health

Department:
Health
REPUBLIC OF SOUTH AFRICA

GUIDELINES

THESE DRAFT GUIDELINES ARE APPLICABLE TO THE DRAFT REGULATIONS RELATING TO THE LABELLING AND ADVERTISING OF FOODS FOR COMPLIANCE PURPOSES (R3337 OF 21 APRIL 2023)

NB: (R3320 AND R3337 ARE SAME REGULATIONS)

This Guidance is made available to provide advice and best practice on the relevant legal requirements for labelling and advertising of foodstuffs as provided for in the Regulations. It remains the responsibility of manufacturers, importers, and retail businesses to ensure their compliance with the provisions of the legislation.

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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GUIDELINE 1

RAW MATERIAL AND FOODSTUFFS INFORMATION IN TERMS OF TRACEABILITY

The following EXAMPLE of a Supplier Ingredient Information File for individual raw materials (additives and single ingredients) is a guideline or template which suppliers/manufacturers can use as a basis document to record the information about ingredients, additives and processing aids used in the manufacturing of foods. Suppliers/manufacturers may use their own formats, provided all the relevant information that is required by the Regulations Relating to the Labelling and Advertising of Foodstuffs is recorded.

A Supplier Ingredient file is not intended for an end product.

RAW MATERIAL INFORMATION

Depending on the type and complexity of raw material (additive, single- or compound ingredient), the required information will differ and the template may have to be adjusted to reflect relevant information.

RAW MATERIAL NAME:	Code:

SUPPLIER

Company name	
Contact person	
Contact number(s)	
E-mail address	

MANUFACTURER

Company name			
Manufacturing site			
Food Safety Management System	Accredited System*	Certificate Number	Comments
			Copy of certificate available on request
Material Safety	Safety Classification		Comments
			MSDS available on request

**Examples: HACCP; ISO 22000; BRC Standard; FSSC 22000, SQF, IFS.*

MATERIAL IDENTIFICATION

Common/Chemical name		
Registry number(s)	C.A.S. Number:	INS Number:
Description		

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Production steps	Short description according to flowchart with Critical Control Points (CCP's).
	Flowchart available on request

PACKAGING, STORAGE AND TRACEABILITY

Packaging

Unit weight	Net weight:	Gross weight:
Packaging materials		
Sealing of packed unit		
Safety of materials	There are no regulations pertaining to substances (that come into direct contact with food under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972). The only Act speaking to this is Act 13 of 1929, regulation 3 (1) which states: "No package, wrapper, container, or appliance used in connection with food shall be of such composition or nature as to yield, to its food contents, or to food with which it comes into contact, any unwholesome, injurious or poisonous substance." The onus therefore rests upon the manufacturer, packer, distributor or seller to ensure that his/her product is not unwholesome, injurious or poisonous. For this purpose, the standards/regulations of the EU can be used.	

Storage & Shelf life

Storage	
Shelf life	

Traceability

Coding method*		
Date code(s) example	Manufacturing date:	Best Before date**:
Batch code example		
Interpretation of code		

Sticker, inkjet, stamped, etc.* *"Best Before" / "Use-by" / "Use by end" / "Expiration date" or "Best Before Quality"*

MATERIAL[1] COMPOSITION IN DECENDING ORDER

Ingredients / Additives	Derived from (processing and origin)	Sourced from (country/ies)
Processing Aids	**Derived from (processing and origin)**	**Sourced from (country/ies)**

[1]If material is/contains palm oil or derivatives thereof (e.g., emulsifiers) indicate Certified Sustainable Palm Oil Status

Supply chain model	
Certificate number	Copy of certificate available on request

GMO TECHNOLOGY STATEMENT

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(Tick and/or complete relative statement)

	In the case of any raw material, additive and processing aid used in the production of food containing or consis of GMO's or has been produced from genetic modification technology, shall comply to Regulation 7 of Regulati R293 of 1 April 2011 under The Consumer Protection Act, 2008 (Act NO. 68 of 2008).

NANO TECHNOLOGY

Is this material or additives/ingredient in the material nano-engineered? Yes ☐ No ☐

MICROBIAL REDUCTION AND INFESTATION TREATMENTS

(Indicate the status of microbial and infestation reduction treatments used in the production of this material)

Processing Treatments	Yes	No	Specifications (type/temp/time/level etc.), as applicable
Thermal processing*			
Irradiation (ionising radiation)			
Ethylene oxide			
Other fumigants or sterilising agents			

*****Pasteurisation, steam sterilisation, hot spray-drying etc.*

PURITY AND LEGAL STATUS

(Tick compliance to the following local and international regulations/standards as applicable)

	South African Agricultural Product Standards Act (Act 119 of 1990)
	South African Foodstuffs, Disinfectant and Cosmetic Act (Act54/1972)
	Codex General Standards for Food Additives (GSFA)
	Other (specify)*

*****If "Other", the following footnote to be added: "Local regulations should be consulted concerning the status of this product, as legislation regarding its use may vary from country to country".*

MATERIAL SPECIFICATIONS / STANDARDS

√	Items ticked with a checkmark (√) are specifications which are batch-tested and reported on COA.
*****	Items ticked with an asterisk (*) are specifications which are only periodically tested. If reported on COA with a checkmark (√) it is to be interpreted as a "guaranteed" value, based on surveillance data. ***Surveillance reports available on request***.
X	Items ticked with a cross (X) are not tested as they do not form part of specifications or standards.
–	Items ticked with a hyphen (−) serves as additional information as requested by customer.

Note: Test methods available on request.

Sensory	Specification/Standard	Frequency of testing	Tick
Colour Appearance Smell (odour)	Free from lumps, infestation and foreign matter.		
Physical/Chemical	**Specification/Standard**	**Frequency of testing**	**Tick**

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Particle size: Sieve size: (specify) Bulk density: -Loose -Tapped		% Throughs: % Overs:		
Microbiological		**Specification/Standard**	**Frequency of testing**	**Tick**
Total Plate Count Yeast & Moulds Enterobacteria Coliforms E. Coli Salmonella Listeria *Other (specify)*				
Contaminants		**Specification/Standard**	**Frequency of testing**	**Tick**
Heavy metals:	Total (As Pb) Lead (Pb) Arsenic (As) Cadmium (Cd) Fluoride (F) Aluminium (Al) *Other (specify)*			
Contaminants		**Specification/Standard**	**Frequency of testing**	**Tick**
Pesticides residues*				
Mycotoxins*:	Aflatoxin Total Aflatoxin B_1 Aflatoxin M1 Ergot sclerotia *Other (specify)*			
Veterinary residues*:	Antibiotics rBST (hormone) *Other (specify)*			
Other contaminants*:	Melamine *Other (specify)*			

******If applicable*

FOOD ALLERGEN INFORMATION				**A**	**B**
Contains	**Yes**	**No**	**Source (If applicable)**	**Yes**	**No**
Fish and derivatives thereof *Excluding: Fish gelatin as carrier for vitamin or carotenoid preparation or as fining agent in beer and wine*					
Crustacean/Mollusc and derivatives thereof					

Milk (Specify cow's or goat's) and derivatives thereof. *Excluding: Whey for making alcoholic distillates including ethyl alcohol of agricultural origin; lactitol*					
Egg and derivatives thereof					
Gluten-containing cereal and derivatives thereof *Excluding: Wheat based glucose syrups / dextrose / maltodextrins; barley-based glucose syrups and cereals for making alcoholic distillates including ethyl alcohol of agricultural origin)*					
Soybean and derivatives thereof *Excluding: Fully refined oil/fat; phytosterols and phytosterol esters; stanol esters; natural tocopherols and its salts from soybean sources)*					
Tree nuts and derivatives thereof *Excluding: Nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin) pine/coconut)*					
Peanuts and derivatives thereof					
Lupin and derivatives thereof					
Sulphur dioxide and sulphites (>10 mg/kg)					
An Allergen cross-contact present on same production line **B** Allergen cross-contact in same facility (e.g., warehouse)					
Allergen control program in place. Copy of preventative measures available on request **Yes / No / N.A.**					

TYPICAL NUTRITIONAL INFORMATION (record information according to Annexure 2 of the Regulations*
Use correct conversion factors according to Annexure 2 of the Regulations*
***Regulation Relating to the Labelling and Advertising of Foodstuffs**

VEGETARIAN STATUS

Suitable for	Yes	No	Comments
Strict (vegan) vegetarian diet			
Lacto-vegetarian diet			
Ovo-vegetarian diet			
Honey vegetarian diet			

RELIGIOUS STATUS

Religious Group	Certification Body	Suitable	Certified	Comments
Halal (Muslim diet)				Copy of certificate available on request
Kosher (Jewish diet)				Copy of certificate available on request

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GUIDELINE 2

THE MAJOR DIETARY CARBOHYDRATES

RECOMMENDED METHODS OF ANALYSIS

1. Glycaemic carbohydrate:

For purposes of energy evaluation, a standardised, direct analysis of available carbohydrates (by summation of individual carbohydrates) (FAO, 1997; Southgate, 1976) is preferable to an assessment of available carbohydrates by difference which is done by calculation rather than analysis. Direct analysis allows separation of individual monosaccharides, disaccharides, and starch, which is useful in the determination of energy values. Direct analysis is considered the only acceptable method for analysis of carbohydrate in foods, especially when any type of carbohydrate claim or carbohydrate related claim is made.

Glycaemic carbohydrates, namely glucose, fructose, galactose, sucrose, lactose, maltose, trehalose, maltodextrin, glycaemic polyols as indicated in the table below and starch should be determined by adding together all the analytical values of the individual components.

Estimated Glycaemic carbohydrates content of various sugar alcohols/Polyols*

Sugar Alcohol/Polyol	Estimated glycaemic carbohydrate content g/100 g
Erythritol	0
Xylitol	50
Mannitol	0
Sorbitol	25
Lactitol	0
Isomalt	10
Maltitol	40
Maltitol syrup, (regular, intermediate, and high maltitol syrups	50
Maltitol syrup, (high polymer maltitol syrup	40
Polyglycitol	40

*Source: Table A.1 from ISO26642

2. Definition of dietary fibre

The definition of dietary fibre is clearly linked to fruits, vegetables, and whole-grain cereals.

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This structural polysaccharides is a major part of plant cell walls, and by determining this characteristic component it is possible to indicate the presence of other beneficial substances, such as micronutrients and phytochemicals that are present in the plant. This approach is preferable to the determination of all the individual parts of plant cell wall material, which is both impractical and would not add to the nutritional message that is provided by focusing on the polysaccharides of the plant cell wall. Therefore, lignin and other substances are not included in the definition of dietary fibre when measured for non-starch polysaccharides (NSP).

Other carbohydrates such as resistant starch and insoluble fibre 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 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 definition for dietary fibre does not include non-digestible oligosaccharides, which have a degree of polymerization (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 whole-grain cereals, fruits and vegetables. Furthermore, each of these various carbohydrates has distinct properties other than non-digestibility, which should be measured and exploited separately from dietary 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 functions.

This emphasizes that dietary fibre reflects fruits, vegetables and whole-grain cereal foods. The "carbohydrate polymers which have been obtained from food raw materials by physical, enzymatic 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 (polyols, oligosaccharides (non-α-glucan), resistant and modified starches, non-starch polysaccharides) would best be served by individual health claims that take into account their specific efficacy and dosage issues.

TABLE: METHODS OF ANALYSIS FOR DIETARY FIBRE AND NOVEL FIBRES

Recommended method for measuring dietary fibre as NSP as defined in the Regulations Governing the Advertising and Labelling of Foods.[2]				
Standard	**Component(s) measured**	**Method**	**Principle**	**Type**
All foods containing fruit, vegetables and whole-grain cereals	Non-starch polysaccharides (NSP) [3]	Englyst H N, Quigley M E, Hudson G J, (1994) Determination of Dietary Fibre as non-starch Polysaccharides with Gas–Liquid Chromatographic, High-performance Liquid Chromatographic or Spectrophotometric Measurement of Constituent Sugars, Analyst, 119, 1497–1509.	Enzymatic Gas–Liquid Chromatographic method	IV
General methods that do not measure the lower molecular weight fraction (i.e., monomeric units <=9)[2]				
All foods[1]	Method applicable for determining dietary fibres that do not include the lower molecular weight fraction. [4]	AOAC 985.29 AACC Intl 32-05.01 (1991,1999)	Enzymatic gravimetric	I
All foods[1]	Method applicable for determining dietary fibres that do not include the lower molecular weight fraction and also	AOAC 991.43 AACC Intl 32-07.01 (1999, 1991) NMKL 129, 2003	Enzymatic gravimetric	I

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

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All foods[1]		AOAC 2001.03 AACC Intl 32-41.01 (2002)	Enzymatic gravimetry and Liquid Chromatography	I
All foods[1]	Method applicable for determining the content of dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches.	AOAC 2009.01 AACC Intl 32-45.01 (2009)	Enzymatic gravimetry-High-Pressure Liquid Chromatography	I
Methods that measure individual specific components (monomeric units: the whole range for type of components is covered)[2]				
All foods[1]	(1→3)(1→4) *Beta*-D-glucans	AOAC 995.16 AACC Intl 32-23.01 (1999,1995)	Enzymatic	II
All foods[1]	Fructans (oligofructoses, inulin, hydrolyzed inulin, polyfructoses, fructooligosaccharides) (applicable to added fructans)	AOAC 997.08 AACC Intl 32-31.01 (2001)	Enzymatic & HPAEC-PAD	II
All foods[1]	Fructans (oligofructoses, inulin, hydrolyzed inulin, polyfructoses, fructooligosaccharides) (not applicable highly depolymerised fructans)	AOAC 999.03 AACC Intl 32-32.01 (2001)	Enzymatic & colorimetric	III
All foods[1]	Polydextrose	AOAC 2000.11 AACC Intl 32-28.01 (2001)	HPAEC-PAD	II

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All foods[1]	Trans-galacto-oligo saccharides	AOAC 2001.02 AACC Intl 32-33.01 (2001)	HPAEC-PAD	II
All foods[1]	Resistant starch (Recommended for RS3)	AOAC 2002.02 AACC Intl 32-40.01 (2002)	Enzymatic	II
Other methods[2] that have not been subjected to interlaboratory evaluation under AOAC international guidelines				
All foods[1]	Insoluble glucans and mannans of yeast cell wall (for yeast cell wall only)	Eurasyp (European association for speciality yeast products) – LM Bonnano. Biospringer- 2004 – online version: http://www.eurasyp.org/public/technique.home.screen	Chemical & HPAEC-PAD	IV
All foods[1]	Fructo-oligosaccharides (monomeric units<5)	Ouarné et al. 1999 in *Complex Carbohydrates in Foods.* Edited by S. Sungsoo, L. Prosky & M. Dreher. Marcel Dekker Inc. New York	HPAEC-PAD	IV

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

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GUIDELINE 3

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

The Regulations Relating to the Labelling and Advertising of Foodstuffs (No. 3337 of 2023), which were published by the Minister of Health under Section 15 of the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), provides for in Regulation 9(1)(a) the prohibition of certain information or declarations to be reflected on a label or advertisement of a foodstuffs, including words, pictorial representations, marks, logos or descriptions which create an impression that such a foodstuff is supported, endorsed, complies with or has been manufactured in accordance with recommendations by organizations, associations, foundations and other entities. The regulation also requires that the use of such information or declarations be considered by the Department of Health and approved by the Director-General, based on the evidence provided as verification that your organization is involved in generic health promotion, supported by evidence-based nutrition, as well as that the aims of your organization do not contradict the requirements of these regulations related to nutritional claims, based on the criteria thereof.
It is for this purpose that the Department of Health, Directorate: Food Control compiles these Guidelines to assist in the compilation of applications for endorsement of certain logos as explained below.

1. **Which types of endorsements are ***excluded*** from the requirement to obtain permission from the Director-General of Health?**
   Endorsing entities such as:
   - religious certifying entities
   - any Fauna and Flora related certifying and endorsing entities
   - other entities which focus on certifying certain quality aspects of foodstuffs

2. **Which types of endorsements are required to obtain permission from the Director-General of Health through an independent entity?**
   The endorsement logos of endorsing entities which are involved in generic health promotion activities which promote the reduction of risk of developing one or more particular non-communicable disease(s) of lifestyle (e.g. cancer, coronary heart disease, diabetes mellitus, obesity, poor oral hygiene, osteoporosis, et cetera).

3. **What process should be followed to obtain approval from the Director-General of Health?**
   - A hard copy of the dossier (in triplicate, unless otherwise indicated) should be delivered to the offices of the Department of Health, addressed to the Director-General. The dossiers shall contain all the information indicated below under point 8.
   - The physical address is:

Department of Health
Directorate: Food Control
Dr AB Xuma Building, Block C, 4th floor.
1113 Voortrekker Road
Thaba Tshwane
Pretoria, 0001

- An electronic copy of the dossier shall be forwarded to: foodcontrol@health.gov.za

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

The requirement to obtain approval can be found in Regulation 9(1)(a) of the current Regulations Relating to the Labelling and Advertising of Foodstuffs, 3337 of 21 April 2023.

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

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

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

6. How often are meetings convened?

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

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

7. Are there any financial costs involved?

There are no financial costs involved.

8. What information must be included in each dossier?

8.1 Information regarding the endorsing entity

Proof that-

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

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

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

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

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

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

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

8.2.5 Evidence shall be included in the dossier which provides proof that the endorsement entity is actively involved in projects aimed at promoting "**evidence-based nutrition" and "generic health promotion"** (see definitions of these terms in Regulation 9 in 3337/2023).

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

a) Any brochures, leaflets, posters et cetera.
b) Any media statements, internet information, printed material, advertisements, or any other methods of communication used to communicate to the target group(s);
c) Proof of projects in which the endorsement entity is involved in to educate the public about the particular health concern(s) the endorsement entity is focusing on;
d) Proof that what the logo promotes, is making a difference to the consumer's health/behaviour to improve their attitudes, proof that consumers really benefit from having this endorsement and how the endorsement campaign changed consumers’ shopping behaviour/patterns et cetera;
e) An indication of the population group(s) which is(are) targeted; and
f) A complete, full size, colour copy of the logo printed on a A4-size paper.

8.2.5.2 Evidence-based nutrition:

a) Which public health considerations are considered? Public health considerations are those which are identified by the Department of Health. Any Evidence-based nutrition should be based on generally accepted scientific evidence relative to the relationship between diet, nutrition and health (the scientific rationale);
b) A copy of the endorsement entity’s nutritional criteria that are applied to select a particular product for the endorsement logo and the scientific rationale for it; and
c) The food groups/categories which are targeted.

GUIDELINE 4

EXAMPLES TO ILLUSTRATE NEGATIVE CLAIMS IN REGULATION 10

Regulation number	Examples
Regulation 10(1)(a)	Tomatoes naturally contains lycopene
Regulation 10(1)(b)	Vegetable cooking oils are naturally cholesterol free food. or Rooibos tea is a naturally caffeine free food
Regulation 10(2)(a)	Colourant free tomato sauce or Preservative free tomato sauce
Regulation 10(2)(b)	A preservative free frozen vegetable, as is the case with all frozen vegetables
Regulation 10(2)(c)	No added colourant guava juice

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GUIDELINE 5

RULES ON QUANTITATIVE INGREDIENT DECLARATIONS (QUID)

1. SCOPE OF QUID

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

2. WHEN QUID DECLARATIONS ARE NOT REQUIRED

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

(b) A QUID declaration will not apply to foods, which, although mentioned in the name of a food, have not been used in its manufacture or preparation. Examples are "Cream Crackers" – a customary name used to describe a dry biscuit which never contains cream, or "Lemon Creams" – another customary name used to describe a sweet biscuit which never contains cream or real lemons in any form. There must be evidence of long traditional usage of such name. A period of 40 years or more is advised.

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

(d) A QUID declaration is not a mandatory requirement unless specified for canned fish and marine products, canned meat, frozen fish and seafood products, agricultural fishery products and agricultural products for which compositional standards or regulations already exist under the National Regulator for Compulsory Specifications Act, 2008 (Act 5 of 2008), and the Agricultural Products Standards Act, 1990 (Act 119 of 1990), and the Liquor Products Act, 1989 (Act No. 60 of 1989), except for:
   (i) processed meat products, excluding traditional biltong and dry sausage under SANS 885;
   (ii) raw-processed meat products;
   (iii) blended fruit juices, fruit nectars, and fruit drinks, but do not include blended fresh fruit juices;
   (iv) dairy products and imitation dairy products with added ingredient(s)
   (v) edible ices
   (vi) canned meat, fish and seafood products

(e) A QUID declaration is not required for canned products, excluding canned meat, fish and seafood as specified in (d) above, 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.

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

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

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

(h) A QUID declaration will not be required for an ingredient or category of ingredients that is used in small quantities for the sole purpose of flavouring, provided that section 5 of the Act (concerning false or misleading descriptions) is not infringed in any manner. This exemption applies to flavourings, such as quinine in tonic water, which are additives, garlic (in garlic bread) or other herbs and spices. Flavouring that are not part of a compound ingredient are regarded as being additives and do not need a QUID declaration.

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

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

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

3. WHEN QUID DECLARATIONS ARE REQUIRED

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

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

(aa)

The ingredient is included in the name of the food	**Examples* would include**
	"Chicken and mushroom pie", "chicken polony", "olive oil margarine", tomato sauce", "honey and oats biscuits, "banana loaf",

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

(bb)

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

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

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

(ii) The second part of this provision would require a QUID declaration on products where the ingredient or category of ingredients is usually associated with the name of the food. This is most likely to apply when products are described by the use of customary names without additional descriptive names.

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

Product	Example of description	QUID for
"Cottage Pie"	Minced beef topped with mashed potatoes	Minced beef

The intention is not that all ingredients associated by the consumer with a particular product name should require a QUID declaration under this part of the 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,) will not require a QUID declaration.

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

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(i) This requirement is likely to be triggered when a particular ingredient is given emphasis on the label other than in the name of the food. For example, by means of flashes such as -

* "with extra chicken"
* "made with butter".

*"with real Cheddar cheese"

or by the use of different size, colour and/or style of lettering to refer to particular ingredients anywhere on the label other than in the name of the food.

(ii) When pictorial representation is used to emphasise selectively one or a few ingredients, for example, fish casserole with a prominent picture or illustration of only a selection of the fish ingredients. However, this emphasis provision may not be triggered by the following:

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

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

Regulation 22(2) permits ingredients used in concentrated or rehydrated form which are reconstituted at the time of manufacture to have their order in the ingredients list determined as if they had been used as "whole" ingredients (e.g., reconstituted dried skimmed milk used in a milk pudding or dairy dessert). This same principle applies to the QUID declaration, which may be based on the weight of the "whole' ingredient.

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

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

1000 g fresh chicken meat + 100 g formulated solution (100 g includes both water and soluble solids (additives salt etc) equals 1100 g raw-processed chicken meat end product

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

100 g formulated solution / 1100 raw-processed chicken meat end product x 100 = 9.09% (rounded off to 9.1%)
Conclusion: QUID % for water* = 9.1% and QUID % for chicken meat = 90.9%

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

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 70 x 100/112 = 62,5 %
Fish	70 g	
Batter	20 g	
Crumb	20 g	
Total before frying.	110 g	
Frying oil taken up	7 g	
Total food item	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** **<u>50</u> x 100/169** **= 29.6%**
Flour Sugar Butter Eggs Total food item bowl Total after baking	100 g 35 g 50 g 10 g 195 g 169 g	

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

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

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

products, which are intended to (or which may optionally) be reconstituted by the addition of other liquids (e.g., milk or stock) if the ingredient listing information is also given on this basis.

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

GUIDELINE 6

EXAMPLES OF FLAVOURING MIXTURES CONSIDERED TO BE COMPOUND INGREDIENTS

Examples include:

- flavoured emulsions that also provide a technological function in the end product
- sprinkle flavourings
- snack food flavourings
- flavoured coatings etc., all of which incorporate non-flavouring food ingredients and/or additives such as salt, sugar, MSG, colourants, preservatives, cloudifiers, pre-packed additives which are intended to accomplish a technological function in the food itself. This includes products sold as “Sprinkle” or “Dusting” flavourings intended for use on/in snack foods or/and other foods.

GUIDELINE 7

ALLERGEN RISK ANALYSIS AND ALLERGEN CONTROL POLICY (ACP)

1. PURPOSE AND SCOPE

The intent of this guideline is to provide food manufacturers with a framework for allergen control and for the development of an allergen control plan (ACP), introducing the parameters and considerations that should typically be included in such a plan. It is important to note that, based on a company's specific needs, many variations on these recommendations could achieve acceptable results. These guidelines should thus not be regarded as a definitive or all-inclusive protocol for the control of allergens in a food manufacturing facility. However, each recommendation and the extent to which it applies to the food manufacturer, or its suppliers should be considered.

2. ALLERGEN CROSS-CONTAMINATION AND THE ACP

2.1. Allergen cross-contamination

Allergen cross-contamination occurs when one or more allergens are unintentionally introduced into a food product that should not ordinarily contain the allergen(s). Cross-contamination can occur at any stage of production, from cultivation and harvesting through to distribution and retailing. Allergen cross-contamination is not always preventable. However, through the development and implementation of an effective ACP, the risk can be minimised.

2.2. The ACP

The ACP is a company's written document outlining all those controls that have been put into place in terms of the storage, handling and processing of allergens, as well as the identification of those areas or steps in the processing procedures where cross-contamination is likely to occur. The preventative actions and monitoring methods used to minimise the risk of cross-contamination should be included in the plan.

The ACP is not a stand-alone initiative or a one-time effort. Effective allergen control relies critically on pre-requisite programs (PRPs), including good manufacturing practices, being in place prior to the development of the ACP. The ACP, in turn, should be implemented, audited and updated on a continual basis. With each change in suppliers, products, processes and personnel, it is essential that the ACP be revisited, and altered where applicable.

2.3. Documenting the ACP

It is recommended that the following points be considered and included, where appropriate, in the ACP documentation:

1. **Assignment of an ACP team**.
2. **Allergen Policy Statement**, describing the organisation's intent and commitment to control allergens, including:
   (i) Scope of allergen control;
   (ii) Reference to applicable regulations;

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3. **Allergen risk assessment** (identification of all allergen cross-contamination or mislabelling risks at each process step of each product produced);
4. **Supplier control procedures**, including:
   (i) Approved supplier lists;
   (ii) Supplier information forms;
   (iii) Material risk assessments
5. **Allergen matrix** (allergens tabulated against raw materials);
6. **Allergen grid** (allergens tabulated against final products);
7. **Allergen map**, indicating material, personnel and air flow;
8. **Receiving control procedures**;
9. **Material storage / segregation procedures**;
10. **Production control procedures**, including:
    (i) Production scheduling procedures;
    (ii) Rework control procedures;
    (iii) Utensil / equipment control procedures; and
    (iv) Personnel control procedures
11. **Plant maintenance procedures**;
12. **Waste management procedures**;
13. **Allergen cleaning procedures**;
14. **Allergen validation and verification procedures**, including sampling and testing procedures;
15. **Allergen labelling and label check procedures**;
16. **Product development and formula change procedures**;
17. **Personnel training procedures**;
18. **Allergen auditing procedures**;
19. **Traceability and crisis management / recall procedures**;
20. **Allergen plan review procedures**

3. ALLERGEN RISK ANALYSIS

The development and implementation of appropriate allergen controls are reliant on the determination of the risk of allergen cross-contamination throughout the supply chain, from raw materials through to the final product. Both the likelihood and severity of each risk should be considered in the risk analysis.

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

3.1. Allergen risk assessment

A comprehensive risk assessment should be carried out to determine whether specific food products, their ingredients or their packaging materials intentionally contain one or more allergens, and whether there is potential for allergen cross-contamination of other food products, ingredients or packaging materials on the premises.

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The first step in allergen control should be to identify all possible allergen sources and possible areas of allergen cross-contamination. These could include:

a) Raw materials, including ingredients, sub-ingredients (e.g., ingredient carriers or allergen-derived ingredients), processing aids, reworked ingredients and packaging materials;
b) Cross contact, e.g., through the use of shared equipment, utensils and work surfaces, or via personnel or environmental contamination.

3.2. Identification of hidden allergens in foods and ingredients

Label terminology that may indicate the presence of egg protein		
▪ Albumin	▪ Ovomucin	▪ Lecithin
▪ Lysozyme	▪ Emulsifier	▪ Vitellin
▪ Binder	▪ Ovomucoid	▪ Livetin
▪ Ovalbumin	▪ Globulin	
▪ Coagulant	▪ Ovovitellin	
Label terminology that may indicate the presence of milk protein		
▪ Artificial butter flavour	▪ Milk derivate	▪ Sour cream (or solids)
▪ High protein flavour	▪ Caramel colour	▪ Cream curd
▪ Butter	▪ Caramel flavouring	▪ Sour milk solids
▪ Lactalbumin	▪ Casein	▪ De-lactosed whey
▪ Butter fat	▪ Natural flavouring	▪ Whey or whey powder
▪ Lactalbumin phosphate	▪ Caseinate	▪ Dry milk solids
▪ Buttermilk solids	▪ Rennet casein	▪ Whey protein concentrate
▪ Lactose	▪ Cheese	▪ Milk solids
Label terminology that may indicate the presence of soy protein		
▪ Bulking agent	▪ Miso	▪ Thickener
▪ Emulsifier	▪ MSG**	▪ Tofu
▪ Hydrolysed vegetable protein (HVP)	▪ Protein	▪ Vegetable broth
▪ Textured vegetable protein (TVP)	▪ Protein extended	▪ Vegetable gum
▪ Lecithin#	▪ Stabiliser	▪ Vegetable starch
# Mostly produced from soy but may be manufactured from egg ** Sometimes produced from soy or wheat but now mostly by synthetic means		
Label terminology that may indicate the presence of wheat protein		
▪ All-purpose flour	▪ Gelatinised starch# (or pre-gelatinised)	▪ Semolina

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▪ Bleached and unbleached flour	▪ Gluten or Vital gluten	▪ Spelt
▪ Bulgur (cracked wheat)	▪ Graham flour	▪ Starch
▪ Bran	▪ High protein flour	▪ Vegetable gum#
▪ Couscous	▪ Kamut	▪ Vegetable starch#
▪ Durum wheat/flour	▪ Malt	▪ White flour
▪ Enriched flour	▪ Miller's bran	▪
▪ Farina	▪ Modified food starch or modified starch#	▪
#May alternatively be manufactured from other grains, such as cassava(tapioca), maize or rice.		

3.2. Allergen risk management

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

Allergen control should form part of an organisation's PRPs to its food safety and quality system. The following should incorporate allergen control measures:

• Premises and equipment design for easy clean-up;
• Sanitation and control in standard operating procedures; during receiving and storage and at distribution points;
• Separate preparation areas;
• Education/personnel training;
• Traceability protocols

3.2.2. Processing procedures

Appropriate processing methods/procedures should be followed to prevent or minimise allergen cross-contamination. These can include, but are not limited to, designating areas or production lines for non-allergen-containing products or by employing allergen scheduling procedures together with validated allergen cleaning programs.

3.2.3. Supplier control

Specification sheets and supplier information forms should be documented for each ingredient or additive to ensure that appropriate allergen controls can be implemented. An example of such a supplier ingredient form is provided in Guideline 1 of this document. Additional information pertaining to the suppliers ACP, as required for effective allergen control, should be documented.

3.2.4. Allergen audit

An ACP audit can identify possible problem areas and their potential severity. An allergen audit can be conducted in a similar manner as a hygiene or food safety 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 receiving, storage, manufacture and distribution should be inspected.

3.3. Allergen risk communication

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

3.3.1. Personnel

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

- Procedures on the management of allergens should be available and/or posted wherever there is a risk for allergen cross-contamination.
- Allergen awareness and management should form part of basic employee training, and should at least include:
  - Recognition of which ingredients are allergens of concern;
  - Identification of potential allergen cross-contamination situations;
  - Identification of dedicated equipment for the processing of allergenic ingredients;
  - Movement of equipment around the plant, e.g. maintenance tools, trays and utensils;
  - Effective hand washing;
  - Re-work procedures;
  - Waste management procedures;
  - Cleaning procedures

3.3.2. Communication to the consumer: Labelling and Packaging

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

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

Risk assessment systems to assist the food industry in assessing the impact of allergen cross-contamination and in making informed decisions relating to the use of allergen precautionary labelling on food products exist. These allow~~s~~ for the assessment of likely sources of allergen cross-contamination from both raw materials and the processing environment, permit~~s~~ an evaluation of the amount of allergen present and promote~~s~~ a review of the capacity to reduce the levels of allergenic material from all contributing sources. These systems make~~s~~ use of, among other, a decision tree and an interactive calculator, including action levels based on scientifically established Reference Doses for allergenic residues. Although the systems do not form part of the South African regulatory framework, their voluntary use is recommended where appropriate, to minimise the risk to allergic consumers, to provide a consistent approach to risk communication and to avoid the indiscriminate use of precautionary labelling.

3.4. RISK REVIEW

3.4.1. Allergen testing in the ACP

Allergen testing is a useful tool for monitoring the effectiveness of the ACP in reducing the risk of allergen cross-contamination. The testing method used for allergen testing should be fit for

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purpose and should be sufficiently accurate, specific and sensitive to ensure that credible and meaningful results are obtained. Where a risk of allergen cross-contamination is identified, allergen testing should be part of an on-going strategy for monitoring the risk of such contamination.

3.4.2. Sampling

There are currently no official guidelines pertaining to specific sample sizes and sampling procedures required for allergen testing. Sample sizes and procedures may differ depending on the purpose of the test, as well as on the matrix being tested. Sampling plans and procedures should be established based on the manufacturer's risk assessment/HACCP/quality plan. These should take into account the nature of the expected cross-contaminating allergen, i.e., whether contamination is likely to be readily dispersed or particulate. Whenever feasible, samples taken for allergen testing should be representative and sampling plans should be based on appropriate statistical methods. The sampling plan should also address any factors that need to be controlled to ensure the validity of the test results.

3.4.3. Methods of analysis for gluten

The quantitative determination of gluten in foods and ingredients shall be protein-based (proteomic, immunologic or other method providing at least equal sensitivity and specificity to the methods listed in Codex Stan 118/1981, as revised in 2004 onwards).

3.4.4 **The role of allergen thresholds**

Reputable and current allergen threshold data may be used to aid in complete allergen risk assessments. Allergen thresholds are not to be confused with regulated allowable levels and is only meant to serve as a risk assessment tool as described in section 3.3.2.

GUIDELINE 8

ADDITIVES AND OTHER INGREDIENTS DERIVED FROM NON-VEGETARIAN ORIGIN

INS = International Numbering System

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

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GUIDELINE 9

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

Food based dietary guideline	Food example	
	X	√
Make starchy food part of most meals	• Fish fingers • Potato chips	• Whole grain wheat (pearled wheat) • Whole grain barley • Brown rice
Fish, chicken, lean meat or eggs could be eaten daily	• Soya mince • Biltong and dried sausage • Processed meats excluding whole muscle meats	• Canned fish, fresh and frozen fish (without any added crumbs or batter) • Eggs • Lean or extra lean meat • Chicken without skin • cheese
Have milk, maas or yoghurt every day	• Frozen yoghurt • Ice cream • Cream cheese	• Plain yoghurt • Skim and low fat milk and maas
Eat plenty of vegetables and fruit every day	• Fruit juice except single fruit juice • Fruit nectar • Canned fruit in syrup	Fresh, frozen and dried vegetables and fruits
Eat dry beans, split peas, lentils and soya regularly	Flavoured, dehydrated soya mince	• Canned legumes • Uncooked legumes

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Food based dietary guideline	Food example	
	X	√
		• Unflavoured, dehydrated soya mince
Use salt and food high in salt sparingly	Any food which contains more than 120 mg Sodium per 100 g	Dried herbs and unsalted spices
Use fat sparingly; choose vegetable oils rather than hard fats	Hard margarine Butter Ghee (Clarified butter)	• Soft bread spreads in tubs • Vegetable oils • Nuts • Avocado
Use sugar and food and drinks high in sugar sparingly	• Soft drink sweetened with sugars • Sweetened flavoured milk • Fruit nectars • Jams • Syrups • Sweets	Muesli without added sugar
Drink lots of clean safe water	Soft drinks	Packaged water (water and/or CO_2)

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GUIDELINE 10
FAKE FOOD EXAMPLES

Description:

Fake foodstuffs means a foodstuff or beverage which consist mainly of a mixture of food additives not ordinarily consumed on its own in the same form as the ingoing additive in the formulation/receipe, and/or ingredients such as water and/or salt and/or the flavouring or extract of a real ingredient but not the ingredient itself, and contains no or any significant amount of energy, protein, carbohydrates or fat.

1. SOLID FOODSTUFF EXAMPLE (BASED ON A REAL EXAMPLE)

The following product is presented as a peanut spread, in appearance similar to peanut butter.

LIST OF INGREDIENTS:

Purified water, vegetable fibre, sea salt, corn starch, xanthan gum, roasted peanut flavour, peanut extract, caramel colour, lactic acid, Preservative: Sodium benzoate, Sucralose, Colourants: tartrazine and sunset yellow (INS 110).

2. NON-ALCOHOLIC BEVERAGE EXAMPLE (BASED ON A REAL EXAMPLE)

The following product is presented as a soft drink:

LIST OF INGREDIENTS:

Carbonated water, caramel colourant, phosphoric acid, non-nutritive sweeteners (Aspartame and Acesulfame K), acidity regulator, preservative: Sodium benzoate, caffeine, flavouring.

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GUIDELINE 11

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

Example 1:

Regular food contains 5 grams of fat per 100 g; "Lite" food contains 3.8 grams of fat per 100 g.

5 g – 3.8 g = 1.2 g

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

Conclusion: A comparative claim is not permitted.

Example 2:

Regular food contains 150 kilojoules 100 g/ml; "Reduced" food contains 100 kilojoules per 100 g/ml.

150 kJ – 100 kJ = 50 kJ

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

Conclusion: A comparative claim is permitted.

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

- Reduced oil mayonnaise
- Reduced oil salad cream
- Reduced oil salad dressing
- Oil-free salad dressing
- Light tuna (referring to the colour of the meat)

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GUIDELINE 12

MISLEADING STATEMENTS

NB: The following source of information is hereby acknowledged and adapted in terms of the Open Government Licence of the UK government: Abstract from Part 3 of the *Criteria for the use of the terms such as fresh; pure; natural; etc. in food labelling"* by the Food Standards Agency of the United Kingdom, as revised July 2008 and can be accessed from:
https://www.food.gov.uk/sites/default/files/media/document/markcritguidance.pdf

1. GENERAL BEST PRACTICE ADVICE

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

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

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

Pictures and illustrative representations on labels and in advertisements, leaflets and on websites can have a powerful effect on prospective purchasers and, in some product sectors, may have a greater significance than names and other descriptive material. These representations should be subject to the same scrutiny and control as the words used to portray similar images and concepts. Care should be taken to ensure that background

illustrations and pictures do not mislead the consumer as to the type, quality or origin of the product. For example, kitchen scenes may lead a consumer to believe a product is hand-made or at least produced in a small-scale operation.

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

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

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

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

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

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

The description “fresh” can be helpful to consumers where it differentiates produce that is sold within a short time after production or harvesting. However, modern distribution and storage methods can significantly increase the time period before there is loss of quality of a product,

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and it has become increasingly difficult to decide when the term" fresh" is being used legitimately.

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

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

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

General:

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

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

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

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

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

Fruit and vegetables:

The term "fresh" is now used generically to indicate that fruit and vegetables have not been processed (e.g. canned, pickled, preserved or frozen), rather than that they have been recently

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harvested. This is acceptable provided it is not used in such a way as to imply the product has been recently harvested (e.g. “fresh from the farm”; “freshly picked”) if this is not the case.

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

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

Meat:

Virtually all carcase meat is chilled following slaughter, principally as a hygiene measure. The term “fresh” is traditionally used to differentiate raw meat from that which has been (chemically) preserved. It would serve no purpose to disqualify chilled meat from use of the term “fresh”. Use of the term “fresh” in these circumstances is acceptable.

Meat that has been previously frozen but which is sold thawed would not be considered by the average consumer to be “fresh”. The term “fresh” should not be used in these circumstances.

Fish

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

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

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

Fruit juice:

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

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

Milk:

“High temperature pasteurised” or “ultra pasteurized” milk has a recognised meaning and should not carry the term “fresh”.

Fresh pasta:

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

Fresh bread:

Terms such as “freshly baked”, “baked in store” and “oven fresh” may mislead consumers into believing that they are being offered/sold products that have been freshly produced on site from basic raw materials. Some stores sell bread made from part-baked products that have been packed in an inert atmosphere or frozen off-site then “baked off” at in-store bakeries. Use of terms like “freshly baked”, “baked in store” and “oven fresh” on these products could potentially infringe the general legal provisions referred to in paragraph 14 above.

Frozen or processed foods or ingredients:

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

- **“frozen from fresh”** should only be used to indicate a food was fresh (i.e. recently made or harvested) when it underwent freezing;
- **“made with fresh ingredients”** should only be used only where the intended meaning is that no processed ingredients (i.e. ingredients that have been dried, freeze-dried, frozen, concentrated, powdered, smoked, canned, etc) were used;

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

Fresh taste:

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

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

Chilled foods:

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

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

"Natural" means essentially that the product is comprised of natural ingredients, e.g., ingredients produced by nature, not the work of man or interfered with by man. It is misleading to use the term to describe foods or ingredients that employ chemicals to change their composition or comprise the products of new technologies, including additives and flavourings that are the product of the chemical industry or extracted by chemical processes.

Bottled water:

The name "natural mineral water" may be used in accordance with the consolidated regulations for Packaged water published under the Regulations relating to all Packaged Water, No. R. 718 of 28 July 2006 (R718/2006).

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Health and Nutrition Claims:

References to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being must comply with the Regulations Relating to the Labelling and Advertising of Foods (R 3287 of 21 April 2023). Where these afore-mentioned regulations also allow the use of “naturally” or “natural” as part of the claim (e.g., negative claims), only when the food naturally meets the condition(s) laid down in the regulations for the use of such a nutrition claim. Within the context of the health and nutrition claims legislation it is suggested that “naturally / natural” means that either nothing has been removed or nothing has been added to the food, and additionally that the food has not been subjected to any processes or treatment such that it meets the condition.

General:

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

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

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

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

(iii) Processes such as freezing, concentration, pasteurisation, and sterilisation, whilst clearly playing a significant role in both making food safe and preserving it do not accord with current consumer expectations of “natural” foods. However, the process to which a “natural” product has been subjected can be described using these terms (e.g., “pasteurised natural lemon juice”, “frozen, unsweetened, natural orange juice”).

(iv) (aa) Other processes such as non-traditional enzymatic treatment, production by immobilised micro-organisms or non-traditional fermentation processes, solvent extraction, carbon filtration and ion exchange purification, or acid or alkali treatment (outside of traditional pickling) or non-traditional distillation are also not in line with current consumer expectations of “natural”, and so if used

then products should not be referred to as natural foods or ingredients. Bleaching, oxidation (outside of treatment of Natural Mineral Water), smoking (with chemicals), tenderising (with chemicals), hydrogenation and similar processes also fall outside the meaning of this term.

(bb) Foods containing flavourings other than natural flavourings as defined by the regulations relating to flavourings may not be described as “made from natural ingredients”.

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

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

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

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

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

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

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

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

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

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

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

CRITERIA FOR THE USE OF THE TERM “NATURAL”

	Criteria		
Distinction that applies to natural food or natural ingredient	**Natural**	**vs**	**Non-Natural**
Single ingredient or compound food to which nothing non-natural is added.	Single foods to which nothing is added. * = Compound foods where all ingredients are natural may be described as “Made from natural food ingredients”.		Compound foods (not as such but see opposite) *. Compound foods that include non-natural ingredients.
Not interfered with by man – treated only with processes by the use of chemicals.	Foods or ingredients not altered by use of chemicals		Foods or ingredients that have been chemically changed. Foods or ingredients that have been extracted with solvents.
Not interfered with by man by use of technology or not normally consumed by man.	Foods or ingredients that are as in nature and normally consumed by man.		Foods or ingredients that are novel foods or made with genetic modification or cloned.

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	Criteria		
Distinction that applies to natural food or natural ingredient	**Natural**	**vs**	**Non-Natural**
Not interfered with by man in that treated only with processes that are traditionally used in food preparation, Including fermentation	Foods or ingredients that have been treated with traditional food preparation processes such as baking or roasting. Foods or ingredients that employ traditional fermentation processes. If foods are treated with processes such as concentration# or pasteurisation, they should not be described as "natural" but may be described for example as "pasteurised natural orange juice"		Foods ion ingredients that have been treated with novel processes or processes not in accord with consumers' expectations of what is natural, such as bleaching, ion exchange chromatography etc. Foods or ingredients that have been synthesised with the use of immobilized microorganisms or non-traditional fermentations or non-traditional enzyme treatments. Foods that have been concentrated etc (not as such but see opposite)#.

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

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

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

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

(a) to describe a single ingredient food; or

(b) to which nothing has been added;

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

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

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

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

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

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

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

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

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

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

Recipes of what might be described as “traditional” products may change over time to accommodate consumer demands and expectations (e.g., Christmas puddings and mince pies made with vegetable rather than animal fat/suet; and other foods that are traditionally consumed at certain times of the year). Such foods should not be described as “traditional X”. However, reference may be made to the traditional nature of these products, provided this does not imply that the product itself has been made traditionally/to a traditional recipe unless this is the case. For example - “Christmas pudding – a rich, steamed fruit pudding traditionally eaten on Christmas day with custard, brandy butter or cream”.

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

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

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

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

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

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

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

The term “authentic” is used:

(a) to indicate the true origin of a product where the description may be in wider, generic use;
(b) to convey to consumers that a product has particular characteristics that have not been adjusted for the South African palate (e.g. authentic Indian-recipe curry dishes); or
(c) to indicate single types of rice, where this is important because they have particular characteristics.

The current, widespread use of terms such as “real”, “genuine” etc in relation to individual food ingredients (e.g., “made with real fruit juice”) is usually unjustified and repetitive. Such use may be taken to imply that the food or its ingredients possess higher compositional quality than other similar products. In view of the fact that ingredients and flavourings should already be clearly indicated on the label, it is recommended that this use of these terms should be

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considered carefully and implemented only where the product is sufficiently different to others in the same range. Care should be taken not to mislead when flavourings are used, for example it may not be helpful to use “real” to emphasise the presence of fruit juice when it is only at a low percentage level and most of the flavour arises from added flavourings.

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

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

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

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

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

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

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

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

(a) made or prepared in the home; of domestic manufacturer;
(b) made at home using traditional methods rather than by a manufacturer;
(c) made by oneself; or
(d) crudely or simply made.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These terms are each seen as ways in which manufacturers differentiate their ranges of products to indicate the one that is ‘top of the range’. It would be advantageous if

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manufacturers and retailers could help consumers to understand why a claim of high level of overall quality is justified and why the particular term is used.

GUIDELINE 13

GUIDANCE DOCUMENT FOR WEIGHT MANAGEMENT CLAIMS

Background

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

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

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

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

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

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

Energy uptake describes the absorption by a tissue of an energy providing substance, such as a macronutrient, and its utilization; while energy intake describes the ingestion of energy providing substances, or quantities thereof.
Substances or ingredients in a food; or a food that have been suggested to play a role in achieving beneficial physiological effects to support these mechanisms have been described in the literature, but very few have been supported by significant scientific agreement to substantiate health claims.

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

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

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

Nutrient / Substance / Food or Food category	Claim category	Claimed cause and effect of Nutrient / Substance / Food or Food category and Weight Loss or Maintenance	Sufficient evidence to substantiate claim	Reference / Journal number / Supporting information
Protein	Satiety /weight management	Dietary intake of protein and a sustained increase in satiety leading to a reduction in energy intake	NO	EFSA Journal 2010;8(10):1811
Protein	Satiety/weigh t management	Dietary intake of protein and contribution to the maintenance or achievement of a normal body weight	NO	EFSA Journal 2010;8(10):1811
Gamma-linolenic acid	Reduces regaining weight	Dietary intake of gamma-linolenic acid and the contribution to weight maintenance after weight loss	NO	EFSA Journal 2010; 8(2):1477 [21 pp.]. doi:10.2903/j.efsa.2010.1477
Phaseolamine	Lower calorie intake	Dietary intake of phaseolamine inhibit α-amulase activity, hindering the conversion of complex carbohydrate to simple sugars, which	NO	EFSA Journal 2011;9(6):2253 [13 pp.]. doi:10.2903/j.efsa.2011.2253

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

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

7. The use of sustained weight loss claims shall only be permitted if the following conditions are met:
   (a) the presence, absence or reduced content in a food or category of food or a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence, namely a sustained intentional reduction in total body fat or total body weight.

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

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

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

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

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

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

Scientific requirements for weight management claims

8. The following information should be provided by applicants in preparing and submitting their applications for the authorization of weight loss claims:
   (a) Proof that:
      (i) A relationship exists between the food, nutrient, substance or proposed mechanism and weight loss or weight maintenance;
      (ii) Sufficient scientific evidence exists to substantiate such a claim
      (iii) The evidence is applicable to the food matrix (food)and is not extrapolated
      (iv) Evidence was obtained from an independent third party
      (v) The substance, nutrient or food is safe and lawful under levels necessary to justify a claim
      (vi) Analytical data is available to show the amount of substance that is present in the representative food / product
   (b) Summary of Scientific data as described
   (c) Proposed model weight management claim;
   (d) Scientific data (as described below) supporting the claim;
   (e) Copies of computer literature searches;
   (f) Copy of all research articles relied upon for support the proposal
   (g) Information concerning adverse effect or consequences pertinent to the proposed target
   (h) The following documentation in terms of scientific evidence for the substantiation of sustained weight loss claims shall be included in the dossier*:*
      (i) Should be obtained from human intervention studies in overweight or obese subjects treated with lifestyle measures only (diet and exercise); extrapolation of results from studies obtained from obese subjects under

treatment with weight loss medications could be considered on a case by case basis;

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

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

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

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

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

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

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

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

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

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Acknowledgements and references:

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

- Codex Alimentarius: Codex Standard for Formula Foods for Use In Weight Control Diets, Codex Stand 181-1991
- EFSA:
  - Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations; EFSA Journal 2012;10(3):2604.
  - Scientific Opinion on the substantiation of health claims related to meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/20061; EFSA Journal 2010; 8(2):1466.
  - Scientific Opinion on the substantiation of health claims related to protein and increase in satiety leading to a reduction in energy intake (ID 414, 616, 730), contribution to the maintenance or achievement of a normal body weight (ID 414, 616, 730), maintenance of normal bone (ID 416) and growth or maintenance of muscle mass (ID 415, 417, 593, 594, 595, 715) pursuant to Article 13(1) of Regulation (EC) No 1924/20061; EFSA Journal 2010;8(10):1811REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 on nutrition and health claims made on foods
  - COMMISSION REGULATION (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.
- CANADA
  Food and Drug regulations, CRC 870, of the department of Justice Canada, , current to 4 September 2012
- FDA
  - 'Guidance for Industry - Evidence Based Review System for the Scientific Evaluation of Health Claims' http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm
  - Code of Federal Regulations Title 21 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.14
  - 'Guidance for Industry: A Food Labelling Guide; 12. Appendix D Qualified Health Claims' http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064923.htm

- ‘Calories Count: Report of the Working Group on Obesity’ http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081770.htm

GUIDELINE 14

CODEX GUIDELINES ON DATE MARKING (2018)

REVISED GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CODEX STAN 1-1985): DATE MARKING

1. DEFINITION OF TERMS:

For use in **Date Marking** of pre-packaged food**:**

"Date of Manufacture" means the date on which the food becomes the product as described. This is not an indication of the durability of the product.

"Date of Packaging" means the date on which the food is placed in the immediate container in which it will be ultimately sold. This is not an indication of the durability of the product.

"Best Before Date" or "Best Quality Before Date" means the date which signifies the end of the period, under any stated storage conditions, during which the unopened product will remain fully marketable and will retain any specific qualities for which implied or express claims have been made. However, beyond the date the food may still be acceptable for consumption.

"Use-by Date "or "Expiration Date" means the date which signifies the end of the period under any stated storage conditions, after which the product should not be sold or consumed due to safety and quality reasons.

4.7 **Date marking and storage instructions**

4.7.1 If not otherwise determined in an individual Codex standard, the following date marking shall apply, unless clause 4.7.1(vii) applies:

(i) When a food must be consumed before a certain date to ensure its safety and quality the "Use-by Date" or "Expiration Date" shall be declared[1].

(ii) Where a "Use-by Date" or "Expiration Date" is not required, the "Best-Before Date" or "Best Quality-Before Date" shall be declared[1].

(iii) The date marking should be as follows:
• On products with a durability of not more than three months; the day and month shall be declared and in addition, the year when competent authorities consider consumers could be misled.
• On products with a durability of more than three months at least the month and year shall be declared.

[1] Consideration should be given to other Codex texts.

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(iv) The date shall be introduced by the words:

• "Use-by <insert date>" or "Expiration Date <insert date>" or "Best before <insert date>" or "Best Quality Before <insert date>" as applicable where the day is indicated; or

• "Use-by end <insert date>" or "expiration date end < insert date>" or "Best before end <insert date>"; or "Best Quality Before end <insert date>" as applicable in other cases.

(v) The words referred to in paragraph (iv) shall be accompanied by:

• either the date itself; or
• a reference to where the date is given.

(vi) The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g., DD/MM/YYYY or YYYY/DD/MM).

(vii) Provided that food safety is not compromised, the provision in 4.7.1 (i) or 4.7.1 (ii) is not required for a food if one or more of the following criteria apply:

1. Where safety is not compromised and quality does not deteriorate because the nature of the food is such that it cannot support microbial growth (e.g., alcohol, salt, acidity, low water activity under intended or stated storage conditions;

2. Where the deterioration is clearly evident by physical examination at the point of purchase, such as raw fresh produce that has not been subject to processing and presented in a manner that is visible to the consumer;

3. Where the key/organoleptic quality aspects of the food are not lost;

4. Where the food by its nature is normally consumed within 24 hours of its manufacture, such as some bakers' or pastry-cooks' wares.

For example, foods such as[2]:

• fresh fruits and vegetables, including tubers, which have not been peeled, cut or similarly treated;

• wines, liqueur wines, sparkling wines, aromatized wines, fruit wines and sparkling fruit wines;

• alcoholic beverages containing at least 10% alcohol by volume;

• bakers' or pastry-cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture;

- vinegar;
- non-iodized food grade salt;
- non-fortified solid sugars;
- confectionery products consisting of flavoured and/or coloured sugars;
- chewing gum.

In such cases, the “Date of Manufacture” or the “Date of Packaging” may be provided.

(viii) A “Date of Manufacture” or a “Date of Packaging” may be used in combination with 4.7.1 (i) or(ii). It shall be introduced with the words “Date of Manufacture” or “Date of Packaging”, as appropriate, and use the format provided in clause 4.7.1(vi).

4.7.2. Any special conditions for the storage of the food shall be declared on the label where they are required to support the integrity of the food and, where a date mark is used, the validity of the date depends thereon.

[2] This is an illustrative list.

GUIDELINE 15

GUIDANCE DOCUMENT FOR PREPARING A SCIENTIFIC SUBSTANTIATION FOR A CLAIM WITH A HEALTH OR NUTRITION MESSAGE REGARDING FRUCTOSE AND NON-NUTRITIVE SWEETENERS ACCORDING TO REGULATION 54

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

Independent evaluation by a panel of experts shall be for the cost of the applicant.

This Guideline shall be used to prepare a dossier with conclusive, scientific substantiation for when a claim is made for a foodstuff regarding added purified, crystalline fructose (C6H12O6), or added non-nutritive sweeteners in terms of the following health outcomes:

Proof that can demonstrate—

(a) that according to Guideline 15, scientifically substantiated benefits to health in general, as well as a reduction of the risk of non-communicable disease, including obesity will result;

(b) that neither added purified, crystalline fructose (C6H12O6), or added non-nutritive sweeteners contribute to the risk of developing any disease, especially non-communicable disease in the long term.

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1. BACKGROUND INFORMATION

1.1 Purpose of the Guidance Document

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

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

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

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

1.2 Relevant Regulations

The Regulations Relating to the Labelling and Advertising of Foods (R 3287 of 21 April 2023)

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

1.3 When to Use this Guidance Document

This guidance document should be used in the preparation of a claim with a health message relating to added fructose or added non-nutritive sweeteners.

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

1.4 Guiding Principles

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

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

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

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

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

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

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

- **Biological Relevance of the Claimed Effect:** The claimed effect of the food is biologically/physiologically relevant and expected to benefit the health of the target

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population (target market). To ensure biological relevance of the claimed effect, surrogate markers of the claimed effect must have both methodological validity and biological validity. Markers must additionally be part of the causal pathway between the food and the health outcome.

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

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

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

1 5 Study Designs and Evidence of Interest

1.5.1 Human Studies

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

1.5.2 Validity of Study Designs

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

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

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

1.6 Definitions

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

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

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

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

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

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

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

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

1.7 Organisation of Submission

The submission should meet the requirements below:

- The submission should include all components outlined in the checklist (Table 16).
- Pagination must be sequential for the entire submission.
- Paper copies must be bound or organised in a binder.
- The applicant’s identification (*e.g.*, company name) should be included on all pages of the submission.
- Submissions must be in English. Relevant submission material in other languages must be translated into English.
- Applicants are responsible for clearly indicating parts of the application that contain proprietary or confidential data (*e.g.*, results from an unpublished clinical trial, details on manufacturing, *etc.*).
- Applicants are responsible for the accuracy of all cited references, published or unpublished. An established style for citing references must be used.
- The application must be signed by the person responsible for the submission. The submission must be signed by the petitioner or by his/her attorney or agent, or, if a corporation, by an authorized official.
- Five hard copies of the submission must be forwarded by mail to the address below (unless otherwise stipulated by DFC). (Electronic copies will be allowed)

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

1.8 Submission to Directorate Food Control

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

Directorate Food Control
Department of Health
Private Bag X828
Pretoria

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

1.9 Review Process Following a Submission

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

1.10 Re-Evaluation of Claim

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

2 SUBMISSION REQUIREMENTS

2.1 Contact Information

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

Procedure:

Complete Table 1 – Applicant Information.

Table 1. Applicant information

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

If information requested is not applicable, please indicate NA.

2.2 Details Pertaining to Proposed Health Claim

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

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Procedure:
Complete Table 2.
Table 2 – Details pertaining to the proposed health claim.

Item	**Details (State N/A where necessary)**			
Food/bioactive substance of interest				
Health outcome of interest (include surrogate markers if used):	Intervention Studies		Prospective Observational Studies	
	Yes	No	Yes	No
Proposed health claim wording:				
Minimum effective intake of the food/bioactive substance to obtain the claimed effect				
Proposed daily intake of the food				
Proposed qualifying criteria for foods to carry a health claim (*e.g.*, minimum or maximum allowable levels of nutrients)				
Target population for the proposed claim				
Rationale for the target population				
Potential adverse effects related to food intake (from human studies)				
Proposed restrictions on use of food (*e.g.*, a subgroup of population, mode of consumption of food)				
Proposed risk management strategies to address adverse effects and/or restrictions on use of food (*e.g.*, indicate wording of recommended warning statements)				

Abbreviations: N/A, not applicable.

2.3 Regulatory Status of the Health Claim in Other Jurisdictions

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

Procedure:

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

Country	**Regulatory Body**	**Date of Submission (day/month/year)**	**Status of Health Claim Application**[1]	**Details for Approved Claims**

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				Wording of approved claim	**Conditions for use of the claim**	**Date of claim authorization**

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

3. CHARACTERIZATION OF THE FOOD

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

Background

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

Procedure:

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

Table 4:

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

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	microbiological characteristics) for the bioactive substance and include a certification of this data in an Appendix. • Summarize the manufacturing process of the bioactive substance and indicate whether it follows a quality system (*e.g.*, good manufacturing practices). • Describe the tests, and their results, used to ensure the bioactive substance meets pre- defined specifications (*e.g.*, batch to batch variability tests). • Describe the studies, and their results, used to ensure stability of the bioactive substance under the recommended storage conditions of the bioactive substance.

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

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

4. CHARACTERIZATION OF THE HEALTH EFFECT

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

Procedure:

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

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

5. EVALUATION OF CLAIM VALIDITY

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

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

5.1 Details of the Steps

5.1.1 Step 1. Describe the Search Strategy for Literature Retrieval

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

Procedure:

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

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

- Literature retrieval will <u>not</u> be limited at this point to the target population in order to maintain a broad evidence base on the food/health relationship as much as possible and to address applicability of the relationship to a population group. Therefore, keywords related to the target population do not require brainstorming.
- Decide on relevant keywords to be used to retrieve the literature and how they will be combined to search the literature within electronic databases.
- Decide on relevant electronic databases that will be used to search the literature. Examples include MEDLINE, Cochrane Library, EMBASE, CINAHL, Food Science and Technology Abstracts, Current Contents, Scopus, Cab health (Global Health), Web of Science, Scholars Portal Search, PsycInfo, AGRICOLA, Science Citation Index. The use of at least MEDLINE and two additional electronic databases is recommended.
- Decide on whether you will consider non-electronic methods to retrieve relevant

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literature – *e.g.*, unpublished literature; hand-searching (systematic reviews, meta-analyses or other relevant articles).

- Decide on your search limitations, such as the date range; languages; whether you will limit the search to publications in humans; etc.
- Complete Table 5 – Identification of databases and search parameters used for literature retrieval.
- Complete Table 6 – Keywords and their combinations used to retrieve literature on the food/health relationship from electronic databases.

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

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

[1] State N/A if not applicable.

5.1.2 Step 2. Implement the Search Strategy for Literature Retrieval

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

Procedure:

- Implement the search strategy outlined in Step 1 in each electronic database.
- Include a copy of the 'search history' in an Appendix (the record of the keywords used, their combinations, and the limitations imposed on the search) by printing it directly from the electronic database.
- Include a copy of the entire literature search in an Appendix by printing it directly from the electronic database.
- Complete Table 7 – Number of references retrieved from electronic and non-electronic sources.

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

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TOTAL (A+B-C):	

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

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

Procedure:

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

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

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

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

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

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

Abbreviations: N/A, not applicable

[1] You may find it helpful to articulate terminologies (in a footer to the table) that could be used in publication titles and that could indicate a relevant publication – *e.g.*, a publication title may reference

"cholesterol-lowering foods" rather than "oats", or "dyslipidemia" rather than "cholesterol-lowering".

5.1.4 Step 4. Filter the Literature

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

Procedure:

Title-Filtering

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

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

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

Abstract filtering:

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

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

Full-text filtering:

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

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

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

Table 9. Results of literature filtering	
Factor	Number of References
References prior to applying inclusion/exclusion criteria	
References excluded at title-filtering stage	
References excluded at abstract-filtering stage	
References excluded at full-text filtering stage	
TOTAL References Excluded (after applying inclusion/exclusion criteria):	
TOTAL References Included (after applying inclusion/exclusion criteria):	

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

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

Procedure:

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

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full-text filtering stage.

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

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

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

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

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

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

5.1.6 Step 6. Tabulate Studies

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

Procedure:

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

(a) Intervention/Experimental studies

(b) Observational studies

(i) Prospective cohort studies

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

5.1.6.2 Summarize relevant information from each of the intervention and observational studies that met the inclusion criteria at the full-text filtering stage using Table 12a (for intervention studies) and 12b (for observational studies) as templates.

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

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

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

Reference and Quality Rating (Author, year)	Aim of study	Design • R (Randomised) • NR (Non-randomised • C (Control group) • SB (Single-blind) • DB (Double-blind) • P (Parallel) • CO (Crossover)	Sample Characteristics • Country • Health Status • Setting(Metabolic unit, free-living subjects) • Age range • Gender (M,F) • No. recruited • No. randomized • No in final sample	Exposure and Duration • Food Matrix • Food dose; method and frequency of consumption • Duration of intervention • Design and/or duration of stabilization period, washouts, follow-ups	Background Diet & Assessment Tool	Results & Statistics • Changes in health effect • Adverse effects	Relevant Author's Conclusions
				oat (Oat-5) + usual diet 3. 10 g beta-glucans from barley (Barley -10) + usual diet 4. 5 g beta-glucans from barley (Barley 5-10) + usual diet 5. Control beverage + usual diet		decreased gradually for all subjects after 1-2 wks of consumption.	

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

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

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

5.1.7 Step 7. Evaluate Study Quality

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

Procedure:

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

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

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

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

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

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

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

Abbreviation: NR, not reported

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

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

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

NB: Comments submitted on the earlier versions of the Draft Regulations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

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

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

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

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

Abbreviation: NR, not reported

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

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

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analysis.

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

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

5.1.8 Step 8. Tabulate Study Findings per Health Outcome

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

Procedure:

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

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

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

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

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

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

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

[3] Reporting the magnitude of effect as a number and as a percentage may require computations by the petitioner.
Use a system to differentiate the computed values *versus* those taken directly from the study – *e.g.*, italicize all computed values.

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

[5] For studies with a control/comparison group, report the effect as: [(Mean end-of-treatment – Mean

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

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

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

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

NB: Comments submitted on the earlier versions of the Draft Regullations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

5.1.9 Step 9. Assess Causality

5.1.9 Step 9a. Rate Consistency

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

Procedure:

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

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<table>
<tr><td colspan="8">Table 15a. Rating of consistency in direction of effect for intervention studies, considering study quality</td></tr>
<tr><td colspan="8">HEALTH OUTCOME 1
A. Total number studies included: ____</td></tr>
<tr><td colspan="8">Statistical Significance (SS)</td></tr>
<tr><td colspan="4">B1. # studies with a SS effect of exposure (p<0.05): _____</td><td colspan="4">B2. # studies with a non-SS effect of exposure (p>0.05): _____</td></tr>
<tr><td colspan="8">Direction of Effect[1]</td></tr>
<tr><td colspan="2">C1. # studies from B1 with a SS favourable effect of the exposure: _</td><td colspan="2">C2. # studies from B1 with a SS unfavourable effect of the exposure: _</td><td colspan="2">C3. # studies from B2 with a non-SS favourable effect of the exposure: _</td><td colspan="2">C4. # studies from B2 showing either a non-SS unfavourable effect or no distinguishable effect of the exposure: _</td></tr>
<tr><td colspan="8">Study Quality</td></tr>
<tr><td>D1. # higher quality studies from C1:__</td><td>D2. # lower quality studies from C1: _</td><td>D3. # higher quality studies from C2:__</td><td>D4. # lower quality studies from C2:__</td><td>D5. # higher quality studies from C3: _</td><td>D6. # lower quality studies from C3:__</td><td>D7. # higher quality studies from C4:__</td><td>D8. # lower quality studies from C4:__</td></tr>
<tr><td colspan="8">Consistency Rating on Direction of Favourable Effect</td></tr>
<tr><td colspan="4">(C1 + C3) / A1 x 100 % =</td><td colspan="4">High (≥ 75%) □ Moderate (60-74%) □ Low (< 60%) □</td></tr>
<tr><td colspan="8">Consistency Rating on Direction of Favourable Effect in Higher Quality Studies</td></tr>
<tr><td colspan="4">(D1 + D5) / (D1 + D3 + D5 + D7) x 100% =</td><td colspan="4">High (≥ 75%)
Moderate (60-74%)
Low (< 60%)</td></tr>
</table>

[1] Direction of effect assesses whether the health outcome is changing in a favourable (*i.e.*, beneficial) direction with exposure to the food, or in an unfavourable (non-beneficial) direction, without regard to statistical significance.

NB: Comments submitted on the earlier versions of the Draft Regulations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

<table>
<tr><td colspan="6">Table 15b. Rating of consistency in direction of effect for prospective observational studies, considering study quality</td></tr>
<tr><td colspan="6">HEALTH OUTCOME 1</td></tr>
<tr><td colspan="6">A. Total Number of Studies Considered: _____</td></tr>
<tr><td colspan="6">Direction of Effect</td></tr>
<tr><td colspan="2">B1. # studies from A showing trend for risk reduction (p < 0.05)[1]: _</td><td colspan="2">B2. # studies from A showing a trend for increase in risk (p < 0.05): _____</td><td colspan="2">B3. # studies from A showing no effect (p > 0.05): _____</td></tr>
<tr><td colspan="5">Study Quality</td><td></td></tr>
<tr><td>C1. # higher quality studies from B1: ---</td><td>C2. # lower quality studies from B1: _____</td><td>C3. # higher quality studies from B2: __</td><td>C4. # lower quality studies from B2: _____</td><td>C5. # higher quality studies from B3: _____</td><td>C6. # lower quality studies from B3: _____</td></tr>
<tr><td colspan="2">Consistency Rating on Direction of Favourable Effect (Risk Reduction)</td><td colspan="2">Consistency Rating on Direction of Unfavourable Effect</td><td colspan="2">Consistency Rating on No Effect</td></tr>
<tr><td><u>B1</u> x 100% = A</td><td>High (≥ 75%)
Moderate(60-74%)
Low (< 60%)</td><td><u>B2</u> x 100% = A</td><td>High (≥ 75%)
Moderate (60-74%)
Low (< 60%)</td><td><u>B3</u> x 100% = A</td><td>High (≥ 75%)
Moderate (60-74%)
Low (< 60%)</td></tr>
<tr><td colspan="6">Consistency Rating on Direction of Favourable Effect in Higher Quality Studies</td></tr>
<tr><td colspan="3">C1 / (C1 + C3 + C5) x 100% =</td><td colspan="3">High (≥ 75%)
Moderate (60-74%)
Low (< 60%)□</td></tr>
</table>

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

NB: Comments submitted on the earlier versions of the Draft Regulations (R2986 of 21 January 2023 and R3287 of 14 April 2023), would still be considered as there are no significant differences in terms of the technical content)

5.1.9 Step 9b. Rate the Strength of the Association

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

Procedure:

- Consider studies of higher and lower quality from Table 15a [(D1 + D2) / A] and comment on whether all or most of the studies show a statistically significant favourable effect. Consider study features and discuss factors that may have contributed to statistical significance not being reached (e.g., power calculations, sample size, duration, etc.).
- Consider studies of higher quality from Table 15a [D1 / (D1 + D3 + D5 + D7)] and comment on whether all or most of the higher quality studies show a statistically significant favourable effect.
- Consider studies of higher and lower quality from Table 15b [B1/A] and comment on whether all or most of the studies show a statistically significant favourable effect. Consider study features and discuss factors that may have contributed to statistical significance not being reached (e.g., power calculations, sample size, duration, etc.).
- Consider studies of higher quality from Table 15b [C1 / (C1 + C3 + C5)] and comment on whether all or most of the higher quality studies showed a statistically significant favourable effect.

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

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

Procedure:

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

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

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

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population.

Procedure:

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

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

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

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

Procedure:

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

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

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

Procedure:

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

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

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5.1.14 Step 13. Make Conclusions

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

Procedure:

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

6. CHECKLIST FOR SUBMISSION

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

Procedure:

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

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

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

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APPENDIX: Additional Definitions

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

- **Biomarker/surrogate marker of a health effect:** Whenever possible, a claimed health benefit should measure the true endpoint. However, when it is not possible to measure

in a practical way, a more easily measured surrogate, or biomarker, of the true endpoint may be used. Biomarkers can relate to health effect or to food intake. A biomarker of a health outcome is a proxy measure (an intermediate measure) of a true endpoint. It predicts development of a final health effect because it lies on the causal pathway between exposure to the food and development of the final health effect. For example, LDL cholesterol is a well-accepted biomarker for heart disease because it can reasonably predict that individuals who have higher LDL cholesterol levels will have a higher probability of developing heart disease. A biomarker of intake or exposure to a food is a measure that supports that the food was consumed by study participants.

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

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

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

- **Control group:** A control group is a group that has not received the exposure of interest and is being compared to the treatment or intervention group in the randomized trial. In a cross-over design, subjects serve as their own controls.
- **Intention-to-treat analysis:** A strategy for analysing data in which all participants are included in the group to which they were assigned, regardless of whether they completed the intervention given to the group. This analysis prevents bias caused by loss of participants which may disrupt the baseline equivalence established by random assignment and may reflect non-adherence to the protocol (Altman *et al.*, 2001).

- **Intervention Studies:** In an intervention study, human subjects are administered the food of interest (intervention group) and the health outcome is subsequently measured. The gold standard intervention study includes randomization, a control group and double blinding. The composition and quantity of the food should be

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controlled for the intervention group and for the control group. Randomized, controlled studies offer the best assessment of cause and effect since a temporal relationship between the food and health effect – *i.e.*, administration of the food precedes observation of the effect – can be demonstrated. Randomized, controlled intervention studies have either a parallel or cross-over design. Parallel studies involve two groups of subjects, the test group and the control group, which simultaneously receive the test food or the control, respectively. In cross-over studies subjects from the intervention group cross over to the control group and vice versa.

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

- **Observational Studies:** Observational studies measure associations between a food and a health effect. These studies lack the controlled setting of intervention studies and are thus often susceptible to confounders. They are most reflective of free-living populations. Because the subjects are not randomized at the beginning of the study, known confounders of the health effect need to be collected and adjusted for to minimize bias. Evaluating the method of dietary assessment is critical to ensure the food of interest is reliably measured. Observational studies may be prospective or retrospective. In prospective studies, investigators recruit subjects and observe them prior to occurrence of a health effect. Prospective observational studies measure incidence of a health effect, and relative risk of developing the health effect associated with food or other risk factors of interest. In retrospective studies, investigators interview subjects after the health effect has occurred. Retrospective studies are vulnerable to measurement error and recall bias because they rely on subjects' recollections of what they consumed in the past.

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

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

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

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