in the list of ingredients.

(2) No ingredient shall be emphasised in any manner if the ingoing percentage of the emphasised ingredient is less than 2% by weight calculated from the recipe at the mixing bowl stage, except in the case of an ingredient or category of ingredients used in small quantities for the sole purpose of flavouring, such as quinine in tonic water, garlic and other herbs and spices when used at a level of 2% or less.

(3) Notwithstanding the provisions of regulations 28(1 and 2), where a foodstuff contains whole grains, fruit or vegetables, the ingoing percentage of the whole grains, fruit or vegetables at the time of manufacture, shall be declared on the main panel.

Compound ingredients

29. Where a compound ingredient is used in the preparation of a foodstuff, the names of the ingredients of the compound ingredient shall be listed in parenthesis after the name of the compound ingredient in the list of ingredients.

30. Where a compound ingredient for which a name has been established in a Codex Alimentarius Standard or in South African legislation, constitutes less than 5% of the foodstuff as sold, the ingredients need not be listed, excluding food additives which serve a technological function in the finished product and those common allergens which are known to cause allergic or intolerance reactions and which are specified in regulations 46 to 50, and which shall be listed regardless of the amount.

Added Water

31. Subject to regulations 21, 32 and 73(1)(c), water that is added as an ingredient of a foodstuff shall be declared in the list of ingredients of such foodstuff unless-

(a) it is used in the manufacturing of the foodstuff solely for the purpose of wetting a dry additive or ingredient; or

(b) it is part of brine or syrup and declared as "brine" or "syrup" in the list of ingredients; and

(c) the water, which is added, does not exceed 5% of the finished product.

Labelling of manufactured, processed and fresh processed meat products and mechanically recovered meat

32. (1) Manufactured meat products shall -

(a) specify all the protein sources in descending order of prevalence in the list of ingredients; Provided that the type of animal or bird, where applicable, forms part of the name of protein source;

(b) contain only protein sources with a PDCAAS (Protein Digestibility Corrected Amino Acid Score) value of at least 90;

(c) indicate the quantitative ingredient declaration (QUID) as a percentage for all protein sources in parenthesis after each protein source in the list of ingredients; and

(d) wherever mechanically recovered meat is used as an ingredient stated as mechanically recovered meat and the name of the species shall be stated in parenthesis, provided that mechanically recovered meat shall not be abbreviated as "MRM" but written out in full.

(2) Subject to the requirements of Regulation 28(1) processed meat products shall, when having a total lean meat content of less than 100%, indicate the quantitative ingredient declaration (QUID) as a percentage for the meat and water absorbed or injected, whatever is applicable.

(3) Subject to the requirements of Regulation 28(1) fresh processed meat products shall indicate the quantitative ingredient declaration (QUID) as a percentage for the meat, and the water that was absorbed and/or injected, whatever the case may be.

Fats and oils

33. (1) The class name or origin of all fats and oils, single or in combination, which have been used in a foodstuff shall be –

(a) identified in the list of ingredients either as "vegetable", "animal", "fish" or "marine"; and

(b) qualified by the term "hydrogenated", "partially hydrogenated", "interesterified" or a combination of the aforementioned, as applicable.

(2) (a) No health or nutrition claim shall be made for a foodstuff which contains a partially hydrogenated fat; and

(b) Whenever a fully hydrogenated fat or partially hydrogenated fat has been used as an ingredient in a foodstuff, the real analytical values of all the following fatty acid components shall be declared in the table with nutritional information, as follows:

Total fat-		:	…g
of which	saturated		…g
	trans fat		…g
	poly-unsaturated		…g
	monounsaturated		…g

(3) Subject to the requirements of regulation 52(2) and Annexure 6, no vegetable oil or vegetable oil blend shall claim, “cold-pressed”, “mechanically pressed” or any other words with a similar meaning unless it-

(a) has been mechanically pressed without the application of any external heat;

(b) has been certified organic by a competent national or international certifying organisation or contains no trace of any chemical /pesticide residues as the case may be;

(c) still contains all the nutrients in amounts naturally present and typical of the original seed from which the oil has been produced from;

(d) has not been subjected to external heat at any stage in the manufacturing process;

(e) has not been chemically treated in or by any of the following processes: degumming, refining, bleaching or deodorizing; an

(f) contains no trans fats and shall not be interesterified.

(4) No vegetable oil or vegetable oil blend that does not comply with the criteria referred to in Regulation 33(3) above shall make any health or nutrition claim.

Bulk stock

34. Where a foodstuff is sold from bulk stock, such bulk stock container shall be labelled in accordance with all the labelling requirements for individually packed foodstuffs, and the lettering shall be of such a size and so displayed that it is easily legible, unless the contents of the bulk container are individually packed and labelled.

Small packages

35. The packaging of a pre-packed foodstuff that has a total exterior area of 2000mm^2 or less, including single once-off use 10g or less size packages of herbs and spices, are exempted from the requirements of labelling, except for the declaration of the name of the foodstuff, the address of the manufacturer, an appropriate date of marking, the declaration of an allergen, if applicable and the declaration according to Regulation 69 that the product has undergone irradiation if applicable.

Food additives

36. The label of any pre-packed food additive or blend of food additives shall -

(a) bear the words "for use in foodstuff" or "for use in food" or "food additive" or "blend of food additives";

(b) in the case of sulphur dioxide compounds, state the maximum and minimum percentage of sulphur dioxide the contents will yield;

(c) state its common chemical name where applicable;

(d) in the case of a food colourant or a blend of food colourants, bear the words "food colourant" or "food colouring" or "food colour" and the common chemical name or names as well as the Colour Index Number(s) or INS (International Numbering System) number;

(e) in the case of food additives with a shelf-life not exceeding 18 months, indicate the date of maximum durability using such words as "Use before X", where “X” is the latest recommended date for use; and

(f) when available, indicate the INS number.

Frozen and chilled foodstuffs

37. The words -

(a) “RAW - KEEP FROZEN" or "UNCOOKED - KEEP FROZEN", as the case may be, shall appear in capital (upper-case) letters not less than 3,0mm in height on the main panel of the label of every package containing uncooked foodstuffs that must be kept frozen;

(b) "COOKED - KEEP FROZEN" or "PARTLY COOKED - KEEP FROZEN - DO NOT REFREEZE WHEN THAWED", as the case may be, shall appear in capital (upper-case) letters not less than 3,0mm in height on the main panel of the label of every package containing cooked or partly cooked foodstuffs that must be kept frozen;

(c) “KEEP REFRIGERATED" or "KEEP FROZEN", shall appear on the main panel of the label in capital (upper-case) letters not less than 3,0mm in height in respect of foodstuffs that rely on chilling or freezing conditions for preservation;

(d) "PREVIOUSLY FROZEN - DO NOT REFREEZE", in the case of cooked or partly cooked frozen foodstuffs which have been thawed for subsequent sale, must appear legibly in capital (upper-case) letters not less than 3,0mm in height in the immediate proximity to such products and in clear view of the customer; and

(e) “FRESH” in respect of frozen foodstuffs that are thawed for subsequent sale shall not be permitted.

Food vending machines

38. The front of a food vending machine from which any foodstuff is sold shall have a notice indicating the name of the foodstuff, except where such name appears on the label of the foodstuff in such a manner as to be easily visible and legible to a prospective purchaser from the outside of the machine.

Pictorial representation

39. The pictorial representation on the label or any advertisement of a foodstuff -

(a) may not be presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding the contents of the container or its character, origin, composition, quality, nutritive value, other properties in any respect; and

(b) not contained in any package, which might lead the consumer to believe that such foodstuff is contained in such package, shall bear the words "Serving suggestion" or words indicating the justification for the use of such pictorial representation on, or in the immediate proximity to, such pictorial representation, in bold, conspicuously placed, capital letters not less than 3,0mm in height, except in the case of sugar confectionary, chocolate confectionary and table jellies.

Indication of food additives and special ingredients

40. No person shall sell any foodstuff containing the colourant tartrazine, also known as E 102 or Yellow No. 5, unless the word "tartrazine" appears in the list of ingredients.

41. The presence of any preservative shall be indicated on any label by the common chemical name of the preservative, either followed or preceded by the word "preservative" or, in the case of sodium or potassium nitrite and sodium or potassium nitrate used in cured meat products, followed or preceded by the words "curing agent".

42. Anti-oxidants shall be indicated by the common chemical name or abbreviation as appropriate, in the list of ingredients: Provided that where a list of ingredients is required this information shall be included in such list of ingredients.

43. The final amount, single or in combination of preservatives and/or anti-oxidants mentioned in column 1 below, when present in an amount of less than the amount mentioned in column II in the final foodstuff need not be mentioned in the list of ingredients.

I	II
Sulphur dioxide or related compounds such as sodium sulphite, sodium hydrogen, sulphite (sodium bisulphite), sodium metabisulphite, potassium, metabisulphite, calcium sulphite, calcium hydrogen sulphite and calcium bisulphite	10mg per kilogram per foodstuff as packed or ready to eat

44. All preservatives as well as tartrazine and the following glutamates when added to a foodstuff, shall be indicated on the label by the common chemical name in the list of ingredients:

- monosodium glutamate (MSG);
- L-glutamic acid;
- sodium hydrogen L-glutamate;

- potassium hydrogen L-glutamate;
- mono potassium glutamate;
- calcium dihydrogen di-L-glutamate;
- calcium glutamate;
- monoammonium glutamate; and
- magnesium diglutamate.

45. (1) With the exception of preservatives, anti-oxidants and tartrazine, it shall not be necessary to refer in the list of ingredients to any food additive-

(a) that is present in the foodstuff solely because it was a constituent of an ingredient of such foodstuff: Provided that the food additive does not perform the same technological function in the final foodstuff to which it was added, as it had in the original foodstuff of which it was a constituent; and

(b) that, if the foodstuff were labelled with a list of ingredients, would not be required to be named in the list by reason of these regulations.

(2) Notwithstanding the requirements of subregulation (1), any additive which is added to a carrier which may be a common allergen itself or may be contaminated with a common allergen, shall indicate the origin of the carrier in parenthesis after the name of the additive in the manner [name of additive(name of acommon allergen)]

Allergens

46. (a) Where an ingredient derived from egg, milk, crustaceans and molluscs, fish, peanuts, soybeans, tree nuts or wheat or the products of these, is added to a foodstuff or nutritional supplement, the word “egg”, “milk”, “crustaceans”, “molluscs”, “fish”, “peanuts”, “soybeans” or “tree nuts” or “wheat” as the case may be, shall be indicated in parenthesis after the name of such ingredient in the list of ingredients, if it is not self evident from the name of the ingredient; and

(b) Where a natural flavourant is added to a foodstuff or nutritional supplement, the common name of the origin of the flavourant shall be indicated in parenthesis after the name natural flavourant, e.g. “natural flavourant (banana)”.

47. Where an ingredient which is derived from cereals of all *Triticum* species such as kamut and spelt, wheat, durum wheat, rye, barley, oats, or their crossbred varieties or the products thereof, is added to a foodstuff -

(a) the name of the specific cereal species shall be specified in the name of the ingredient in the list of ingredients with the word “gluten” in parenthesis after the name of the cereal; and

(b) the claim “gluten-free” shall not be permitted unless the end-product contains no prolamins from the cereals mentioned above or the products thereof, the gluten level does not

exceed 20 mg per kilogram foodstuff as analysed according to Codex and it is not possible to detect the presence of gluten with the Enzyme-Linked Immunosorbent Assay R5 Mendez (ELISA) test for gluten where 1 mg/kg gliadins corresponds to 2 mg/kg gluten.

48. (a) Common allergens which are hidden in the name of an ingredient and of which some examples are indicated in the Guidelines, shall be indicated in parenthesis after the name of such ingredient in the list of ingredients, or alternatively, the word "egg", "milk", "crustaceans", "molluscs", "fish", "peanuts", "soybeans", "tree nuts", "wheat", "gluten" *etc.,* should form part of the name of the ingredient, e.g., "egg albumin"; and

(b) The presence of rare allergens in or on the foodstuff or its packaging material has to be disclosed by manufacturers upon request by a consumer, inspector or the Department.

49. No foodstuff may be contaminated with a common allergen as a result of the manufacturing of different foodstuffs on the same production line or any other manufacturing circumstances, including packaging material, without informing the consumer in an appropriate manner as follows:

(a) In the case where the manufacturer can demonstrate that the contamination is unavoidable despite having on record documentation to prove that -

(i) a comprehensive Hazard Analysis Critical Control Point (HACCP)–based evaluation of the manufacturing process and ingredient supply as referred to in the Guidelines has been carried out and the manufacturer operates a system of Good Manufacturing Process based on the HACCP assessment according to the Guidelines; and

(ii) suitable testing for the specific allergens is carried out on a regular basis,

the following words shall appear in the list of ingredients or in the direct vicinity thereof, in bold, legible letters **"Not suitable for people with (name of allergen) allergy"**; or

(b) in a case where a manufacturer cannot demonstrate due diligence through HACCP and ELISA testing described in paragraphs (i) and (ii) above, the words **"unavoidably contaminated with…(name of allergen)",** shall be indicated in bold, legible letters in the same font as the rest of the letter size used for the list of ingredients, at the end or under the list of ingredients.

50. (a) No claim shall be made that a foodstuff, neither a single ingredient foodstuff nor a compound foodstuff, is "hypoallergenic " or "non-allergenic" or similar wording, unless the foodstuff is modified by chemical or genetic means so as to reduce the quantity of endogenous allergens in such a way that it is not possible to detect the presence of any possible allergen with testing suitable for the specific allergen;

(b) No claim shall be made that a foodstuff is free from any allergen or similar wording, unless the foodstuff has been tested for the presence of the allergen, using suitable testing for the specific allergen;

(c) The claim 'inherently (name of allergen-)free" may be made for those cereals sold as single ingredient foodstuffs, that naturally do not contain gluten; provided it has been proven both through traceability and ELISA testing on every batch, that the cereal is not contaminated with any cereal referred to in regulation 47; and

(d) The information related to the requirements of subregulations (a), (b) and (c) and regulations 47 and 49 shall be kept on record by the manufacturer, importer or distributor and any manufacturer, importer or distributor who fails to produce the relevant documentation within 24 hours of request by an inspector shall be guilty of an offence.

Misleading descriptions

51. (1) The word "natural" or "nature's" or any other word suggesting that a processed foodstuff or its ingredients occur naturally, shall not be used on the label of a foodstuff in the following instances:

(a) As part of the name in relation to a processed foodstuff and shall not be used to qualify the name or trade name thereof;

(b) To describe a foodstuff which contains any ingredient not present in the natural form of such foodstuff, or if any ingredient present in the natural form thereof has been removed therefrom;

(c) To describe the ingredients of a mixed, compounded or blended foodstuff, unless all the ingredients occurred naturally or have not been processed, except-

(i) honey as described in the Codex and the Agricultural Products Standards Act, 1990 (Act 119 of 1990), including extracted, pressed or drained honey, honey in liquid or crystalline state or a mixture of the two, comb honey and honey with comb; and

(ii) beer which has been produced by a process where the only ingredients are malted barley and water, and where any yeast added is removed in its entirety prior to the product being finished so that the completed product is organoleptically, physically and chemically the same as its natural, original composition, except for the presence of alcohol and provided it has no enzymes, sweetener or other additives added to it.

(2) The words "pure" or "100% pure" may only be used -

(a) to demonstrate microbiological and chemical safety, provided the manufacturer can prove it with appropriate documentation;

(b) to refer to a single-ingredient food to which no additives or nutrients, that are not present naturally, have been added, provided –

(i) in cases where extra processing was used, the process is described (pure refined honey or purified water);

(ii) no claim is made for nutrients that are replaced to the same levels that were naturally present before processing took place; and

(c) subject to paragraphs 2(a) and (b) above, to describe a single ingredient of a compound food.

HEALTH AND NUTRITION CLAIMS

General information

52. (1) Unless otherwise provided in these regulations, no label of any foodstuff shall contain any claim regarding the nutritive value of such foodstuff unless –

(a) the label also contains the following information in the following order:

(i) The heading "Typical nutritional information";

(ii) an indication of the mass or volume of a single serving;

(iii) the prescribed format for the nutritional information declaration as described in point 1 of Annexure 2, expressed per single serving as well as per 100g for solid foodstuffs or 100ml for liquid foodstuffs;

(iv) the amounts of the nutrient(s) that is(are) the subject of the nutrition claim present in a single serving as well as per 100g for solid foodstuffs or 100ml for liquid foodstuffs; and

(v) an indication of what percentage of the MDR for individuals 4 years and older as specified in Annexure 3 is represented in a single serving by the micronutrients in respect of which the claim is made, as well as protein: Provided that no claim shall be made for a micronutrient or protein present in an amount less than 15% of the MDR for individuals 4 years and older as specified in Annexure 3 per single serving;

(b) the serving size of a single serving, as indicated in Annexure 7, is not exceeded.

(c) subject to the requirements of regulations 64 and 65, the nutritional information always refer to the ready-to-eat product or the product as packed, whatever is appropriate, and a statement to that effect shall be indicated directly beneath the Table with nutritional information; Provided that where in the case of end products that are ready to eat or to drink, the serving size of the end product is less or more than 100 g/ml, the criteria as per 100g/ml shall be proportionally calculated for the appropriate serving size as indicated on the label; and

(d) for the purposes of nutrition labelling of foodstuffs, the standard Minimum Daily Requirement of individuals 4 years and older as indicated in Annexure 3 apply.

(2) A foodstuff not regarded essential as part of a healthy diet and healthy lifestyle as listed in Annexure 6, –

(a) shall not be enriched with any nutrient(s) for the purpose of making a nutrition or health claim on the label of such foodstuff: Provided that if any nutrient(s) is(are) added, the fact of the addition of the nutrient shall only be reflected in the list of ingredients and in the nutritional information table;

(b) subject to regulation 59, shall not make any comparative, nutrient content, Glycaemic Index (GI), diabetic, health or any other claim with a health of nutritional

message whatsoever in the advertising or on the label of such foodstuff irrespective of whether a nutrient(s) was(were) added or not;

(c) subject to regulation 68, shall not make a slimming claim or claim with a similar meaning;

(d) shall provide the nutritional information according to the format stipulated in point 1 of Annexure 2, provided that where, in the case of a foodstuff listed in Annexure 6-

(i) none of the ingoing ingredients contain any fat or trace thereof; the total fat, saturated fat and trans fat values need not be analysed but shall merely be indicated as "0" wherever it is appropriate in the table with nutritional information; and

(ii) sugar is the only ingoing ingredient that contains any carbohydrates, the sugar need not be analysed but may be calculated per 100 g/ml and per serving from the ingoing amount in the recipe;

(e) shall not advertise in any manner, including the label of a foodstuff, to a child younger than 16 years or use a child actor younger than 16 years or use any cartoon-type character or puppet, computer animation or similar strategy or token or gift, in order to encourage the use of such foodstuff;

(f) shall bear the following statement on the main panel of the label in bold letters **"Use in moderation only since excessive consumption on a regular basis may lead to an unhealthy increase in weight/ obesity"** or **"Regular consumption not recommended for a healthy diet";** and

(g) shall not advertise or promote in any manner any foodstuff listed in Annexure 6 in any school tuck shop or on any school or pre-school premises.

(3) The phrase "ONLY EFFECTIVE AS PART OF A HEALTHY DIET AND LIFESTYLE" shall be indicated on the main panel of any foodstuff that makes a health or nutrition claim in bold, capital letters not less than 3,0 mm in height;

(4) No health, nutrition, energy, Glyceamic Index , Glycaemic Load, comparative or any other claim with a health or nutrition related message shall be permitted for bottled water.

53. The label of the food vehicle, in respect of which a claim is made that a food vehicle is fortified as required by regulations relating to the fortification of foodstuffs under the Act, shall bear the format for the prescribed nutritional information declaration as described in point 1 of Annexure 2, expressed per daily serving and per 100g, as well as nutritional information relevant to the fortification specifications: Provided that in the case of dry, uncooked wheat flour and dry, uncooked maize meal as purchased, the daily serving shall be regarded as 100g.

54. A claim regarding the nutrient and/or energy content of a foodstuff shall not refer to any foodstuff not in the package: Provided that in the case of a foodstuff which is an adjunct to the foodstuff in the package but is not itself in the package, such claims may be made, provided that it is clearly indicated that such claim does not refer to the foodstuff in the package and all nutritional information shall be given in respect of the foodstuff actually in the package.

55. When a health, nutrition or Glycaemic Index claim is made in the advertising of a foodstuff, the foodstuff when sold pre-packed, shall also be labelled with the said statement.

56. In the case where nutritional information is provided, the label of a foodstuff packed in a liquid medium shall indicate whether the nutritional information applies to the drained weight or to the net contents of the container and for the purposes of this regulation, "liquid medium" means water, or aqueous solutions of sugar or salt, fruit juice or vegetable juice in canned fruits and vegetables only, or spirit such as brandy in the case of typical traditional South African dishes or vinegar or oil, either singly or in combination.

Nutrient content claims for foodstuffs

57. (1) No claim that describes the level of a nutrient contained in a foodstuff shall be made on a label or in an advertisement of a foodstuff, unless it complies with conditions set out in Table 1 below (PARTS A and B).

(2) When a nutrient content claim that is listed in Table 1 is made, the conditions specified in Table I for that claim shall apply.

(3) No nutrient content claim shall be worded in any way different from the prescribed wording as specified in Table 1, namely "low", "free or virtually free", "source" or "high".

(4) No person shall use words such as "rich in" or "excellent source" or "good source" or "enriched" or "enriched with (name of nutrient)" or "with added (name of nutrient(s))'' or "contains (name of nutrient(s))" or any similar wording in relation to the nutrients mentioned in Table 1 as a substitute for the prescribed wording options for claims in Table 1.

(5) No person shall use words such as x% fat free or any other nutrient referred to in component A of Table 1 free, where x referred to any percentage or to any similar wording as a substitute for the prescribed wording options in Table 1.

(6) In the case where a mineral is added to a foodstuff, the name of the compound from which the elemental mineral was derived shall be listed in the list of ingredients and name of the elemental mineral only shall be mentioned in the appropriate table with nutritional information.

(7) Vitamins and minerals which are present naturally or added, in amounts of less than 5% of the MDR for individuals of 4 years and older as referred to in Annexure 3 per single serving, shall not be declared in the nutritional information table, except in the case of food vehicles and bottled mineral water.

(8) Where two or more conditions for a nutrient content claim are required in Table 1 (A and B) the foodstuff shall meet all the conditions in order to qualify for the claim.

(9) For the purposes of the conditions for nutrient content claims, foods such as soups (excluding, consummés and bouillons), reconstituted canned soups and reconstituted soup powders, custard, sauces (excluding marinades), chutney and yoghurt shall be considered solids.

(10) Where a nutrient content claim is made for dietary fiber ("source of" or "high in"), both the analytical values for the fiber content that has effects on glucose and lipid absorption (soluble fiber) and fiber content that has more pronounced effects on bowel habits contents (insoluble fiber) shall be indicated as follows in the table with nutritional information:

Total dietary fiber -	… g
of which soluble fiber	… g
of which insoluble fiber	… g

(11) No claim shall be made on the label of a foodstuff regarding the protein content of that foodstuff, unless the following requirements are complied with:

(a) The conditions, as applicable, specified in Table 1, Part B;

(b) the foodstuff provides protein with a protein digestibility corrected amino acid score (PDCAAS) of not less than 90 in accordance with the prescribed method for the determination of the PDCAAS score listed in the Guidelines; and

(c) the source(s) of protein is(are) clearly indicated in the list of ingredients.

(12) In addition to the conditions of Table 1(A and B), where a nutrient content claim is made-

(a) regarding the amount of total fat or the amount and/or type of any fatty acid component or cholesterol, the real analytical values of all the following fatty acid components and cholesterol shall be indicated in the table with nutritional information, immediately after the declaration of total fat -

Total fat -		:	…g
of which	saturated		…g
	trans		…g
	polyunsaturated		…g

	monounsaturated	…g
Cholesterol		…mg

(b) for omega-3 fatty acids, the real analytical values of all the following fatty acid components shall be indicated in the table with nutritional information, immediately after the declaration of total fat -

Total fat		…g
of which	saturated	…g
	trans	…g
	polyunsaturated	…g
	of which omega-3 polyunsaturated	…mg
	monounsaturated	…g
Cholesterol		…mg

(13) Notwithstanding the provisions of regulations 12(a), in cases where a foodstuff contains naturally occurring trans fats from animal origin but no trans fats derived from partially hydrogenated fat, the trans fats need not be declared in the table with nutritional information as indicated.

(14) The claim "no sugar added" or "no added sugar" or other words with a similar meaning shall not be made on the label of a foodstuff that contains added sugars defined by these regulations.

(15) In the case of minced meat, processed meat products and manufactured meat products the conditions for the following claims as an indication of fat content are as follows:

Lean, trim or any similar wording	≤ 10%
Extra lean, extra trim or any similar wording	≤ 5%

(16) Subject to the requirement of regulation 52(1)(c), the following conditions for nutrient content claims shall be applicable:

TABLE 1: CONDITIONS FOR NUTRIENT CONTENT CLAIMS

COMPONENT A	CLAIM	CONDITIONS NOT MORE THAN
Energy	Low	170kJ per 100g (solids*) 80kJ per 100ml (liquids*)
Total fat	Low Virtually free or free from	3 g per 100g (solids*) 1.5g per 100 ml (liquids*) 0.5g per 100g/ml
Saturated fat	Low Virtually free or free	1,5g per 100g (solids*) 0,75g per 100ml (liquids*) and 0,1g trans fatty acids per 100g/ml and 10% **of combined energy value for saturated fat and trans fatty acids 0,1g per 100g (solids*) 0,1g per 100ml (liquids*)
Trans fatty acids	Virtually free or free	0,1g per 100g (solids*) 0,1g per 100ml (liquids*)
Cholesterol	Low Virtually free or free	20mg per 100g (solids*) 10mg per 100ml (liquids*) 5mg per 100g (solids*) 5mg per 100ml (liquids*) and for both claims, low and free of, less than: 2,0g saturated fat and trans fatty acids combined per 100g (solids) or 0,75g saturated fat per 100 ml (liquids) and 10% ** of energy of saturated fat
Sugars	Virtually free or free	0,5g per 100g/ml
Sodium	Low Very low Virtually free or free	120mg Na per 100g (305mg NaCl) 40mg Na per 100g (102mg NaCl) 5mg Na per 100g (13mg NaCl)
Alcohol	Non-alcoholic Virtually free or free	0.5% by volume 0.05% by volume

* refers to end product
** percentage expressed per total energy of end product

TABLE 1: CONDITIONS FOR NUTRIENT CONTENT CLAIMS (continued)

COMPONENT B	CLAIM	CONDITIONS NOT LESS THAN
Energy	Source of	80kJ per 100ml
	High in	950kJ per 100g or 250kJ per 100ml
Carbohydrate	High in	13g per 100g or 6,5g per 100ml
Total Fiber	Source of	3 g per 100g (solids) 1.5 g per 100 ml (liquids)
	High in	6g per 100g (solids) 3 g per 100 ml (liquids)
Fiber that has effects on glucose and lipid absorption (Soluble Fiber)	Source of	1,5g-per single serving
	High in	3g per single serving
Protein	Source of	5g per 100g (solids*) 2,5g per 100ml (liquids*) and 2,5g per 418kJ
	High in	10g per 100g (solids*) 5g per 100ml (liquids*) and 5g per 418kJ
Polyunsaturated fatty acids (PUFA's)	Source of	≥ 40% ****PUFA's and ≤ 20%**** saturated fatty acids and ≤ 5%**** trans fatty acids
	High in	≥ 60% ****PUFA's and ≤ 20%**** saturated fatty acids and ≤ 5%**** trans fatty acids
Monounsaturated fatty acids (MUFA's)	Source of	≥35% **** MUFA's and ≤ 20%**** saturated fatty acids and ≤ 5%**** trans fatty acids
	High in	≥ 60%**** MUFA's and ≤ 20%**** saturated fatty acids and ≤ 5% **** trans fatty acids

* refers to end product

**** of total energy from fat

TABLE 1: CONDITIONS FOR NUTRIENT CONTENT CLAIMS (continued)

COMPONENT B	CLAIM	CONDITIONS NOT LESS THAN
Omega-3 fatty acids	Source of	225mg per single serving
	High in	450mg per single serving
Vitamins and minerals excluding potassium# and sodium	Source of	15% of MDR** per serving
	High in	30% of MDR** per serving
Carotenoids:		
Betacarotene	Source of	500mcg per 100g
	High in	1000mcg per 100g
Lycopene	Source of	2mg per 100g**
	High in	4mg per 100g***
Lutein	Source of	0.5mg per 100g
	High in	1mg per 100g
Zeaxanthin	Source of	0.1mg per 100g
	High in	0.5mg per 100g

* refers to end product

** MDR for individuals older than 4 years

*** Wet weight

The claims ("source of" and "high in"), shall only be permitted for potassium *naturally* present in foodstuffs.

Glycaemic Index (GI) Category claims

58. The glycaemic index category claim shall, if used, be the category as determined in accordance with the method described in Part A of the Guidelines and shall not include any method whereby a glycaemic index value is calculated to determine its category and -

(a) shall only be used for foodstuffs which are ready-to-eat or for foodstuffs as packed but which are labelled in accordance with the requirements stipulated in Part B of the Guidelines-

(i) with a glycaemic (available) carbohydrate content of 40% or more of the total energy value of the foodstuff;

(ii) of which the total fat content does not exceed 30% of the total energy value of the foodstuff; and

(iii) of which the total protein content does not exceed 42% of the total energy value of the foodstuff;

(b) shall not be indicated by a specific numerical value;

(c) shall, if used, be indicated as low or intermediate or high Glycaemic Index or low or intermediate or high GI in the table with nutritional information or when used as part of a logo, provided the Glycaemic Index category corresponds with the conditions described hereunder:

CONDITIONS FOR GLYCAEMIC INDEX CATEGORY CLAIMS

GI CATEGORY CLAIM	CONDITION
Low GI	GI Value: 0 to 55
Intermediate GI	GI value: 56 to 69
High GI	GI value: 70 and more

;and

(d) shall in addition indicate the glycaemic load (GL), calculated according to the formula mentioned in the Guidelines, of a single serving, in numerical form, directly underneath the GI category; Provided the serving size is in accordance with the serving sizes listed in Annexure 7 and an indication of the GL is subjected to the indication of the GI;

Glycaemic Index claims

(e) foodstuffs that qualify for one of the following GI category claims may use the following words in support of a relevant claim:

(i) "Low GI" may use the following words to support the claim: " Low GI foods, when eaten in moderate portions at a time, generally provide a slow release of energy and improve blood glucose control and may elicit a higher feeling of satiety.";

(ii) "Intermediate GI" may use the following words to support the claim: "intermediate GI foods generally provide a moderately fast release of energy and are ideal for diabetic individuals after exercise lasting at least one hour or as a special treat."; and

(iii) "High GI" may use the following words to support the claim: "High GI foods generally provide a fast release of energy and are ideal for regular sportsmen after one hour's exercise or during and after exercise lasting more than one hour and diabetic individuals during and after exercise lasting at least two hours or more.";

(f) where a Glycaemic Index claim is made on the label or in advertising, nutritional information shall be given -

(i) in a clear tabular format as per point 1 of Annexure 2; and

(ii) the appropriate nutritional information referred to in paragraph (c) above;

(g) when a food company changes the formulation of a foodstuff carrying a GI claim or logo, the reformulated foodstuff shall be retested in order to legitimise the claim.

Comparative claims

59. (1) No claim which compares the total fat, saturated fat, trans fat, sugar, sodium or salt, energy value or alcohol level of two or more similar foodstuffs by using one of the following words or a similar word "reduced", "less than", "fewer", "light", " lite", shall be made on the label or in an advertisement of a foodstuff, unless the following conditions are complied with:

(a) The foodstuffs being compared are different versions of the same foodstuffs with common base formulations.

(b) The foodstuffs being compared are clearly labelled as follows:

(i) a statement is given of the amount of difference in the energy value or relevant nutrient content, expressed as a percentage; and

(ii) the identity of the foodstuff(s) to which the foodstuff is being compared, appears in close proximity to the comparative claim.

(c) The comparison is 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;

(d) The foodstuff is labelled with the prescribed nutritional information declaration referred to in point 1 of Annexure 2, as well as nutritional information relevant to the comparative claim.

(e) The foodstuff has the same organoleptic properties as the foodstuff it is being compared with.

(f) Comparative claims shall not be allowed for foodstuffs for which compositional standards exist under the Agricultural Products Standards Act, 1990 (Act 119 of 1990), unless specific provision is made in these standards to accommodate comparative claims.

(g) Foodstuffs for which a class name exists under the Agricultural Products Standards Act, 1990, in which the word "reduced" appears and which are listed in the Guideline shall not be regarded as a comparative claim.

(2) Subject to Sub-regulation (1), no other comparative claim in terms of any other nutrient or other food component shall be made for foodstuffs listed in Annexure 6.

(3) Subject to the requirements of subregulation (1)(a to d), a comparative claim may be made that compares the level of a vitamin, mineral, bioflavonoid, carotenoid or other food component with proven nutritional or physiological benefit, by using one of the following words "more than", or "increased" or other similar words; Provided the foodstuff is not listed in Annexure 6.

Colourants

(4) In the case where –

(a) natural colourants are added to foodstuffs, the slogan "Natural colour – the healthier choice" may be used as part of logo 1 as indicated in Annexure 8; Provided no artificial colourants are added to or are present in the particular foodstuff.

(b) artificial colourants are added to foodstuffs, the slogan "Less synthetic colour is better for my health " may be used as part of logo 2 as indicated in Annexure 8; Provided –

(i) the added colourant(s) is(are) at least 50% less than the total maximum levels permitted by the Regulations relating to Food Colourants under the Act, and

(ii) in the case of extruded or expanded savoury snack products, no artificial colourants are added in the pre-extrusion phase.

HEALTH CLAIMS

Function claims

60. (1) Subject to the requirements of relevant Regulations for Foodstuffs for Infants and Young Children made under the Act, a function claim may be made for the nutrients or substances listed in the Guidelines by using all or parts of the approved, appropriate wording in the Guidelines for a nutrient or substance when the nutrient or substance is present in amounts at least equal to or greater than the minimum amount needed to qualify for a "high in" nutrient content claim per single serving, except for food vehicles; Provided that -

(a) where an MDR value is not provided in Annexure 3 for the specific nutrient or substance, a function claim will not be permitted;

(b) the foodstuff is labelled with the minimum prescribed "nutritional information declaration" as described in point 1 of Annexure 2 per single serving and per 100 g/ml;

(c) the nutritional information relevant to the function claim present in a single serving and per 100g/ml; and

(d) an indication is given of the percentage of the MDR for individuals 4 years and older, of the nutrients listed in Annexure 3, which are present in a single serving and per 100 g/ml.

Enhanced function claims

61. Subject to the requirements of relevant Regulations for Foodstuffs for Infants and Young Children made under the Act, enhanced function claims for which the efficacy and functionality of the nutrient or food component has been proven by a meta analysis of randomised control human intervention studies or at least two randomised control human intervention studies done independently from one another and/or supported by other intervention or observational studies or other relevant data such as clinical data, or *In vitro* cell and molecular data or data from genetics or animal studies, will be permitted for foodstuffs: Provided-

(a) these studies were published in recognised scientific nutrition or medical journals;

(b) complete copies of these studies were submitted to the Director-General of Health (for the attention of the Directorate: Food Control) in a dossier of which the order and format is stipulated in the Guidelines;

(c) the claim has been evaluated and received written, pre-market approval from the Director-General: Provided that-

(h) only the claim as approved by the Director General

(i) for a specific foodstuff, may be used in advertising or labeling and is not transferable to another foodstuff or a similar foodstuff under a different brand name;

(ii) the foodstuff shall be labelled with the prescribed "nutritional information declaration" as described in point 1 of Annexure 2 per single serving and per 100 g/ml;

(iii) the nutritional information relevant to the enhanced function claim present in a single serving and per 100 g/ml is indicated in the nutritional information table; and

(iv) the percentage of the MDR for individuals 4 years and older, as specified in Annexure 3, of the nutrients present in a single serving and per 100 g/ml, is indicated in the nutritional information table.

Reduction of disease risk claim

62. (a) The following reduction of disease risk claims that link the consumption of a food or a food constituent in the context of the total diet to the reduced risk of developing a disease or a health related condition, shall be permitted for foodstuffs: Provided the conditions set out in paragraphs (b) to (g) and Table 2 are met:

(i) Calcium and osteoporosis;

(iii) Dietary saturated fat and cholesterol and the risk of coronary heart disease;

(iv) Sodium and hypertension;

(v) Fiber-containing grain products, fruit and vegetables and cancer;

(vi) Fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and the risk of coronary heart disease;

(vii) Fruits and vegetables and cancer;

(viii) Folate and neural tube defects;

(ix) Folate, Vitamins B_{12} and B_6 and coronary heart disease

(x) Oats and coronary heart disease;

(xi) Sugar alcohols and dental caries;

(xii) Psyllium fiber and coronary heart disease;

(xiii) Whole grains and coronary heart disease and cancer;

(xiv) Soy protein and coronary heart disease;

(xv) Plant sterols and plant stanol esters and coronary heart disease;

(xvi) Walnuts and heart disease;

(xvii) Omega-3 fatty acids and coronary heart disease;

(xviii) Olive oil and coronary heart disease

(xix) Potassium, high blood pressure and stroke

(b) The foodstuff shall comply with the characteristics specified in column I of Table 2.

(c) (i) The wording of the reduction of disease risk claim in column II of Table 2 may not be added to, omitted, reduced, or altered in a way which will result in a change of meaning or which will result in a change of emphasis; and

(ii) no health claim may attribute any degree of a disease risk reduction to specific dietary guidelines.

(d) The foodstuff shall be labelled with the prescribed “nutritional information declaration” described in point 1 of Annexure 2 per single serving and per 100 g/ml;

(e) The nutritional information relevant to the reduction of disease risk claim as specified in column I under the heading "Food Characteristics" of Table 2 present in a single serving and per 100 g/ml for foodstuffs shall be indicated.

(f) An indication shall be given of the percentage of the MDR, for individuals 4 years and older, as specified in Annexure 3, of the nutrients present in a single serving and per 100 g/ml.

(g) No reduction of disease risk claim shall be made on a label or in an advertisement of a foodstuff unless the characteristics of the foodstuff, as specified in column I of Table 2, comply with the conditions set out in regulation 60, Table 1 (Parts A and B) as applicable.

TABLE 2: REDUCTION OF DISEASE RISK CLAIMS

	FOOD CHARACTERISTICS	PERMITTED WORDING OF CLAIM
1.	**Calcium and osteoporosis** • "High" in calcium and "source of" magnesium; • Phosphorus content may not exceed calcium content	Regular exercise and a healthy diet with enough calcium may help susceptible individuals maintain good bone health and may reduce their risk of osteoporosis later in life
2.	**Sodium and hypertension** Low sodium	Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many risk factors, in some individuals
3.	**Dietary saturated fat and cholesterol and the risk of coronary heart disease** • Low saturated fat; • Low cholesterol; and • Low total fat	While many factors affect heart disease, diets low in total fat, saturated fat and cholesterol may reduce the risk of heart disease
4.	**Fiber-containing grain products, fruit and vegetables and cancer** • Grain products, fruits or vegetables that are a source of dietary fiber; • trans fatty acid free; • with a total fat profile in line with the WHO's Dietary Goals as referred to in the Guidelines	Low fat diets, rich in fiber-containing grain products, fruits and vegetables may reduce the risk of some types of cancer, a disease associated with many factors
5.	**Fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and the risk of coronary heart disease** • Fruit, vegetable or grain products that are a source of dietary fiber that has an effect on glucose and lipid absorption; • low saturated fat; • low cholesterol; • trans fat free; • contain no fat that has been interesterified and • with a total fat profile in line the WHO's Dietary Goals as referred to in the Guidelines	Diets low in saturated fat and cholesterol and rich in fruit, vegetables and grain products that contain dietary fiber that has effects on glucose and lipid absorption may reduce the risk of heart disease
6.	**Fruits and vegetables and cancer** • Fruit or vegetables; • low total fat; • high in vitamins A or C or dietary fiber	Low fat diets rich in fruits and vegetables and which contain dietary fiber, vitamins A and C may reduce the risk of some types of cancer, a disease associated with many risk factors
7.	**Folate and neural tube defects** High in folic acid	Women who consume adequate amounts of folate or folic acid, a B vitamin, daily

		throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain and spinal cord or a cleft palate. Such birth defects, while not widespread are very serious. They can have many causes. Adequate amounts of folate can be obtained from diets rich in fruits, dark green leafy vegetables, legumes, fortified grain products, fortified foods or a nutritional supplement.
8.	**<u>Plant sterol esters and plant stanol esters and coronary heart disease</u>** • Foodstuffs that contain at least 0,65 g plant sterols or 1,7 g plant stanol esters per serving; • low in saturated fat; and • low cholesterol • Foodstuffs shall bear a statement on the main panel in capital letter at least 3 mm in height to indicate that the particular foodstuff is suitable for the intended target group only	Diets low in saturated fat and Diets low in saturated fat and cholesterol that include two servings of food that provide a daily total of at least 1,3 g plant sterols or 3,4 g of plant stanol esters in two meals may plant stanol esters in two meals may reduce the risk of heart disease by lowering cholesterol
9.	**<u>Oats and coronary heart disease</u>** At least 60 g whole oats (rolled oats), oatmeal or 40 g oat bran, without enrichment, that provides 3 g or more beta glucan fiber per single serving. The amount of beta glucan fiber per recommended serving shall be indicated in the table with nutritional information.	3 g beta glucan fiber from 60 g whole oats daily, or 40 g oat fiber, as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease.
10.	**<u>Sugar alcohols and dental caries</u>** The sugar alcohol should be the main sweetener in the foodstuff and should be a permitted sugar alcohol in terms of the Sweetener Regulations promulgated under Act No. 54 of 1972	Frequent eating of foods high in sugars and starches that are retained on the teeth between meals can promote tooth decay. The sugar alcohol(s) [name sugar alcohol(s)] used as a sweetener in name the product) does(do) not promote tooth decay/dental caries.
11.	**<u>Psyllium Fiber and coronary heart disease</u>** • 1,7 g fiber that has effects on glucose and lipid absorption per • low saturated fat; • low cholesterol • and low total fat	Diets rich in fiber, such as psyllium, part of a diet low in saturated fat, cholesterol, and total fat, may reduce the risk of heart disease
12.	**<u>Whole grains and coronary heart disease and cancer</u>** • Foodstuffs that contain a least 51% whole grains by weight	Diets rich in whole-grain foods and other plant foods and low in fat and cholesterol may reduce the risk of heart disease and certain cancers

	as the main ingredient; • that provide a minimum of 16 g of whole grains per serving; • 2,8 g fiber per 50 g serving; • are low in total fat, • low in saturated fat; and • low in cholesterol	
13.	**Soy protein and heart disease** • Foodstuffs that contain at least 6,25 g of soy protein per serving; • are low in saturated fat; and • low in cholesterol	Diets which contain at least 25 g soy protein (4 servings) daily and which are low in saturated fat and cholesterol, may reduce the risk of heart disease by lowering cholesterol levels
14.	**Walnuts and Heart disease** 45 g serving of raw walnuts	Eating 45 g walnuts per day as part of a diet low saturated fat and cholesterol may reduce the risk of coronary heart disease.
15.	**Folate, Vitamins B_{12} and B_6 and coronary heart disease** At least 50% of the MDR for persons 4 years and older for folic acid, Vitamin B_6 and vitamin B_{12} per single serving	The daily intake of at least 400 mcg folic acid, 1.7 mg vitamin B_6 and 2.4 mcg Vitamin B_{12} will assist in reducing plasma homocysteine levels. Elevated plasma homocysteine levels is associated with an increased risk of heart disease. Food X will provide at least half of the required amounts all these vitamins per serving..
16.	**Omega-3 fatty acids and coronary heart disease** 850 mg EPA and DHA per single serving	A daily intake of 850 mg EPA and DHA omega-3 fatty acids from fish oil or fatty fish may protect against and reduce the risk of coronary heart disease.
17.	**Olive Oil and coronary heart disease** 100% pure extra virgin and virgin olive oil	Eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increases the total number of kilojoules you eat in a day.
18.	**Potassium, blood pressure and stroke** Foods that naturally contain at least 350 mg Potassium per serving and which are low in sodium	Diets containing foods that naturally contain at least 350 mg potassium and which are low in Sodium may reduce the risk of high blood pressure and stroke

Probiotic and prebiotic claims

63. (1) A claim or implication that a foodstuff is a "probiotic" or has probiotic properties or words with a similar meaning shall not be made on the label of a foodstuff unless the foodstuff complies with the conditions specified in paragraphs (a) to (h), subregulations (2) and (3) and Table 3, and claims for “prebiotic” or words with a similar meaning shall not be made on the label of a foodstuff

unless the claim complies with the conditions specified in paragraphs (a), (b), (d) (e) and (h) below and Table 3-

(a) The claim "probiotic" shall be permitted for one or more live strains of the following probiotic bacteria only:
Lactobacillus acidophilus
Lactobacillus rhamnosus
Bifidobacterium bifidum
Bifidobacterium longum/infantis;

(b) The wording of a claim, excluding the wording approved in column I of Table 3, regarding the efficacy and functionality of a specific strain from the approved species in column II of Table 3 or a prebiotic, which can support and enhance the health of a person suffering from a specified medical condition, and which have been confirmed by a meta analysis of randomised control human intervention studies or at least two randomised control human intervention studies done independently from one another and/or supported by other intervention or observational studies or other relevant data with regard to clinical data, or *In vitro* cell and molecular data or data from genetics or animal studies, will be permitted for foodstuffs: Provided-

(i) these studies were published in recognised, peer-reviewed scientific nutrition or medical journals;

(ii) these studies and the data required by the Guidelines have been submitted for premarket approval to and have been approved by the Director-General of the Department of Health, at least 90 calendar days prior to market appearance; and

(iii) validation of probiotic species was determined in accordance with the methodology specified in paragraph 2 of the Guidelines.

(c) Foodstuffs for which the claim "probiotic" or any words with a similar meaning is made shall indicate, in the table with nutritional information, the number of viable, colony-forming-units of probiotic bacteria at the end of the shelf-life period subject to the provisions of paragraph (f) hereunder, and shall identify the probiotic bacterial strain by its full scientific name, (genus, species, subspecies, etc.) and strain number according to the International Code of Nomenclature as indicated in point 1 of the Guidelines; Provided that the total minimum number of viable colony-forming-units of all the probiotic strains present is not less than $1x10^8$ per single serving; Provided the serving size does not exceed the serving sizes indicated in Annexure 7;

(d) No claim for probiotics or prebiotics may attribute any degree of a disease risk reduction to a specific foodstuff, or ingredient thereof.

(e) The prescribed nutritional information as per point 1 of Annexure 2 of a serving and per 100 g or 100 ml, and in the case of prebiotics the relevant information about the prebiotic as well, shall be provided on the label.

(f) In those cases where the strains are not stable at room temperature, foodstuffs for which a probiotic claim is made shall bear on the main panel of the label the instruction "KEEP REFRIGERATED" or "KEEP FROZEN", as the case may be, in capital (upper-case) letters not less than 3,0 mm in height.

(g) The shelf life stability data, proof of the origin of the strain as well proof that the strain has been deposited in a recognised international culture collection, shall be submitted to the Directorate¨: Food Control at least 30 days prior to market appearance.

(j) The amount, type and source of prebiotic shall be specified in the table with nutritional information.

(2) Probiotic claims shall not be permitted for a foodstuff that requires any further cooking or heating.

(3) The claim "synbiotic " or any other words with a similar meaning shall be permitted for a foodstuff; Provided the product complies with conditions mentioned in subregulations 1 and 2.

TABLE 3: PROBIOTIC CLAIMS

PERMISSIBLE INFORMATION TO ACCOMPANY CLAIM	CONDITIONS	FOODSTUFFS
	For foodstuffs for persons older than 1 year	
When ingested on a regular basis as part of a healthy diet, probiotics should improve the microbial balance in the human intestines and the functioning of the digestive tract. By inhibiting the growth of harmful (pathogenic) micro-organisms, assisting in the digestion of lactose, normalising bowel movement and stimulating the functions of the human immune system, they, significantly improve general health.	The viable count of probiotic bacteria shall be not less than $1x10^8$ colony forming units per single serving of foodstuff at the end of the shelf-life period. Only live, selected strains with premarket approval for their confirmed probiotic properties shall be permitted in accordance with the requirements of Regulation 63. The following species do not need premarket approval: * *Lactobacillus acidophilus;* * *Lactobacillus rhamnosus;* * *Bifidobacterium bifidum;* * *Bifidobacterium longum/infantis;*	Foods without added preservatives except foodstuffs preserved with pimaricin (also called natamycin)
	<u>For foods and formula for infants from birth to 3 years</u>	
No claim shall be permitted in any manner for any foodstuff intended for infants and young children up through the age of 3 years	The probiotic bacterial count should exceed 10^8 colon-forming units per single serving of foodstuff at the end of the shelf-life period. Permitted strains are live *Bifidobacterium infantis or B. longum* only	Foodstuffs for infants from birth through 3 years

TABLE 3: PREBIOTIC CLAIM

PERMISSIBLE INFORMATION TO ACCOMPANY CLAIM	CONDITIONS
Prebiotics are non-digestible food components which have a beneficial effect on human health by selectively stimulating the growth and metabolic activities of one or a limited number of beneficial intestinal bacteria and thus improving the balance of the human intestinal microflora;.Provided that no claim shall be permitted in any manner for any foodstuff intended for infants and young children up through the age of 3	At least 1500 mg pure prebiotic per single serving. The amount, type and source of prebiotic(s) shall be declared on the label

Mandatory nutritional information format

64. (1) Where any health, nutrition, slimming or Glycaemic Index claim is made on the label or in advertising-

(a) the nutritional information shall be given in a clear tabular format as per point 1 of Annexure 2; and

(b) the appropriate nutritional information necessary to substantiate the claim as required in accordance with these Regulations shall be added; Provided that when the ingredients, excluding additives, of a foodstuff is altered in any way, the affected product shall be re-analysed for its nutritional content for labeling purposes.

(2) The appropriate unit of measurement shall appear behind the nutrient or energy value: Provided that –

(a) the energy content of the foodstuff shall be declared in “kilojoules” or “kJ”;

(b) the energy value shall be calculated from total carbohydrates (carbohydrates plus dietary fiber), total fat and total protein, using the conversion factors in point 2 of Annexure 2; and

(c) the amount of each nutrient shall be declared by mass.

(3) A health or nutrition claim that is made on the label shall be accompanied by the appropriate nutritional information on the label –

(a) that represents the real, typical values of the product as determined by chemical, microbiological or allergen analysis as described in these regulations;

(b) that is the result of analysis done on a composite sample, made up of an appropriate number of samples, gathered over a suitable period of time and from a reasonable number of batches, by a reputable laboratory, to provide a true representation of the product;

(c) that is based on a laboratory analysis report compiled by an accredited laboratory;

(d) that is verified at least once every three (3) years by analysis and kept on record, and

(e) that is analysed in accordance with the methods stipulated in these regulations or where no method is stipulated by methods approved and recommended by Codex.

(4) The manufacturer shall –

(a) compile a report on the details of how the sampling was conducted based on the Guidelines;

(b) keep the report referred to in paragraph (a) on record, and provide copies of the report to the importer and/or distributor; and

(c) when presenting the samples to a reputable laboratory for analysis, inform the laboratory that the analysis is for labelling purposes and that the laboratory report must include the information requested in point 3 of the Guidelines.

(5) Any manufacturer, importer or distributor shall be guilty of an offence if the laboratory analysis reports and the sampling plans referred to in subregulation (3) and (4) cannot be produced within 24 hours of request by an inspector.

(6) When nutrient values, obtained as a result of analysis, are prepared for the nutritional information table for labelling purposes, the nutrient value declared in the table with nutritional information, shall be rounded off appropriately as indicated in the Guidelines.

(7) Protein, vitamins and minerals for which an MDR value exist shall be expressed as a percentage of the MDR in accordance with subregulation 52(d)

(h) When the ingredients, excluding additives, of a foodstuff are altered in any way, the affected product shall be re-analysed for its nutritional content for labeling purposes.

Voluntary nutritional information

65. When information in respect of the nutrient and/or energy value is provided on the label of a foodstuff and no claim as described in these regulations is made -

(a) the nutritional information shall be indicated in accordance with the prescribed format as per point 1 of Annexure 2, except that in cases where the size of the label is restricted by the physical size of the product and less than 900 mm^2 remains after the minimum requirements in terms of these regulations have been met, the information may be indicated in a linear format; and

(b) the label may, in addition, contain any other nutritional information of the manufacturer's choice per serving and per 100 g/ml, providing the information can be substantiated by either an analysis report from a reputable laboratory or in the case of single ingredient agricultural commodities from the national food composition tables, preferably from the South African Food Composition Tables or where the South African information is not

available, from another international reputable Food Composition Database.

Special characteristics or properties

66. No claim shall be made on the label of a foodstuff that the foodstuff has acquired nutritive value from nutrients or substances added for technical or sensory reasons.

Claims, which depend on another foodstuff

67. No claim shall be made that a foodstuff has a particular value or benefit if the value or benefit is derived wholly or partly from another foodstuff that is intended to be consumed with the foodstuff in relation to which the claim is made, but which is not included in the package.

Slimming claims

68. (1) Subject to regulation 52, no claim shall be made on a label that a foodstuff is an aid to slimming or mass control or mass reduction or that it has a reduced or low energy value, and the foodstuff shall not be described as "diet" or in words to a similar effect unless the following requirements are complied with:

(a) when a claim is made on the label that a foodstuff is an aid to slimming or mass control or mass reduction -

(k) the foodstuff shall be labelled with the words "ONLY EFFECTIVE AS PART OF AN ENERGY-CONTROLLED PRUDENT DIET AND AN INCREASE IN MODERATE PHYSICAL ACTIVITY" in capital letters not less than 3,0 mm in height;

(ii) the energy provided by the fat content of the foodstuff shall not exceed 10% of the total energy of the single serving;

(iii) the foodstuff shall not be one of the foodstuffs listed in Annexure 6;

(iv) a statement shall be written in capital letters not less than 3,0 mm in height to the effect that the slimming claim is only applicable when consumption of the foodstuff is in accordance with the recommended serving size on the label: Provided that the recommended serving size is not more than those mentioned in Annexure 7;

(v) the GI of the foodstuff is low, and the GL is equal to or less than 10 for a snack or a carbohydrate-rich main meal component, equal or less than 20 for a complete breakfast or light meal and equal or less than 25 for a complete main meal.

(b) the case of a claim that a soft drink is described as "diet", the energy value of the soft drink shall not be more than 30 kJ per 100 ml; and

(b) in the case of an uncooked foodstuff, which naturally has a low energy value, the claim "a naturally low energy food" may be used after the name of such foodstuff.

(2) In the case where a slimming claim is linked to a specific formulation of the foodstuff or the presence of one or more specific ingredients or substances, the claim shall be evaluated according to and subjected to the requirements of regulation 61.

Irradiation

69. (1) All containers of irradiated foodstuffs shall be unambiguously labelled with the word "irradiated" or "radurised" or any other word(s) indicating treatment with ionising radiation in close proximity to the name and the internationally recognised Radura emblem may also appear on the label of an irradiated foodstuff;

(2) Where bulk containers of irradiated foodstuffs are opened at the point of sale in such a manner that the statement that the foodstuff has been irradiated is obscured from the consumer's view, a notice with the information prescribed in sub-regulation (1) shall be displayed in the immediate proximity of such a foodstuff and in clear view of the purchaser.

(3) The qualifying words shall be printed in capital letters not less than 3 mm in height and shall be legible against a contrasting background, and the emblem shall, if used, be clearly visible.

(4) In the case of foodstuffs containing an irradiated component(s) in more than 10% of the mass of the finished product, the words "irradiated" or "radurised" shall appear in parenthesis after the relevant component(s) in the list of ingredients on the label.

(5) Where a foodstuff containing an irradiated component(s) in more than 10% of the mass of the finished product is presented for sale in such a manner that the consumer can no longer see that the foodstuff contains an irradiated component(s), a notice with the information prescribed in sub-regulation (1) shall be displayed in immediate proximity to such a foodstuff and in clear view of the purchaser.

(6) The producer of an irradiated foodstuff may, in addition to the labelling requirements, indicate the purpose of irradiation of such foodstuff, e.g., "IRRADIATED FOR PURPOSES OF INSECT CONTROL", or "IRRADIATED FOR PURPOSES OF MICROBIOLOGICAL CONTROL".

Vegetarian claims

70. (a) Claims that a foodstuff is suitable for vegetarians shall specify the category of vegetarian by adding one or a combination of the following prefixes to the word "vegetarian":

(i) "Lacto (milk)" – means milk and milk products are included but products in which animal rennet is used during preparation are excluded.

(ii) "Ovo (egg)" – means unfertilised eggs (preferably free-range) and egg products are included.

(iii) "Honey" – means honey is included.

(iv.) "Strict" – means ingredients of multicellular plant, fungal, algal and bacterial origin are included but all ingredients and additives derived from animal origin are excluded, and the term "vegan" may be used instead of "strict vegetarian".

(b) When a foodstuff is manufactured for the "strict vegetarian" or "vegan" market and a claim in respect of "strict vegetarian" or "vegan" is made on the label and it is not possible to conclude from the name of the ingredient or additive that it is derived from non-vegetarian origin, any additive (refer to Annexure 1) or ingredient (refer to Annexure 5) derived from non-vegetarian origin which is added to the foodstuff shall declare "non-vegetarian origin" or words that specify the source in parenthesis after the name of the additive or ingredient.

Claims for "organically produced foodstuffs"

71. Claims which indicate that a foodstuff has been organically produced/grown shall be subject to the provisions of regulations promulgated under the Agricultural Products Standards Act, 1990 (Act 119 of 1990).

EXEMPTIONS

72. (1) The following ingredients of a foodstuff need not be named in the list of ingredients:

(a) Constituents of an ingredient, which have become temporarily separated during the manufacturing process and are later re-introduced in their original proportions;

(b) any substance other than water which is used as a solvent or carrier for a food additive or nutrient and which is used in an amount that is consistent with good manufacturing practice:, Provided that the solvent or the carrier shall not be nor contain traces of a common allergen specified in these regulations;

(c) water or other volatile ingredients evaporated in the course of manufacture;

(2) The following foodstuffs need not be labelled with a list of ingredients:

(a) Water to which no ingredient other than carbon dioxide has been added and the name of which indicates that it has been carbonated;

(b) vinegars which are derived by means of natural fermentation exclusively from a single basic product and to which no other ingredient has been added; or

(c) a foodstuff which consists of a single ingredient and the name of which clearly identifies the product.

(3) All ingredients of a mixture, compound or blend as well as foodstuffs for which compositional standards have been laid down under the Act or any other Act shall be exempt

from the provisions of section 3 (1) of the Act relating to the specification on the label of the proportions or amounts in which the ingredients are present, unless explicitly otherwise provided by regulation.

(4) The following foodstuffs, sold as such, are, unless otherwise provided in these regulations, be exempt from the requirements regarding labelling except when a health or nutrition claim is made in which case the mandatory nutritional information referred to in Regulation 64 above shall appear on the label:

(a) Hens' eggs and ostrich eggs except for a “Best before” date;

(b) fresh, unprocessed vegetables and fruit which have not been mixed;

(c) wheat products, which are not pre-packed (naked bread) except for information on the list of ingredients, including allergens, which must be available at the point of sale upon request;

(d) any drink referred to in the Liquor Products Act, 1989 (Act 60 of 1989): Provided that where the drink contains the colourant "tartrazine", and where health statements/warnings are prescribed, these facts shall be indicated on the label in accordance with the provisions of the Act;

(e) unprocessed fish, unprocessed marine products, unprocessed meat of bovines, goats, sheep, pigs and unprocessed poultry that have not been pre-packed;

(f) unprocessed fish, unprocessed marine products, unprocessed meat of bovines, goats, sheep, pigs and poultry pre-packed in such a way that the purchaser is able to identify the contents of the package, except for an indication of the type of animal, fish or bird and a date as required by these regulations;

(g) any foodstuff prepared and sold on the premises of a catering establishment for immediate consumption, except for information on the list of ingredients, including allergens and the information required by regulation 33, which must be available at the point of sale upon request;

(h) unpacked or transparently-packed portions of foodstuffs that are sold as snacks on the premises of preparation;

(i) any foodstuff which is sold in bulk other than by retail and which is accompanied by relevant trade documents reflecting all particulars required by these regulations to appear on the label of a pre-packed foodstuff;

(j) flour confectionary intended to be consumed within 24 hours of manufacture, except for information on the list of ingredients, including allergens and the information required by regulation 33, which must be available at the point of sale upon request; and

(k) ice, except for the name and address of the manufacturer.

REPEAL

73. The regulations promulgated under Government Notice No. R. 908 of 27 May 1977, as amended by Government Notices Nos. R.1389 of 22 July 1977, R.1843 of 28 August 1981, R. 2298 of 26 October 1984, R. 2567 of 15 November 1985, and Government Notice No. R. 2034 of 29 October 1993, as amended by Government Notices Nos. R. 932 of 30 June 1995, R. 129 of 2 February 1996, the definition of "gluten free" and regulations 5 (2) (e) and 5 (3 (e) of the Regulations relating to Foodstuffs for Infants, Young Children and Children (R. 1130 of 8 June 1984), are hereby repealed in so far as they relate to foodstuffs.

COMMENCEMENT

74. These regulations –

(a) except regulations 28 and 57(5) shall come into operation 12 months after the date of final publication;

(b) regulation 57(5), shall come into operation 3 months after date of final publication;

(c) regulation 28 shall come into operation 3 years after the date of final publication.

MINISTER J.T.RADEBE
ACTING MINISTER OF HEALTH

REFERENCE INDEX

SUBJECT OF REGULATIONS	REGULATION NUMBER
Commencement of these regulations	74
Definitions	1
General provisions	
Accreditation of methods of analysis	1(reputable laboratory, SANAS, typical values), 4 and 64(3), 78
Advertising principles	Title of regulations, 2, 55
Batch identification	1, 11
Country of origin	10
Date marking	1, 12, 13, 72(d)(i and vi) and Annexure 4
Declaration of	
Mandatory warning/statements on certain Foodstuffs as applicable	17,49, 52(2) and 72(4)(d)
Net contents	8, 9, 56
General principles	1, 2, 3, 4, 5 & 8
Foodstuffs not considered essential for a healthy diet for which no nutrient content, GI, health, slimming or any other claim with a health or nutritional message are permitted	1, 52(2) and Annexure 6
Identification of product	8
Label legibility, visibility and indelibility	5
Label reference to the Act or Local, or Provincial or National Government	16
Language	5
Letter sizes – general	6 and 7
Letter sizes – warnings and mandatory statements when applicable	17, 37, 39, 63(1)(f), 62(Claim no 8), 68(a)(i), 70(1 and 6)
Name and description of product	1, 6
Prohibited statements	14 and 16
Special provisions	
Labeling of -	
Added water	20, 31 and 72(1)(c)
Allergens	1, 46 to 50 and Guideline 4
Bulk stock	1, 34
Claims for “gluten free”, “hypo-allergenicity”	47(2), 50

or “non- allergenic”	
Claims for organically produced foodstuffs	71
Claims that depend on another foodstuff	67
Colourant claims and approved logos	59(4) and Annexure 8
Compound ingredients	29 and 30
Energy conversion factors	Point 3 of Annexure 2
Exemptions	26, 35, 39, 43, 45, 72
Fats and oils	33
Labeling of partially/fully hydrogenated fat/oil	33, 72(4)(h and j)
Origin of…	33
Food additives	40 to 45
Food vending machines	38
Frozen and chilled food products	37
Health and nutrition claims	
Dossier to substantiate health claims for pre-market approval	Guideline **13**
General information	1, 52 to 56
Fortification of food vehicles	1, 53
Nutrient content claims:	1, 57
General provisions	57
Table 1 (A and B)	57
Carbohydrate claims	1, 57 [Table 1(B)] and Guideline 3
Carotenoid claims	57 [Table 1(B)]
Comparative claims	1, 59 and Guideline 9 and Annexure 8
Diabetic claim	15(g)
Dietary Fiber claims	1, 57(10) and Table 1(B)
Energy claims	57 [Table 1(A and B)]
Fatty acids and cholesterol claims	1, 57(12) and Table 1(A)
Polyunsaturated fatty acids	57(12) and[Table 1 (B)]
Monounsaturated fatty acids	57(12) and [Table 1 (B)]
Omega 3 fatty acids	57(12)(b) and [Table 1 (B)]
Glycaemic Index claims	1, 58 and Guideline 6
Protein claims	1, 57(11) and Table 1 (B) and Guideline 2
Sodium claims	57 [Table 1(A)]
Sugar claims	1, Table 1 (A)
Vitamin and mineral claims	57 [Table 1 (B)]
Function claims	60

Enhanced function claims	1, 61 and Guideline 13
Function claims	1, 60, and the Guideline 8
Prebiotic claims	1, 63, and Table 3
Table 3	63
Probiotic claims	1, 63, Table 3 and Guidelines 7 and 13
Reduction of disease risk claims	1, 62 and Table 2
Table 2	62
Labeling of manufactured, processed, fresh processed and mechanically recovered meat	32
Labeling of irradiated foodstuffs	69 (1, 2, 3 & 6)
Labeling of irradiated ingredients/components	69 (4 and 5)
Laboratory analysis reports	1, 4, 64
List of ingredients required - yes or no?	19, 72(b)
Methods of analysis	47,58, 64, Guidelines 2, 3, 4, 6, 7
Misleading descriptions	1 (processed), 51
Naming of ingredients excluding additives	24, 27
Naming of food additives	25, 26, 40 to 45 and Annexure 1
Naming of microbiological cultures excluding probiotics	15, 24
Negative claims	15
Nutrition information format	
Mandatory:	64 and Annexure 2, Point 1
Voluntary, foodstuffs	65 and Annexure 2, Point 1
Order of list of ingredients	19 to 23
Pictorial representation	39
Prepacked food additives sold as such	36
Product and ingredient information sheets in terms of ingredient/additives traceability	Guideline 11
Quantitative Ingredient Declarations (QUID)	28 and Guideline 5
Minimum Daily Reuirements (MDR) tables	1, 64 and Annexure 3
Recommended methods of analysis	1, 4, 47, 50, 64 and Guidelines 2, 3, 4, 6 and 7
Repeal notices	73
Rounding off of energy and nutrient values in table with nutritional information	Guideline 12
Sampling procedure for nutritional information	64 and Guideline 10
Seasonal ingredients	18
Serving sizes	1 (serving vs daily serving), 53,and Annexure 7
Small packages	35

Special characteristics or properties	66
Slimming claims	68
Vegetarian claims	1, 70 and Annexures 1 and 5
WHO's dietary and health goals	Guideline1

ANNEXURE 1

CATEGORIES OFADDITIVES THAT MAY BE IDENTIFIED BY THEIR CATEGORY NAME IN A LIST OF INGREDIENTS

*Acids
*Acidity regulators
*Anticaking agents
*Antifoaming agents
*Bulking agents
*Carrier solvents
*Chewing-gum bases
*Clouding agents
*Colour retention agents
*Colourants (except tartrazine)
*Chemically modified starches
*Emulsifiers
*Emulsifying salts
*Enzymes ##
*Firming agents
*Flavourants
*Flavour enhancers (except MSG and sodium chloride)
*Flour improvers (flour treatment agent)
*Foaming agents
*Gelling agents ##
*Glazing agents
*Herbs or mixed herbs and spices or mixed spices, as appropriate
*Humectants
*Propellants
*Raising agents
*Sequestrants
*Stabilisers
*Starches
*Thickeners

Refer to Regulation 71

ANNEXURE 2

PRESCRIBED NUTRITIONAL INFORMATION DECLARATION

1. Format

The prescribed **"**nutritional information declaration**"** means the following nutritional information in the prescribed format on any foodstuff with mandatory or voluntary nutritional information, as the case may be, on the label.

TYPICAL NUTRITIONAL INFORMATION (as packed /ready-to-eat)

Quantified single serving size expressed in grams or millilitres, whatever is appropriate

	Per 100 g/ml	Per per serving	% MDR* per serving
Energy (kJ)		-	
Protein (g)			
Carbohydrate (g) of which sugar		-	
Total fat (g)		-	
Saturated fat (g)		-	
Trans fat (g)			
**			
**			
***			
Total dietary fiber (g) **		-	
Sodium (mg)		-	
(insert any other nutrient or food component to be declared in accordance with these Regulations here or as appropriate under the relevant main nutrient heading in g, mg, mcg, or other units as appropriate) in the order: vitamins, minerals, any other nutrient not made provision for already, in alphabetical order			

* Minimum Daily requirement (MDI) for individuals 4 years and older (see Annexure 3)

Place for the statement required by regulation 52(1)(c) or regulation 56, whatever is appropriate

** place for a subgroup nutrient, such as monounsaturated fat, polyunsaturated fat, omega-3 fatty acids, soluble fiber et cetera

***place to insert cholesterol when cholesterol information is given

PRESCRIBED NUTRITIONAL INFORMATION DECLARATION

2. **Energy conversion factors**

In the calculation of the energy value of a foodstuff for the purposes of the prescribed energy statement referred to in this Annexure the following conversion factors shall be employed:

(a) 1 g of carbohydrates expressed as monosaccharides and/or disaccharides shall be deemed to contribute 16 kJ;

(b) 1 g of starch and glycogen shall be deemed to contribute 17 kJ;

(c) 1 g of carbohydrates which reaches the colon shall be deemed to contribute 8 kJ, excluding polydextrose, fructo-oligosaccharides and maize bran;

(d) 1 g of polydextrose shall be deemed to contribute 5 kJ;

(e) 1 g of glycerol shall be deemed to contribute 18 kJ;

(f) 1 g of sugar alcohol not specified hereunder shall be deemed to contribute 10 kJ;

(g) 1 g of Erythritol shall be deemed to contribute 1 kJ;

(h) 1 g of Isomalt or Lactitol shall be deemed to contribute 11 kJ;

(i) 1 g of Maltitol shall be deemed to contribute 16 kJ;

(j) 1 g of Mannitol shall be deemed to contribute 9 kJ;

(k) 1 g of Sorbitol or Xylitol shall be deemed to contribute 14 kJ;

(l) 1 g of Fructo-oligosaccharides shall be deemed to contribute 11 kJ;

(m) 1 g of Maize bran shall be deemed to contribute 1,3 kJ;

(n) 1 g of protein shall be deemed to contribute 17 kJ;

(o) 1 g of alcohol (ethanol) shall be deemed to contribute 29 kJ;

(p) 1 g of fat shall be deemed to contribute 37 kJ;

(q) Novel fats:

Salatrims*, general family: 1 g shall be deemed to contribute 22 kJ

Olestra®: 1 g shall be deemed to contribute 0 kJ;

(r) 1 g of organic acid shall be deemed to contribute 13 kJ.

* Salatrims means random short- and long-chain triacylglycerol molecules

ANNEXURE 3

MINIMUM DAILY REQUIREMENTS FOR THE PURPOSES OF THESE REGULATIONS

NUTRIENT	unit of measurement	INDIVIDUALS 4 YEARS AND OLDER*
Protein	g	56
Vitamin A	µg [a]	900
Vitamin B_1 or thiamine	mg	1,2
Vitamin B_2 or riboflavin	mg	1,3
Nicotinic acid, nicotinamide or niacin	mg	16
Vitamin B_6 or pyridoxine	mg	1,7
Folic acid or folate	µg	400
Vitamin B_{12} or cyanocobalamin	µg	2,4
Biotin	µg	30
Pantothenic acid	mg	5
Vitamin C or ascorbic acid	mg	90
Vitamin D	µg [b]	15
Vitamin E	Mg te [c]	15
Vitamin K	µg	120
Calcium	mg	1300
Chromium	µg	35
Copper	mg	0.9
Iodine	µg	150
Iron	mg	18
Magnesium	mg	420
Manganese	mg	2.3
Molybdenum	µg	45
Phosphorus	mg	1250
Selenium	µg	55
Zinc	mg	11
Choline	mg	550

* The values used in this Table are based on Recommended Dietary Allowances (RDAs) which will meet the needs of nearly all (97 to 98%) healthy individuals to prevent nutrient deficiencies. RDA values are not necessarily enough to maintain optimum nutritional status and prevent chronic disease. These values are therefore considered to be the minimum amounts necessary to achieve and maintain optimum nutritional status which will assist in the reduction of disease, specifically degenerative diseases of lifestyle.

a Retinol equivalents (RE) = 1 mcg retinol = 3,33 I.U. (International units) vitamin A = 12 mcg trans beta-carotene = 24 mcg other provitamin A carotenoids, excluding carotenoids from red palm oil, red palm oil carotenoids = 2 mcg red palm oil carotenoids;

b As cholecalciferol: 1 mcg cholecalciferol = 40 I.U. of Vitamin D; and

c As d alpha tocopherol: mg = TE. 1 mg (d alpha tocopherol) = 1,49 I.U. of Vitamin E.

ANNEXURE 4

1. LIST OF FOODSTUFFS AND INGREDIENTS EXEMPTED FROM A DATE OF DURABILITY

- Any alcoholic beverage as described in the Liquor Products Act, 1989 (Act 60 of 1989)
- Chewing gum
- Confectionary products consisting of flavoured and/or coloured sugars
- Fresh fruits and vegetables which have not been peeled or cut or similarly treated
- Processed meat products such as biltong and dried sausage which have not been pre-packed
- Honey, provided the date the honey was pre-packed is printed on the label in a similar format and letter size as the “best before” date
- Ready-to-eat flour confectionary, provided that the date of manufacture is indicated on the label or in the direct vicinity where the products are displayed
- Sugars
- Unprocessed, unpacked fish, unprocessed, unpacked meat and poultry which have not been pre-packed
- Vinegar.

2. LIST OF FOODSTUFFS AND INGREDIENTS FOR WHICH A USE BY DATE IS REQUIRED

- Any other foods which at ambient or chilled temperatures are capable of supporting the formation of toxins or multiplication of pathogens to a level which could lead to food poisoning if they are not stored properly
- Any other foods intended for consumption either without cooking or after treatment such as reheating, unlikely to be sufficient to destroy food poisoning organisms, which may be present.
- All chilled dairy products such as milk, soft cheese, yoghurt and dairy-based products such as beverages and desserts
- Cooked products, whether or not they are intended to be eaten without further reheating
- Prepacked, processed meat products such as biltong and dried sausage
- Fresh fruit juices and juices with a limited shelf life of 5 days or less
- Infant formulas Chilled Patés
- Prepacked, prepared, ready-to-eat vegetables with added ingredients such as cream, cheese mayonnaise, etc
- Uncooked or partly cooked pastry and dough products including pizzas, sausage rolls or fresh pasta containing meat, poultry, fish or seafood

ANNEXURE 5

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.

ANNEXURE 6

FOODSTUFFS NOT CONSIDERED ESSENTIAL FOR A HEALTHY DIET AND FOR WHICH *NO* NUTRIENT CONTENT, GI, CERTAIN COMPARATIVE, HEALTH, SLIMMING OR ANY OTHER CLAIM WITH A HEALTH OR NUTRITIONAL MESSAGE WILL BE PERMITTED

Beverages

- Carbonated or uncarbonated soft drinks intended to be consumed cold, which contain sweetener(s) and additives in any form (e.g. powders, concentrates or ready-to-drink type etc.)
- Fruit nectars
- Soft drinks bearing the word "energy" or "sport" or "power" in any way on the label, with or without caffeine
- Iced teas in any form (e.g. powders, concentrates or ready-to-drink type etc.), which contain sweetener(s) and additives Powders to prepare hot or cold beverages for which any one or more of the following criteria apply:
    - Contain more than 10 g sugar per single serving
    - Contain fully or partially hydrogenated fat
    - Contain any non-nutritive sweetener(s)
    - Contain any artificial colourant(s)

Sweet biscuits and flour confectionary

- All sweet, dry biscuits, unless–
    - the biscuit has been specifically developed and formulated for the purpose of preventing or correcting a demonstrated nutrient deficiency as recognised by the Department;
    - the impact of the special biscuit on the target population/group has been scientifically evaluated by at least one human intervention trial;
    - written proof of the outcome has been published in an acceptable medical or nutrition journal or reported at a national nutrition congress; and
    - a request for approval accompanied by the above-mentioned documentation has been granted by the Directorate: Food Control prior to retail market appearance
- All cakes
- Other sweet flour confectionary such as muffins, doughnuts, sweet pastries and others, unless the product is high in fiber and has a low Glycaemic Index value
- Sweet tarts

Candies and chocolate confectionary

- All chocolate confectionary
- All sugar confectionary, including toffees
- Chewing gum

Fast foods

Any fast food meal of which any one or more of the following criteria apply-

- which contains any trans fats;
- of which the main carbohydrate component of the meal (e.g., bread bun of a hamburger) has a high Glycaemic Index value;
- has a fiber content of less than 3 g per 100 g end product;
- has a salt content of 1,25 g salt per 100 g end product or more; and
- has a saturated fat content of more than 5 g per 100 g end product
- which has been prepared/cooked in an vegetable oil that has been subjected to any of the following processes: any form of heat treatment, degumming, refining, bleaching and deodorizing

Savoury foodstuffs

- Ready-to-eat savoury snacks such as potato crisps, extruded or expanded maize snacks etc.
- Ready-to-eat dips or dip powders intended to be reconstituted with a fat content of more than 3 g per 100 g

Desserts

- Baked type desserts, with a fat content of more than 10 g per 100 g and a sugar content of more than 15 g per 100 g
- Chilled, ready-to-eat desserts
- Ice cream, frozen joghurt, frozen desserts, frozen treats, sorbets, edible ices and any other similar product containing more than 20 g per 100 g carbohydrates and/or more than 3 g total fat per 100 g
- Instant dessert powders
- Jellies

Other

- Any vegetable oil that has been subjected to any of the following processes: any heat treatment, degumming, refining, bleaching and deodorizing, and packed in see-through plastic containers
- Commercially prepared meat pies and sausage rolls and pies wit a savoury filling
- Dry soup powders
- Flavoured fat spreads or margarine
- Speads, toppings, glazes or filling sold as such for cakes, desserts and tarts
- “Health” bars, breakfast bars, seed bars or energy bars with a sugar content more than 10 g per bar, a saturated fat content of more than 1 g per 100 g or any trans fat

- Fruit bars, fruit roles or fruit flakes with any added suger, non-nutritive sweeteners and/or added fat
- Margarines and fat spreads containing any hydrogenated or interesterified plant oil
- Manufactured meat products, unless at least compliant with the condition for lean/trim and low in sodium
- Mayonnaise
- Non-nutritive table sweeteners
- Ready-to-eat candy breakfast cereals with a sugar content of 15 g or more per 100g
- Sugar (white, yellow, brown), castor sugar, icing sugar, et cetera.
- Sweetened, condensed milk
- Syrups, excluding molasse
- Tea creamers and coffee creamers
- Foodstuffs (solids and liquids) sweetened with added fructose

ANNEXURE 7

REFERENCE AMOUNTS FOR SINGLE SERVING SIZES

Unless otherwise noted, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the foodstuff. 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
	Bakery Products	
1.	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 graham 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 fortified maize porridge or maize pap	40 g dry 250 ml prepared
29.	Ready-to-eat breakfast cereals, puffed and uncoated (less than 20 g per 250 ml)	15 g
30.	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
31.	Read-to-eat breakfast cereals, fruit and nut type, granola (43 g or more per 250 ml) and biscuit type cereals	55 g
32.	Bran and wheat germ	15 g
33.	Flours, including cornmeal	30 g
34.	Grains, such as rice or barley	45 g dry 140 g cooked
35.	Pastas without sauce	85 g dry 215 g cooked
36.	Pastas, dry and ready-to-eat, such as fried canned chow mien noodles	25 g
37.	Starch, such as cornstarch, potato starch, tapioca starch or wheat starch	10 g
38.	Stuffing	100 g
39.	***Dairy Products and Substitutes*** Cheese, including cream cheese and cheese spread, except those listed as a separate item	30 g
40.	Cottage cheese	125 g
41.	Cheese used as an ingredient, such as dry cottage cheese or ricotta cheese	55 g
42.	Hard cheese, grated, such as parmesan or Romano	15 g
43.	fresh cheese and fresh dairy desserts	100 g
44.	Cream and cream substitute, except those listed as a separate item	15 ml
45.	Cream and cream substitute, powder	2 g
46.	Cream and cream substitute, aerosol or whipped	15 g
47.	Eggnog	125 ml
48.	Milk, evaporated or condensed	15 ml
49.	Plant-based beverages, milk, buttermilk and milk-based drinks, such as chocolate milk	250 ml
50.	Shakes and shake substitutes, such as dairy shake mix	250 ml
51.	Sour cream	30 ml
52.	Yoghurt	175 ml
53.	Ice cream, ice milk, frozen yoghurt and sherbet	125 ml
54.	Dairy desserts, frozen, such as cakes, bars, sandwiches or cones	125 ml
55.	Non-dairy desserts, frozen, such as flavoured and sweetened ice or pops, or frozen fruit juices in bars or cups	75 ml
56.	Sundaes	250 ml
57.	Custard, gelatine and pudding	125 ml
58.	***Dessert Toppings and Fillings*** Dessert toppings, such as maple butter and marshmallow cream	30 g

59.	Cake frostings and icings	35 g
60.	Pie fillings	75 ml
61.	***Eggs and Egg Substitutes*** Egg mixtures, such as egg foo young, scrambled eggs or omelettes	110 g
62.	Eggs	50 g
63.	Egg substitutes	50 g
64.	***Fats and Oils*** Butter, margarine, shortening and lard	10 g
65.	Vegetable oil	10 ml
66.	Butter replacement, powder	2 g
67.	Dressings for salad	30 ml
68.	Mayonnaise, sandwich spread and mayonnaise-type dressing	15 ml
69.	Oil, spray type	0.5 g
70.	***Marine and Fresh Water Animals*** Canned anchovies, anchovy paste and caviar	15 g
71.	Marine and fresh water animals with sauce, such as fish with cream sauce or shrimp with lobster sauce	140 g cooked
72.	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
73.	Marine and fresh water animals, canned	55 g, drained of brine or oil where applicable
74.	Marine and fresh water animals, smoked or pickled, or spreads	55 g
75.	***Fruit and Fruit Juices*** Fruit, fresh, canned or frozen, except those listed as a separate item	140 g 150 ml canned (drained)
76.	Candied or pickled fruit	30 g
77.	Dried fruit, such as raisins, dates or figs	40 g
78.	Fruit for garnish or flavour, such as maraschino cherries	4 g
79.	Fruit relishes	60 ml
80.	Avocado, used as an ingredient	30 g
81.	Cranberries, lemons and limes, used as ingredients	55 g
82.	Watermelon, cantaloupe, honeydew and other melons	150 g
83.	Juices, nectars and fruit drinks	250 ml
84.	Juices, used as ingredients, such as lemon juice or lime juice	5 ml
85.	***Legumes*** Bean curd (tofu) and tempeh	85 g
86.	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)
87.	***Meat, Poultry, Their Products and Substitutes[3]*** Pork rinds and bacon	54 g uncooked 15 g cooked
88.	Beef, pork and poultry breakfast strips	30 g uncooked 15 g cooked
89.	Dried meat and poultry, such as jerky, dried beef or parma ham,	

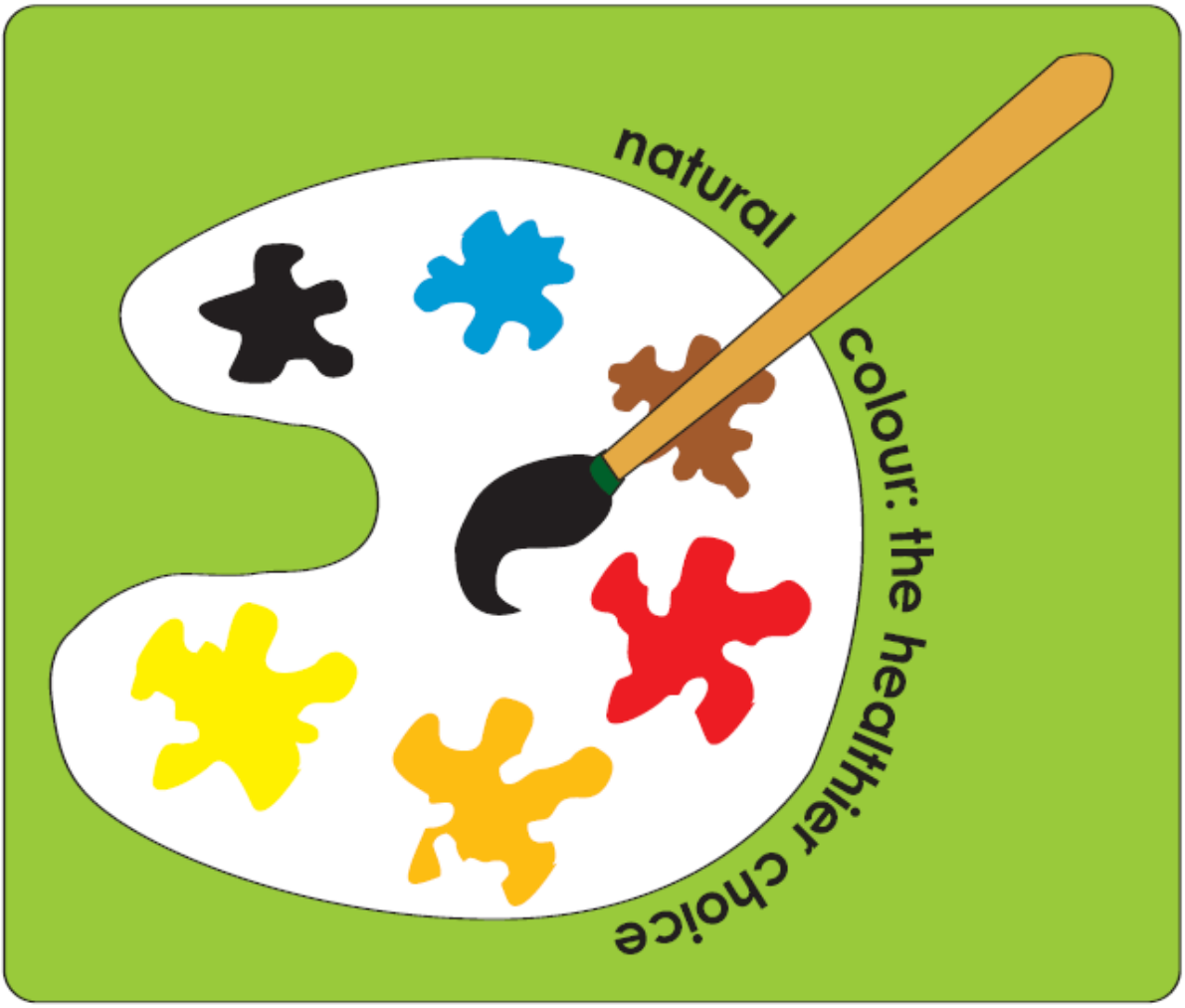
	as well as sausage products with a water activity of 0.90 or less, such as salami, dried thuringer or cervelat	30 g
90.	Luncheon meats, such as polony, liver sausage, ham and cheese loaf; pâté; meat pie fillings	75 g uncooked 55 g cooked
91.	Sausage products, such as linked sausage, Vienna sausage, wieners, breakfast sausage, frankfurters, pork sausage, bratwurst, smoked sausage, pepperoni, knackwurst	75 g uncooked 55 g cooked
92.	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
93.	Patties, cutlettes, chopettes, steakettes, meatballs, sausage meat and ground meat, with or without breading or batter	100 g raw 60 g cooked
94.	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
95.	Canned meat and poultry	55 g
96.	Meat and poultry with sauce, such as meat in barbecue sauce or turkey with gravy, but excluding combination dishes	140 g
97.	***Miscellaneous*** Baking powder, baking soda and pectin	0.6 g
98.	Baking decorations, such as coloured sugars or sprinkles for cookies	4 g
99.	Bread crumbs and batter mixes	30 g
100.	Cooking wine	30 ml
101.	Cocoa powder	5 g
102.	Non-alcoholic drink mixers, such as pina colada	250 ml
103.	Chewing gum	3 g
104.	Salad and potato toppers, such as salad crunchies, salad crispins or substitutes for bacon bits	7 g
105.	Salt and salt substitutes, as well as seasoned salt, such as garlic salt	1 g
106.	Spices and herbs	0.5 g
107.	***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
108.	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
109.	Hors d' oeuvres	50 g
110.	***Nuts and Seeds*** Nuts and seeds, not for use as snacks: whole, chopped, sliced, slivered or ground	30 g shelled
111.	Butters, pastes and creams, other than peanut butter	30 g

112.	Peanut butter	15 g
113.	Flours, such as coconut flour	15 g
114.	***Potatoes, Sweet Potatoes and Yams*** French fries, hash browns, skins and pancakes	85 g frozen French fries 70 g prepared
115.	Mashed, candied, stuffed or with sauce	140 g
116.	Plain, fresh, canned or frozen	110 g fresh or frozen 125 g vacuum packed 160 g canned (drained)
117.	***Salads*** Salads, such as eggs, fish, shellfish, bean, fruit, vegetable, meat, ham or poultry salad, except those listed as a separate item	100 g
118.	Gelatine salad	120 g
119.	Pasta or potato salad	140 g
120.	***Sauces, Dips, Gravies and Condiments*** Sauces for dipping, such as barbecue, hollandaise, tartar, mustard or sweet and sour sauce	30 ml
121.	Dips, such as legume or dairy-based	30 g
122.	Major main entrée sauce, such as spaghetti sauce	125 ml
123.	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
124.	Major condiments, such as ketchup, steak sauce, soy sauce, vinegar, teriyaki sauce or marinades	15 ml
125.	Minor condiments, such as horseradish, hot sauce, mustard or Worcestershire sauce	5 ml
126.	***Snacks*** Chips, pretzels, popcorn, extruded snacks, grain-based snack mixes and fruit-based snacks, such as fruit chips	50 g
127.	Nuts or seeds for use as snacks	50 g shelled
128.	Meat or poultry snack food sticks	20 g
129.	***Soups*** All varieties	250 ml
130.	***Sugars and Sweets*** Candies, including chocolate bars and other chocolate products, except those listed as a separate item	40 g
131.	Hard candies, except those listed as a separate item	15 g
132.	Baking candies, such as chocolate chips	15 g
133.	Breath mints	2 g
134.	Roll-type hard candies and mini size hard candies in dispenser packages	5 g
135.	Confectioner's or icing sugar	30 g
136.	Bread spreads, except those listed as a separate item, honey and molasses	20 g
137.	Jams, jellies, marmalades, fruit butters and spreads	15 ml
138.	Marshmallows	30 g

139.	Sugars, except those listed as a separate item	4 g
140.	Sugar substitute	Amount equivalent in sweetness to 4 g of sugar
141.	Syrups, including chocolate, maple and corn syrup	30 ml as ingredient 60 ml other uses
142.	***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
143.	Vegetables with sauce	110 g fresh or frozen 125 ml canned
143.	Vegetables without sauce, canned	85 g, canned (drained)
144.	Vegetables primarily used for garnish or flavouring, fresh, canned or frozen, but not dried, such as parsley or garlic	4 g
145.	Chilli pepper and green onion	30 g
146.	Seaweed	15 g
147.	Lettuce and sprouts	65 g
148.	Vegetable juice and vegetable drink	250 ml
149.	Olives	15 g
150.	Pickles	30 g
151.	Relish	15 ml
152.	Vegetable pastes, such as tomato paste	30 ml
153.	Vegetable sauce or purée, such as tomato sauce or tomato purée	60 ml

ANNEXURE 8

Logo 1: The phrase **"Natural colour – the healthier choice"** shall, if used, be written around the top of the colour palette in bold black letters in Century gothic font. The colours as indicated below shall be used and the logo may not be altered in any way.



Colour indication:

- Green background: Pantone 390 (45c, 100y)
- Green part of brush: Pantone 349 (100c, 100y, 54k)
- Orange paint 'blob', middle right: Pantone 123 (28m, 100y)
- Yellow paint 'blob', bottom right: Process yellow (100y)
- Brown paint 'blob', top left: Pantone 470 (56m, 78y, 40k)
- Red paint 'blob', top right: Pantone 485 (100m, 100y)
- Black part of brush, paint 'blob', bottom left, frame of logo, frame of pallet and letters: Process black
- Light brown brush stick: Pantone DS 26-4 (10c, 35m, 85y)
- Blue paint blob, middle left: (100c, 13k)

Logo 2: The phrase **"Less synthetic colour is better for my health"** shall if used, be written around the top of the colour palette in bold black letters in Century Gothic font. The colours as indicated below shall be used and the logo may not be altered in any way.

Colour indication:

- Green part of brush: Pantone 349 (100c, 100y, 54k)
- Orange paint 'blob', middle right: Pantone 123 (28m, 100y)
- Yellow paint 'blob', bottom right: Process yellow (100y)
- Brown paint 'blob', top left: Pantone 470 (56m, 78y, 40k)
- Red background and paint 'blob', top right:
  Pantone 485 (100m, 100y)
- Black part of brush, paint 'blob', bottom left, frame of logo, frame of pallet and letters: Process black
- Light brown brush stick: Pantone DS 26-4 (10c, 35m, 85y)
- Blue paint blob, middle left: (100c, 13k)

GUIDELINE 4

HIDDEN ALLERGENS

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

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

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

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

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

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

* Thickener
* Tofu
* Vegetable broth
* Vegetable gum
* Vegetable starch

Mostly produced from soy but may be manufactured from egg

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

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

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

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

METHODS OF ANALYSIS FOR GLUTEN

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

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

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

ALLERGEN CONTROL POLICY (ACP)

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

a) Raw materials:
- Ingredients
- Sub-ingredients, e.g. natural flavours, other allergen-derived additives or ingredients
- Reworked ingredients, e.g. peanut-containing biscuit dough re-worked into plain biscuit dough
- Processing aids, e.g. wheat starch
- Packaging materials, e.g. wheat derivative used in packaging material

b) Cross-contact: shared equipment, utensils, work surfaces, staff members.

PROCESSESING PROCEDURES

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

ALLERGEN AUDIT

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

SUPPLIER CONTROL

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

SUPPLIER INFORMATION QUESTIONNAIRES

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

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

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

LABELLING AND PACKAGING

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

COMPANY ALLERGEN POLICY

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

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

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

SAMPLING

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

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

GUIDELINE 5

RULES ON QUANTITATIVE INGREDIENT DECLARATIONS (QUID)

1. SCOPE OF QUID

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

2. WHEN QUID DECLARATIONS ARE NOT REQUIRED

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. WHEN QUID DECLARATIONS ARE REQUIRED

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

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

(aa)

The ingredient is included in the name of the food	**Examples*would include**
	"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";

(cc) when a pictorial representation is descriptive of the agricultural origin of certain ingredients without emphasising the quantity of the ingredients concerned (e.g., a picture of wheat or hops on a beer label);

(dd) when a pictorial representation presents all the food ingredients (with the exception of minor ingredients such as seasonings and additives) without emphasising any particular one;

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

(ff) in the case of a food mix, a pictorial representation of what should be made from the product, having regard to the instruction given.

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

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

4. EXPRESSION OF QUANTITY

(a) Foods in general:

(i) The quantity of an ingredient or category of ingredients should generally be expressed as a percentage. The percentage may be rounded to the nearest whole number, or in those cases where it is below 5%, to the nearest 0,5 decimal place.

(ii) The percentage should normally be calculated by using the same method as that used for determining the order in the list of ingredients. This means that the weight of an ingredient to be quantified would need to be divided by the total weight of all of the ingoing ingredients (except the weight of any added water or volatile ingredients lost in processing). For example, the fish content of a "fish finger" would be calculated as follows:

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

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

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

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

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

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

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

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

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

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

(i) QUID declarations on concentrated or dehydrated products intended to be reconstituted before consumption (including dry mixes for cakes and desserts) may relate to the ingredients in the reconstituted product if the ingredient listing information is also given on this basis. Although the provision applies to products that are intended to be reconstituted by the addition of water, a similar approach may also be used for those products, which are intended to (or which may optionally) be reconstituted by the addition of other liquids (e.g., milk or stock) if the ingredient listing information is also given on this basis.

(ii) In deciding whether to give ingredient listing and QUID information based either on the dehydrated or reconstituted product, consideration should be given to avoiding giving QUID and any nutrition labelling information for industry sectors, to ensure that a common practice is adopted for all similar products, to enable consumers to make appropriate comparisons.

GUIDELINE 6

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

PART A:

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

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

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

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

]

PROCEDURE

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

5. Decide on type of subjects [healthy and/or IDDM and/or NIDDM, age (subjects shall be older than 18 years), BMI]. Subjects may be made up of singular groups, e.g., non diabetics or diabetics or mixed groups, e.g., non diabetics and diabetics together:

(a) No pregnant and lactating women may be included.

(b) Diabetics used as subjects should

i. have a normal renal function;

ii. be well controlled with an HbA_{1c} within the optimal South African reference range, namely <7 - 8% (Ref: SEMDSA Guidelines for diagnosis and management of diabetes mellitus, 2002).

(c) The details of the type of subjects must be written in the final report.

6. Recruit a minimum of 10 subjects based on willingness to comply with protocol and inclusion and exclusion criteria, since Truswell, AS, recommended this requirement in his article: Glycaemic Index of foods (European J of Clin Nutr 1992, 46: Suppl. 2, S91 – 101).

7. All subjects must give signed informed consent to participate in the study.

8. All medication, including complementary or natural medicines and the use of nutritional supplements used by subjects before and during the test, should be the same during the reference and the test period. Records should be kept of all medications used by all subjects and be available on request.

9. All known factors that influence glucose responses should be minimised as far as possible and should remain consistent in both the reference and test-food testing periods. This includes factors such as stress levels, smoking and alcohol intake.

10. If new test subjects are recruited to test food products, randomisation of volunteers to treatments should be done, i.e., the three glucose tests should be randomly alternated with the test foods in the different subjects.

11. All subjects must receive all test foods and the standard.

12. The total carbohydrate intake for the three days prior to the testing should be in line with the prudent diet and therefore contain at least 50% of total energy as CHO, 30% fat and 20% protein, as recommended for the pre-evening meal by Gresse A. & Vorster H.H.: The Glycaemic index and second meal effect of a typical African meal in black non-insulin dependent diabetic subjects. (SA J Fd Sc Nutr 1992; 4: 64 – 69).

13. Any of the standard pre-test meals described in Appendix B can be chosen and given as the evening meal the previous night and must be consumed 10 to 12 hours before testing.

14. The pre-test meal is defined (see Appendix B). The selected pre-test meal must be detailed in the final report. Any of the prescribed pre-test meals may be used by the subjects for any test, seeing that they are about identical in composition of macronutrients.

15. Subjects should not consume anything other than water from 22:00 the night prior to testing. *(This is what all medical laboratories recommend the night before a glucose tolerance test is done the next day).* However, no water or other liquids should be taken on the morning of the test, except for the amount that is allocated with the test food, as it has been shown that this can dilute blood plasma and affect blood glucose concentration.

16. Subjects should not do any unusual physical activity for 24 hours prior to the test and physical activity should remain consistent in both the reference and test-food testing periods.

17. Subjects should arrive at the testing center by car and not be physically active during testing.

18. Subjects should remain stationary during the duration of the test.

19. Baseline capillary glucose measurement should be taken after an overnight fast of 10 to 12 hours.

20. GI tests should not be conducted by test subjects closer than two, but preferably three days apart.

21. Capillary glucose must be measured in compliance with Good Laboratory Practice Guidelines and in strict adherence to prescribed methodology as follows:

(a) Wash hands with soap and warm water.

(b) Never use alcohol swabs to disinfect the finger.

(c) Prick the side of the finger and let the hand hang by the side to allow the blood to gravitate to the finger. Squeeze the finger gently (Hand may be held in warm water to improve blood flow before the finger is pricked).

(d) Apply only one large drop of blood to the test pad on the pad on the blood glucose sensor electrode (in the case of a blood glucose sensor) OR put two to three large drops of blood (in the case of the YSI analyser) in the test tube containing the required amount of anticoagulant.

(e) In the case of the YSI analyser: Wait for the sipper to appear, after the appropriate button had been pressed. Place the test tube under the sipper and press the appropriate button. Wait for the sipper to take up the blood. Remove the test tube once the sipper has removed itself from the tube. Wait for the blood glucose reading to appear on the blood glucose measuring device and note it down on the provided form.

(f) Never "milk" the finger to get a larger drop of blood.

(g) The appropriate calibration must be done and appropriate glucose controls must be used to ensure the accurate functioning of glucose measuring devices. One control measurement must be done per instrument per test day.

22. Test foods and standards must be prepared and the precise amount given to each subject according to the randomisation schedule. Subjects must consume the test foods or standard within the first 10-15 minutes after the fasting value was obtained and the timer has been started. Capillary finger-prick blood samples are taken for normal subjects fasting and at 15, 30, 45, 60, 90 and 120 minutes after the START of the test meal and for diabetic subjects fasting and at 30-min intervals for 3 hours The test meal is started within a few minutes of the fasting blood sample (it doesn't have to be immediately after, but should be within 5 min. or so). The timer starts with the first bite of the test meal – so the first blood sample is 15 min. after the first bite (or start) of the test meal. The standard for healthy volunteers must consist of 50 g glucose powder (in cases where dextrose monohydrate is used as glucose, 55 g dextrose monohydrate is to be used since it contains 10% water) dissolved in 300 ml water. For diabetic subjects the standard must consist of the same load but the monitoring period is longer.

23. Number of measurements:

(a) The reference food requires 3 measurements.

(b) The test food requires 1 measurement.

(c) Testing of the reference food must be redone every 6 months if the same subjects are used on a regular basis.

24. Timings: Capillary blood glucose samples must be taken as follows:

<u>Non-diabetic subjects:</u>

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

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

Diabetic subjects:

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

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

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

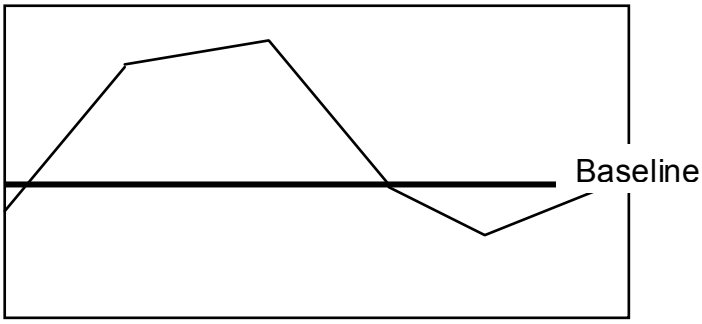


Figure 1. The area under the blood glucose curve above the baseline (fasting) value

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

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

$$AUC=\sum_{x=1}^{n} Ax$$

where, Ax = the AUC for the xth time interval

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

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

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

otherwise, $A_1 = 0$

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

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

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

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

if $G_x<G_0$ and $G_{x-1}<G_0$, $Ax = 0$

25. The final report must include the following information:

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

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

APPENDIX A

GLYCAEMIC INDEX TESTING – INFORMATION FORM

Product to be tested_____Date of test_____

Name of subject_____

Informed consent signed (yes/no)_____

Method of preparation

_____

_____

_____

_____

Percentage energy from carbohydrate of test food

Total carbohydrate of food _____g/100 g analytical method _____

Dietary Fiber _____g/100 g analytical method _____

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

Glycaemic carbohydrate _____g/100g analytical method _____

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

Subject information

Healthy	Yes / No	Male		Age	years
NIDDM	Yes / No	Female		BMI	Kg/m^2
IDDM	Yes / No				
If diabetic					
	HbA_{1c}	%			
	Normal renal function	Yes / No			

Medication usage

_____

_____

_____

_____

_____

Nutritional supplements usage

_____

_____

_____

Test results

Name of glucose measuring device used for test_____

Calibration strip lot No. _____

Name of control solution used _____

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

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

Control value 1 _____

Capillary glucose in mmol/L

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

Area under the blood glucose response curve _____

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

APPENDIX B

PRE-TEST MEAL

FOR GLYCAEMIC TESTING

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

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

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

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

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

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

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

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

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

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

APPENDIX C

LABORATORY CERTIFICATION AND QUALITY CONTROL

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

The criteria are as follows:

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

PART B

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

GUIDELINE 7

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

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

1. IDENTIFICATION OF THE GENUS, SPECIES AND STRAIN[1]

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

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

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

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

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

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

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

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

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

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

2. SCREENING FOR THE SAFETY OF POTENTIAL PROBIOTIC MICROORGANISMS (PHASE I)[1]

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

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

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

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

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

(iii) Assessment of side effects during human studies.

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

(iv) Determination of the hemolytic activity is required.

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

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

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

3. ASSESSMENT OF EFFICACY (PHASE II)[1]

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

(a) Resistance to gastric acidity.

(b) Bile acid resistance.

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

(d) Antimicrobial activity against known human pathogenic microorganisms.

(e) Ability to reduce pathogen adhesion to surfaces.

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

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

(a) **Identification of probiotic bacteria**

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

(b) **Enumeration of probiotic bacteria**

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

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

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

5. GENERAL REQUIREMENTS

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

GUIDELINE 8

APPROVED FUNCTION CLAIMS

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

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

Vitamin A	Important for the maintenance of good vision, normal growth and a healthy gut and immune system.
Vitamin B_1 (Thiamine)	Helps the body change the food you eat into energy. Maintains growth and healthy nerve function.
Vitamin B_2 (Riboflavin)	Helps the body change the food you eat into energy. Essential for growth.
Vitamin B_6 (Pyridoxine)	Helps the body change the food you eat into energy. Plays a role in protein metabolism. Essential for growth.
Vitamin B_{12}	Contributes to a healthy nervous system and is necessary to form red blood cells. Required for the normal functioning of all cells.
Vitamin C Ascorbic acid	Plays a role in maintaining a healthy immune system, gums, skin and connective tissue. Helps with the absorption of iron from food. Functions as a tissue antioxidant thereby keeping cells healthy/Antioxidant/Works with vitamin E and beta-carotene to find and attack free radicals. Aids in tissue growth and repair. Protect against infection.
Vitamin D	For the maintenance of healthy bones and teeth. Helps the body utilise calcium and phosphorus, which are necessary for the normal development and maintenance of strong bones and teeth. Protects against muscle weakness. Involved in regulation of heartbeat. Enhances immunity. Necessary for thyroid function. Necessary for normal blood clotting.
Vitamin E	Functions as a tissue antioxidant thereby keeping cells healthy. Helps maintain a healthy immune system. Protects unsaturated fatty acids and vitamin A against oxidation in the body (natural antioxidant). In combination with vitamin E, beta-carotene, and selenium, associated with a reduced risk of significantly reduced total cancer mortality. Prevents cardiovascular diseases, reduces blood pressure; Promotes normal blood clotting and healing. Necessary for tissue repair, promotes healthy skin and hair. Protects other fat-soluble vitamins and aids in utilisation of vitamin A. Protects normal blood circulation. Protects against damage to red blood cells.
Zeaxanthin	A carotenoid which acts as a tissue antioxidant and so keeps cells healthy
Zinc	Essential for growth and maintains a healthy immune system. Important in prostate gland function and growth of reproductive organs. Required for protein synthesis and collage formation. Vital for bone formation. Promotes healing of wounds. Helps to fight and prevent formation of free radicals. Needed for normal taste and smell. Protects liver from chemical damage. Is a constituent of insulin & many vital enzymes. Sufficient intake and absorption of zinc is needed to maintain proper vitamin E levels in blood and increases the absorption of vitamin A.

GUIDELINE 9

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

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

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

Notes:
The principle is always to compare "apples with apples"

Examples of incorrect comparisons:

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

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

Examples of correct comparisons:

- Vienna sausage of one brand name with another brand name Vienna sausage (e.g., difference in fat content)
- A doughnut with chocolate topping with a doughnut with a caramel topping
- One iced tea with another iced tea (difference in sugar content or energy value)
- One brand name of frozen potato chips with another brand name of frozen potato chips (difference in added fat content)
- Bacon with lower sodium content with a bacon with the nearest higher sodium content. The following example refers:
    - Bacon with sodium level of 500 mg /100 g compared to -
        - Bacon with 600 mg sodium/100 g ☑
        - Bacon with 750 mg sodium/100 g ☒
        - Bacon with 945 mg sodium/100 g ☒
        - Average of the above-mentioned 3 types ☒
- One brand name beer with another brand name beer (difference in carbohydrate content or alcohol content)

GUIDELINE 10

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

The best practice process of selecting the sample to be sent for analysis is a **random**[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 foodstuffs, a minimum of twelve (12) samples from various batches according to the specific, relevant sampling plan (e.g., random sampling, stratified sampling or representative sampling) shall be taken. Examples are margarine, muesli, composite cereals, ready-to-eat meals etc.

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

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

The laboratory shall -

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

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

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

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

4. Handling

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

5. Verification (claim versus no claim)

(a.) **Claims**

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

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

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

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

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

(b) **No claims**

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

GUIDELINE 11

PRODUCT INFORMATION IN TERMS OF INGREDIENT/ADDITIVES TRACEABILITY

2 examples of Supplier Ingredient Information Files

1. CALCIUM PROPIONATE

MATERIAL TECHNICAL AND NUTRITIONAL DATA SHEET

CALCIUM PROPIONATE

Supplier:	
Product:	

Document Date
May2007

Identification

Chemical Names	**Chemical Formula and Weight**		**ID Numbers**
Calcium propionate	$C_6H_{10}CaO_4$	Wt: 186.22	CAS No: 4075-81-4
Calcium propanoate	$Ca(CH_3CH_2COO)_2$		INS No: E 282

Description and Application

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

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

Labelling: Preservative (calcium propionate)

Sensory Information

Form: Solid - Crystalline powder

Colour White

Odor Faint odour of proppionic acid

Material Breakdown

Ingredients	**Derived from (where applicable)** **%**
Calcium propionate	100% Synthetic product
Diluents/Carriers/Anticaking agents	None
Other processing aids (specify)	None

Country of Origin

A product of South Africa made with local materials, only

Packaging, Storage and Shelf life

Unit size: 1 x 25 kg (net)

Packaging: Woven polypropylene bag with polyethylene liner

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

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

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

Technical Properties

Solubility: Freely soluble in water. Soluble in ethanol.

Hygroscopicity: Mildly hygroscopic

Thermal Decomp: Above 250°C

Technical Specifications

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

Typical Nutritional Information per 100g Calcium Propionate

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

Food Allergen Information

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

Food Intolerance Information

Contains:	Yes	No	Specify level and source (if applicable)
Sulphur dioxide (SO_2)		X	
Sulphites (SO_3)		X	
Benzoic acid / benzoates		X	
BHA (Butylated hydroxyanisole)		X	
BHT (Butylated hydroxytoluene)		X	
TBHQ (Tertiary butylhydroquinone)		X	
Glutamates (e.g. MSG, L-glutamic acid)		X	
Tartazine		X	
Alcohol (ethanol, only)		X	

Vegetarian Status

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

Religious Status

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

Genetic Modification Status

Guaranteed GMO-Free

Manufacturer's Warrant

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

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

Name of compa

Document control offic

E-mail addres

2. SUGAR: SUCROSE< LIGHT BROWN (RAW)

MATERIAL TECHNICAL AND NUTRITIONAL DATA SHEET

SUGAR: SUCROSE, LIGHT BROWN (RAW) **RM041**

Supplier:	
Product:	

Document Date
21 May 2007

Identification

Chemical Names	**Chemical Formula and Weight**		**ID Numbers**
Sucrose	$C_{12}H_{22}O_{11}$	Wt: 342.30	CAS No: 57-50-1
β-D-fructofuranosyl-α-D-glucopyranoside			INS No: NA

Description and Application

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

Application: Primarily used in the baking and canning industry.

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

Sensory Information

Appearance: Solid – Crystalline

Colour: Light brown

Odour: Odourless

Material Breakdown

Ingredients	**%**	**Derived from (where applicable)**
Raw (brown) sugar	100%	Sugar cane
Diluents/Carriers/Anticaking agents	0%	
Other processing aids (specify)	0%	

Country of Origin

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

Packaging, Storage and Shelf life

Unit size: 1 x 25 kg (net)

Packaging: Multi-ply paper bag

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

Shelf life: Unlimited if stored under specified conditions

Date marking:	Not applicable			
Batch coding:	**Example: 0610:25 030**	**06**	**10:25**	**030**
		Year	Time	Day of year
		2006	10h25	30 Jan

Technical Properties

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

Technical Specifications

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

Typical Nutritional Information per 100g Brown (Raw) Sugar

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

Food Allergen Information

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

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

Food Intolerance Information

Contains:	**Yes**	**No**	**Specify level and source (if applicable)**
Preservative: Sulphur dioxide (SO_2)		X	
Preservative: Sulphites (SO_3)		X	
Benzoic acid / benzoates		X	
Antioxidant: BHA (Butylated hydroxyanisole)		X	
Antioxidant: BHT (Butylated hydroxytoluene)		X	
Antioxidant: TBHQ (Tertiary butylhydroquinone)		X	
Glutamates (e.g. MSG, L-glutamic acid)		X	
Colourant: Tartazine		X	
Alcohol (ethanol, only)		X	

Vegetarian Status

Suitable for:	**Yes**	**No**	**Comments**
Strict vegetarian diet	√		All material derived from non-animal origin.
Lacto-vegetarian diet	√		
Ovo-vegetarian diet	√		
Lacto-ovo vegetarian diet	√		

Religious Status

Religious group:	**Suitable**	**Certified**	**Comments**
Halaal (Muslim diet)	Yes	Yes	Certificate available on request
Kosher (Jewish diet)	Yes	Yes	Certificate available on request

Genetic Modification Status

Derived from genetically modified cane sugar

Manufacturer's Warrant

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

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

Name of company:

Document control officer:

E-mail address:

GUIDELINE 12

GUIDELINES FOR THE MANNER OF EXPRESSION OF ENERGY, NUTRIENT OR OTHER SUBSTANCES VALUES FOUND IN FOODSTUFFS AND NUTRITI0NAL SUPPLEMENTS IN THE TABLE WITH NUTRITIONAL INFORMATION

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

INFORMATI0N	DESCRIPTION	UNIT	MANNER OF EXPRESSION
Energy value	"KiloJoules", Total kiloJoules', "Total energy", Total kJ	The amount is expressed in kilojoules per serving of stated size	The amount is rounded off- (a) if it is less than 5 kJ as "0 kJ"; (b) if it is 5 kJ or more but less than 30 kJ to the nearest multiple of 1 kJ; and (c) if it is 30 kJ or more to the nearest multiple of 5 kJ.
Amount of fat	"Fat", "Total fat"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) (i) if it is 0.5 g or less as "0 g", provided no other fatty acid is declared in an amount greater than 0 g, in which case it shall be declared as "< 0.5 g" (ii) in all other cases to the nearest multiple of 0.1 g; (b) if it is more than 0.5 g but not more than 5 g to the nearest multiple of 0.5 g; and (c) if it is more than 5 g to the nearest multiple of 1 g.
Amount of saturated fatty acids	"Saturated fat", "Saturated Fatty acids", Saturated", "Saturates"	The amount is expressed in grams (g) per single serving and per 100 g/ml	The amount is rounded off- (a) if it is 0.1 g or less as "0 g"; (b) if it is more than

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

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

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

GUIDELINE 13

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

CONTENTS

1. INTRODUCTION

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

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

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

(a) Interested party initiates early discussions with the Directorate: Food Control about viability of health claim.

(b) Interested party prepares and submits a dossier of evidence to the Directorate: Food Control for validation of health claim according to the guidelines provides in these Guideline.

(c) The Directorate: Food Control Secretariat undertakes preliminary assessment of dossier to ensure its completeness prior to submission to an *Ad hoc* independent Expert Committee. The Secretariat accepts or rejects a dossier. In the case of a dossier being rejected the Secretariat will inform the interested party in writing of the shortcomings. It remains the interested party's choice to resubmit the dossier or not. In the case where a dossier is not resubmitted within the next 3 months from the date of the above-mentioned communication, the process will automatically be terminated at this stage.

(d) By receipt of the written confirmation mentioned above, to proceed with the evaluation process explained in paragraph (e) below, the Directorate: Food Control may requests 3 or more copies of the approved dossier from the interested party.

(e) A completed dossier is then posted to each scientist on the *Ad hoc* Scientific Expert Committee for assessment of the scientific validity of the health claim.

(f) The *Ad hoc* Scientific Expert Committee advises Directorate: Food Control of its recommendation about the validity of the health claim.

(g) The Directorate: Food Control considers the expert recommendation in light of legal and consumer perception issues.

(h) The Directorate: Food Control finalizes decision to adopt or reject a particular health claim, based on the information stipulated in paragraphs (f) and (g) above.

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

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

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

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

2. OVERVIEW OF DOSSIER CONTENT

The dossier should follow the format below:

(a) Systematic Review of the Evidence

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

Introduction

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

(j) Summary which states the following:

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

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

(b) Methodology

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

Individual summaries of evidence

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

(c) Supplementary Information

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

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

3. A SYSTEMATIC APPROACH TO REVIEWING THE EVIDENCE

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

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

The wording must comply with relevant SA legislation.

A direct, indirect or implied claim in food labelling, advertising and promotion that consumption of a food carries a specific health benefit or avoids a specific health detriment.

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

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

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

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

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

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

STEP 5: Formulate broad inclusion and exclusion criteria

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

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

References that meet the exclusion criteria should also be noted.

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

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

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

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

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

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

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

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

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

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

4. TYPES OF EVIDENCE

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

TABLE 1: Types of Evidence

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

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

5. SUMMARISING THE EVIDENCE

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

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

a) Title of the study

b) Authors

c) Journal reference

d) Objective of the study

e) Study type/design

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

(i) Inclusion/exclusion criteria for the studies, and

(ii) Data extraction from the studies

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

6. DOCUMENTING THE SEARCH FOR EVIDENCE

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

Information should be included to identify:

1. Scientific question to focus the review

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

- biologically valid in that they have a known relationship to the final outcome and their variability within the population is known
- methodologically valid with respect to their analytical characteristics

- Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported.

3. Criteria for excluding evidence

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

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

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

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

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

TABLE 2: Example of Table for Search Results

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

ANNEX 1

CHECKLIST FOR MEETING DOSSIER REQUIREMENTS

The dossier should consist of two key sections:

- The systematic review of evidence
- Supplementary information

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

SECTION 1: Systematic review

☐ **An overview of the health issue and benefits of the claim has been provided.**

☐ **The proposed health claim and related scientific question have been stated.**

☐ **Terminology used in the health claim has been clearly defined and is consistent with definitions used in the evidence.**

☐ **Broad search terms have been used to capture variations in scientific terminology.**

☐ **Inclusion and exclusion criteria has been clearly stated and adhered to (i.e. the criteria explains why evidence has been included or excluded from the review).**

☐ All evidence that meets inclusion criteria has been included, regardless of the outcome.

☐ All references resulting from the search have been documented and categorised according to the Framework for Reviewing Evidence.

☐ Each reference included in the review has been summarised objectively, without interpretation of the results.

☐ Summaries of references included in the review have been grouped according to study type (rather than according to outcome).

☐ A detailed account of the process followed to search and review the evidence has been documented.

☐ The evidence is of good quality and in accordance with well-established scientific methods.

☐ Subjects are representative of the general population, or target population as appropriate.

☐ **The evidence relates to intake levels of the dietary component that can be achieved by the average consumer via realistic quantities in food products.**

☐ **Feeding patterns and serving sizes reflect consumption patterns that can be achieved by the average consumer.**

SECTION 2: Supplementary Information

☐ The claim been set in the context of the South African diet and has consideration been given to how the claim will impact on the overall diet.

☐ Potential implications and any possible adverse effects have been considered.

☐ Information about current intakes in SA has been provided.

☐ Recommended consumption patterns, to demonstrate how consumers obtain the benefits from the dietary component at the levels as shown to be effective by the evidence, have been included.

☐ Examples of typical products likely to carry the claim and any alternative wordings of the claim are noted.

☐ Consideration of the claim against the legal requirements has been documented.

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

ANNEX 2

HELP NOTES: Reviewing the Evidence Systematically

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

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

a) A clearly defined health claim is required before the scientific questions relating to that claim can be formulated. This may require preliminary discussions with the Directorate: Food Control to help clarify the issues.

b) The scientific question will help formulate the search terms and inclusion/exclusion criteria because terminology, which would be considered medicinal as a health claim, may be used freely. However, the scientific question must not alter the meaning of the claim.

c) Terminology and quantities of intake must be clearly defined to ensure consistency and comparability of individual study results.

d) A successful search relies on a carefully considered and well-defined health claim and corresponding scientific question.

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

2. **Keywords and search terms**

a) To provide a scientific focus and ensure maximum efficiency when searching the evidence, clear search terms are required and must relate explicitly to the proposed health claim.

b) Alternative terminology for keywords should be considered if the search results do not seem particularly relevant, or if few references are found (the database thesaurus can help with this). Consider terms in relation to exposure/intervention and outcome measures.

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

3. **Searching for Evidence**

a) Relevant databases include Medline, Embase, Cochrane, Current Contents Search, Science Citation Index and so on, however results can differ depending on the nature of the health claim and search terms entered.

b) Start the electronic database search as comprehensively as possible, covering all fields of the search areas for the defined keywords.

c) It is sensible to search the evidence chronologically, on yearly basis, starting from the present and to organise the results in the reverse chronological order and according the type of the evidence; i.e. systematic reviews, meta-analyses, controlled intervention trials and so on, so results can be compared by study type for consistency.

d) A systematic approach to searching the evidence should be followed for the entire process, according to an explicit and reproducible methodology and should be recorded for transparency while the search is undertaken.

e) Applying a systematic approach to search the evidence requires judgment at every step of the process, about the suitability and quality of the evidence and whether it is linked directly to the health claim. Generally the search should focus on primary studies directly related to the health claim.

f) Selecting only articles in English language is a non-systematic way of excluding articles from the search. However, it may be necessary to do so when articles have not been translated into English.

Check other sources for relevant evidence

g) Hand search the latest issues (the current and past year) of the following periodicals: BMJ, JAMA, Lancet, NEJM and Am J Clin Nutr for the relevant articles. This does not guarantee full coverage of all existing evidence, but provides an idea of the latest articles published in reputable journals, missed by the electronic database search.

h) Once the full articles have been retrieved, check the reference lists of each article for additional appropriate studies.

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

4. Selecting relevant studies from the search results

Set clearly defined inclusion/exclusion criteria

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

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

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

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

Skim read the abstracts

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

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

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

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

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

5. Reviewing the evidence and extracting relevant information

Retrieve the full article

a) Skim read the retrieved full articles to decide whether the study really answers the scientific question posed by the health claim. Reject those studies that do not fit the inclusion criteria or are poorly designed.

b) Read the full articles in detail and extract the relevant information from all eligible studies, for and against the health claim. Refer to the review protocol for an indication of the information required.

Extract and summarise the key relevant points

c) Presenting a summary of individual studies in a standardized way, using the review protocol provided, will help determine whether the study is methodologically sound.

d) It is important to provide the Expert Committee with enough information so it can form its overall opinion about whether the claim is substantiated by scientific agreement. It is also important not to detract from the key facts by providing details that are not directly relevant.

e) Supporting information can be provided within the dossier, but it should not be included in the systematic review unless it was included in the search results and complies with the inclusion criteria.

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

6. Presenting the data

a) Data should be grouped according to study type/design and presented accordingly. If it can be demonstrated that different investigators have achieved the same results, using the same study type and quality methodology but with different populations, the results will increase in validity.

b) Ideally the overall results of the review, (i.e. a summary of all individual study results), should be presented in a Forest plot, or odds ratio diagram, to illustrate the weight of scientific opinion.

ANNEX 3

The Source and Nature of Scientific Evidence

1. INTRODUCTION

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

2. THE TOTALITY OF EVIDENCE

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

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

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

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

3. STUDIES WHICH ARE THE MOST METHODOLOGICALLY SOUND

3.1 The Hierarchy of Evidence

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

(a) Study groups that are representative of the target group

(b) Appropriate controls both for the intervention itself, and for the subject groups

(c) An adequate duration of exposure and follow up to demonstrate the intended effect

(d) Characterisation of the target groups' background diet and other relevant elements of lifestyle

(e) An amount of the food or food component consistent with its intended pattern of consumption

(f) The effect of the food matrix and dietary context on the bioequivalence of the compound

(g) Monitoring of compliance with intake of food or ingredient under test

(h) The statistical power to test the hypothesis

(i) A scientifically substantiated mechanism, which is valuable but not essential

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

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

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

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

SOURCES OF EVIDENCE

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

* RCT = Randomised control trial

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

3.2 The Validity of Studies

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

improved if -

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

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

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

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

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

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

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

4. DRAWING CONCLUSIONS FROM THE EVIDENCE

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

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

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

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

(iv) Are statistically valid.

The following essential supplementary information is strongly recommended namely:

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

Codex Alimentarius: Recommendations on the scientific basis of Health claims

REPORT TO BE COMPLETED BY SCIENTIFIC EXPERT GROUP

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

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

1.

2.

3.

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

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

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

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

* 1 = Information incomplete and unacceptable

2 = Information complete but unacceptable

3 = Information not complete but acceptable

4 = Information is complete and acceptable

Final conclusion and recommendation of the Scientific Expert Group

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

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

Definitions:

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

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

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

GUIDELINE 14

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

The use of enteral foods for special medical purposes shall have been demonstrated, by scientific research in the form of clinical studies, to be safe and effective in meeting the nutritional requirements of the persons for whom they are intended, and a written submission with a request for approval and a dossier containing the required scientific substantiation according to the format provided in this A6nnexure, has been submitted to the Directorate: Food Control at least 6 months before the foodstuff appear on the market.

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

1. INTRODUCTION

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

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

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

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

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

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

2. OVERVIEW OF DOSSIER CONTENT

The dossier should follow the format below:

Introduction

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

(a) Summary which states the following:

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

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

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

REPORT TO BE COMPLETED BY SCIENTIFIC EXPERT GROUP

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

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

1.

2.

3.

Name of product under review:

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

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

* 1 = Information incomplete and unacceptable

2 = Information complete but unacceptable

3 = Information not complete but acceptable

4 = Information is complete and acceptable

Final conclusion and recommendation of the Scientific Expert Group

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

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

DRAFT GUIDELINES

July 2007

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

TABLE OF CONTENT

GUIDELINE 1

WHO DIETARY AND HEALTH GOALS

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

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

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

Goals for body mass index (BMI)	Population (adult) mean of 21-23 kg/m^2
BMI	For individuals: 18,5 – 24,9 kg/m^2 and avoid weight gain of > 5 kg during adult life

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

GUIDELINE 2

METHODS OF ANALYSIS

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

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

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

1. The food's protein content, usually calculated using the factor 6,25 [or specific AOAC factor listed in the Guidelines, multiplied by the nitrogen (N) content of the food as determined by the AOAC method of analysis (AOAC, 1984). Where a food contains more than one protein source, the factor 6,25 shall be used to determine the protein content. Where a foodstuff contains only one protein source, the specific AOAC factor, listed in the Guidelines, shall be used.

2. The food's essential amino acid profile, determined by typical analytical procedures or high performance liquid chromatography (HPLC). The amino acid scoring pattern described in section 8.00, References * and *** shall be used.

3. The food's true digestibility. The Department recognises that a database on digestibility values could be of assistance in implementing the PDCAAS method, and in reducing the expense of implementing this new methodology by eliminating the need for a bioassay. Therefore, the Department provides a limited database on published true digestibility values (determined using humans and rats) of commonly used foods and food ingredients, which manufacturers may use to calculate the PDCAAS of foodstuffs. For labelling purposes, in the case where a food contains more than one protein source, published, true digestibility values for estimating PDCAAS, as listed in the Guidelines, may be used, and where a foodstuff contains only one protein source, published PDCAAS values, listed in Table II, section 9 in the "Protein Quality Evaluation Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation.", Rome, 1990* may be used.

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

Analyse for proximate nitrogen (N) of test product.

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

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

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

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

Determine the amino acid score (uncorrected)

Uncorrected amino = mg of EAA in 1 g of test protein

Acid score mg of EAA in 1 g ***reference protein****

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

4.5 Calculate protein digestibility of test product.

4.6 Calculate the PDCAAS:

PDCAAS = Lowest uncorrected amino acid score x protein digestibility.

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

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

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

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

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

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

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

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

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

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

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

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

1. EEA profile in mg/g of source protein as determined in step 2(b)

2. EEA content per amount of source protein in 100 g of test product

e.g. Histidine from wheat source = 20.366 x 5.824 = 118.611 mg/100g bread

3. Uncorrected EEA Score of Test Product = (mg EAA in 1 g test protein) / (mg EEA in 1 g reference protein)

e.g. Histidine Score = 23.6/19 = 1.242

Step 4: Calculate protein digestibility of test product

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

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

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

References:

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

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

*** Joint FAO/WHO/UNU Expert Consultation. Energy & Protein Requirements. WHO Tech. Rept. Ser. No. 724. World Health Organization, Geneva, Switzerland (1985).

Food Technology, April 1994, pp 74 – 77.

FACTORS FOR CONVERTING TOTAL NITROGEN TO PROTEIN

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

TRUE PROTEIN DIGESTIBILITY VALUES

MAJOR PRODUCT GROUP	PRODUCT	TRUE PROTEIN DIGESTIBILITY VALUE
Cereals and grains:		
Barley	Barley	90
Maize (Corn)	Corn, extruded cereal	62
	Corn, flake	70
	Corn, puffed cereal	76
	Corn, whole	89
	Corn, meal	84
Millet	Millet	79
Oats	Oat flakes	70
	Oatmeal	90
	Oat, quick oatmeal	82
Rice	Rice	91
	Rice germ	87
	Rice, brown, cooked	72
	Rice, high protein	85
	Rice, milled, cooked	86
	Rice, polished	87
	Rice, crisped, cereal	77
Sorghum	Sorghum, cooked	73
Triticale	Triticale	90
Wheat	Bread	96
	Bread, coarse, brown	91
	Bread, white	98
	Bread, whole wheat	92
	Bran	75
	Endosperm	98
	Flour, 90% extracted	89
	Flour, 80% extracted	92
	Wheat germ	81
	Gluten	98
	Puffed wheat	84
	Shredded wheat	73
	White flour	97
	Wheat, whole	87

TRUE PROTEIN DIGESTIBILITY VALUES

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

TRUE PROTEIN DIGESTIBILITY VALUES

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

TRUE PROTEIN DIGESTIBILITY VALUES

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

METHODS OF ANALYSIS

(2) METHOD OF DETERMINING THE FAT CONTENT OF FOODSTUFFS

2.1 Total fat

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

2.2 Analysis of Trans-fatty acids

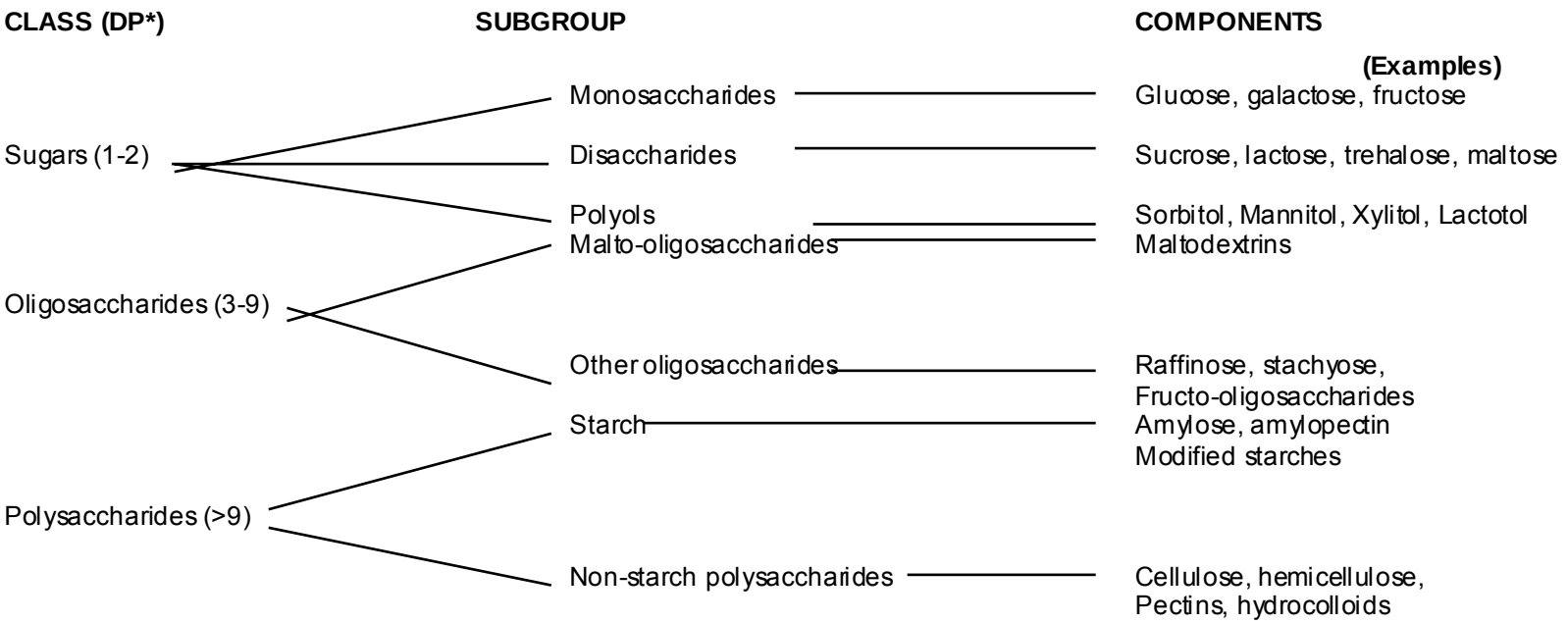
The definition for trans fats may be the first definition to exclude the two major *trans*-fatty acids occurring naturally in foods from animal sources that have potential health benefits, namely *trans*-Vaccenic acid and conjugated linoleic acid. By not mentioning "from animal origin" within the definition,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

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

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

GUIDELINE 3

THE MAJOR DIETARY CARBOHYDRATES



DP* = Degree of polymerisation

THE MAJOR DIETARY CARBOHYDRATES

RECOMMENDED METHODS OF ANALYSIS

1. Glycaemic carbohydrate:

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

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

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

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

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

2. Dietary fiber and prebiotics

Definition of dietary fibre

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

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

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

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

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

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

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

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

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

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

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

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

Methods of analysis

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

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

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

TABLE 1

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

2001.03	foods containing resistant maltodextrin		gravimetric & Liquid chromato graphy	
AOAC 2000.11	Polydextrose	Craig *et al.*, 2001	HPAEC	45.6.06C

- Official Methods of Analysis of AOAC International. 17th edition. Volume II. Editor Horwitz

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

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

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

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

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

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

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

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

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

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

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

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

Comparison of the NSP and the gravimetric AOAC methods with respect to performance and sustainability as a measure of dietary fibre

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

CL 2007/3-CCNFSDU page 12

8. Englyst H N, Quigley M E, Hudson G J, (1994) 'Determination of Dietary Fiber as Non-starch Polysaccharides with Gas–Liquid Chromatographic, High-performance Liquid Chromatographic or Spectrophotometric Measurement of Constituent Sugars', Analyst, 119, 1497–1509.
9. AOAC (2000) Methods 985.29 and 991.45. Official methods of analysis 17th Ed W Horwitz, AOAC International, Gaithersburg, MD, USA
10. Englyst, H.N., Quigley, M.E., Englyst, K.N., Bravo, L. & Hudson, G.J. (1996). Dietary Fibre. Measurement by the Englyst NSP procedure. Measurement by the AOAC procedure.

Explanation of the differences. Journal of the Association of Public Analysts, 32, 1-52.

CL 2007/3-CCNFSDU page 13

11. Wood, R., Englyst, HN, Southgate, DAT, Cummings JH (1993). Determination of dietary fibre in foods - collaborative trials. IV. Comparison of Englyst GLC and colorimetric

measurement with the Prosky procedure. Journal of the Association of Public Analysts, 29, 57-141.
12. Pendlington, A.W., Meuree-Vanlaethem, N. & Brookes, A. (1996). The method specific certification of the mass fraction of dietary fibre in lyophilised haricot beans, carrot, apple,
full fat soya flour and bran breakfast cereal reference materials. CRMs 514, 515, 516, 517 & 518. Office for Official Publications of the European Communities, Luxembourg
CL 2007/3-CCNFSDU page 14
13. USDA/DHHS. (2005) Nutrition and your health: dietary guidelines for Americans. Washington, DC.
CL 2007/3-CCNFSDU page 15

3. Glycogen:

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

4. References:

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

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

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

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

References to methods in the table:

AOAC 985.29:

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

AOAC 991.43:

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

AOAC 994.13:

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