Report on the definition of food and related guidance in the context of the Value-Added Tax Consolidation Act 2010

Anne Nugent BSc PhD PgDip RNutr (Public Health)

24.10.2017

Biography

Anne Nugent BSc (Hons) PhD Pg Dip graduated from Ulster University at Coleraine with a first class Hons degree in Human Nutrition. Following a PhD in nutrition and immunology from Trinity College, she has worked in a variety of sectors, including non-profit (the British Nutrition Foundation, www.nutrition.org.uk), the food industry (the National Dairy Council, Superquinn) and in academia (University College Dublin). Guidance on new product development and interpreting national and EU food regulation formed an integral part of her work at the British Nutrition Foundation and in the food industry. More recently, she has worked for 10 years at University College Dublin where she has lectured on the BSc (Hons) Human Nutrition degree, BAgr Food Science and MSc Food, Diet and Health programmes. She has also acted as a full time lecturer and Programme Option Coordinator for the BSc (Hons) Human Nutrition degree programme. She has created, developed and has coordinated a number of undergraduate and postgraduate modules, including a module on food regulatory affairs and continues to lecture on this module. Her research background focuses specifically on national food consumption surveys and associated data on anthropometry, biochemical markers and intakes of dietary components including nutrients and food chemicals. Currently, she works as an occasional lecturer and part time Research Fellow at UCD as part of a recently funded Department of Agriculture, Food and the Marine research grant, the National Children's Food Survey II. She also works as an occasional lecturer at the Dublin Dental Hospital, TCD and as an independent food consultant. She is a committee member of the Irish Section of the Nutrition Society (one of the largest learned societies for nutrition in the world, www.nutritionsociety.org), the Public Health Nutrition subcommittee at the Food Safety Authority of Ireland (www.fsai.ie). She also advises on Novel Foods at the Food Safety Authority of Ireland. She has published extensively in the area of food and food chemical intake.

Table of Contents

Executive Summary

In response to a tendered request from Revenue, this report provides a critique of academic and scientific literature to provide an evidence-based definition of 'food' in the everyday and ordinary meaning of the word. It seeks to provide principles for determining whether a product is food and to provide guidelines to assist in determining what products fall within the scope of the definition of food and products that fall outside this definition, including food supplements. A secondary objective was to survey the landscape of food supplements on sale in Ireland in 2017 and to identify any emerging trends which could influence type, form and presentation of food supplements for human consumption.

Through a review of scientific and relevant literature key characteristics of 'food' and 'food supplements' were identified. Using a conceptual framework approach, common descriptors or characteristics were identified to extract emergent themes. Whilst some themes were overlapping (e.g. Safety, Nutritive), there was clear differentiation between the characteristics identified for regular 'food' and for 'food supplements'. From these themes, definitions or guiding principles of food and food supplements were developed and tested against a mix of foods and food supplements currently on sale to see if the product types could be differentiated accordingly. Upon successful completion of this task, highly qualified and internationally respected experts in the field of food, food science and nutrition were asked to complete a survey to see if they agreed with the characteristics identified, whether any other characteristics were missing and whether they believed food supplements were food. In general, experts were supportive of the characteristics identified and there was good agreement between the two methods. A key outcome was that food supplements were considered food but a specific type of food. Such supplements were distinguishable in an ordinary and everyday sense from regular, conventional, basic or ordinary food. This notion of food supplements being food, albeit a distinct type of food, broadly reflects regulatory descriptions of food supplements in the EU and globally.

Based on the research completed in this report and recognising that all types of food must be safe for human consumption, from an everyday and ordinary meaning of the word, the following definition of food is proposed:

> "Substances that are understood as ordinary food[1] for human consumption by the average consumer and are presented and labelled as such. Ordinary food is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. It is

not understood or presented as a food (dietary) supplement in forms not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar".

[1] Ordinary, basic or conventional food relates to foods or food ingredients typically in liquid, solid, frozen, dried, dehydrated or concentrated forms. Such foods are ingested or chewed at meals or snacks for their nutritional value or for their sensory attributes not limited to taste. Ordinary food is primarily composed of plant, animal, bacteria, fungi or insect material.

This report also provides two sets of guiding principles for determining whether a product is an ordinary food or, if it is not an ordinary food whether it is a food supplement.

A scan of the market place revealed that the majority of Irish supplement users currently consume vitamin and/or mineral containing products. However, a number of predicted trends were identified: significant growth in supplement sales across all population groups; a shift in their use from traditional positioning as aids to achieve a healthy balanced diet, to products that provide health and wellness and which can improve longevity as part of preventive care plans; growth in terms of botanical containing supplements and using novel presentation forms; growth in direct online sales and a potential shift from generic supplements to tailored or personalised forms.

In conclusion, in addition to describing potential future trends regarding food supplement use by Irish adults, this Report has developed an evidence-based definition of food in an everyday and ordinary meaning of the word. Such ordinary or conventional food can be identified using a series of guiding principles and is distinguishable from food supplements. All food supplements, while food, are not food in an ordinary and everyday sense and can be identified through a separate set of guidelines or principles.

1.0 Background

This document has been prepared in response to a tendered request from Revenue to prepare a report defining food and providing guidance on what constitutes a food in the context of the Value-Added Tax (VAT) Consolidation Act 2010.

As per current legislation, generally food is zero rated for VAT purposes, but certain foods are liable to a reduced rate (13.5%) or standard rate (23%) of VAT. The zero rate exists for 'clearly defined social reasons' which 'benefit the final consumer'. Current Revenue guidance states that food supplements are zero rated if deemed to "fall within the ordinary and everyday meaning" of a 'food or drink' that is zero rated. The supplement must encourage the maintenance of health through the sustenance derived from a normal, healthy diet to meet the social reasons criteria that apply to food benefitting from the zero rate. Further zero rated supplements must form part of a person's normal diet for the purposes of sustenance as opposed to enhancing a person's diet with a view to achieving a particular aim. The supplement must be 'formulated to make good the potential shortfall from the nutrition required for a normal, healthy diet'. Substances outside of this are standard rated.

The primary purpose of this report is to use objective, evidence based methods to define 'food' in the everyday and ordinary meaning of the word and to provide principles for determining whether a product is food. It seeks to provide guidelines to assist in determining what products fall within the scope of the definition of food and what products that fall outside this definition. As a consequence, it should conclude whether all, some or no 'food supplements' come under this definition. A secondary objective is to complete a market scan of supplements on sale in Ireland in 2017 to identify any emerging trends with respect to types, forms and presentation of food supplements for human consumption.

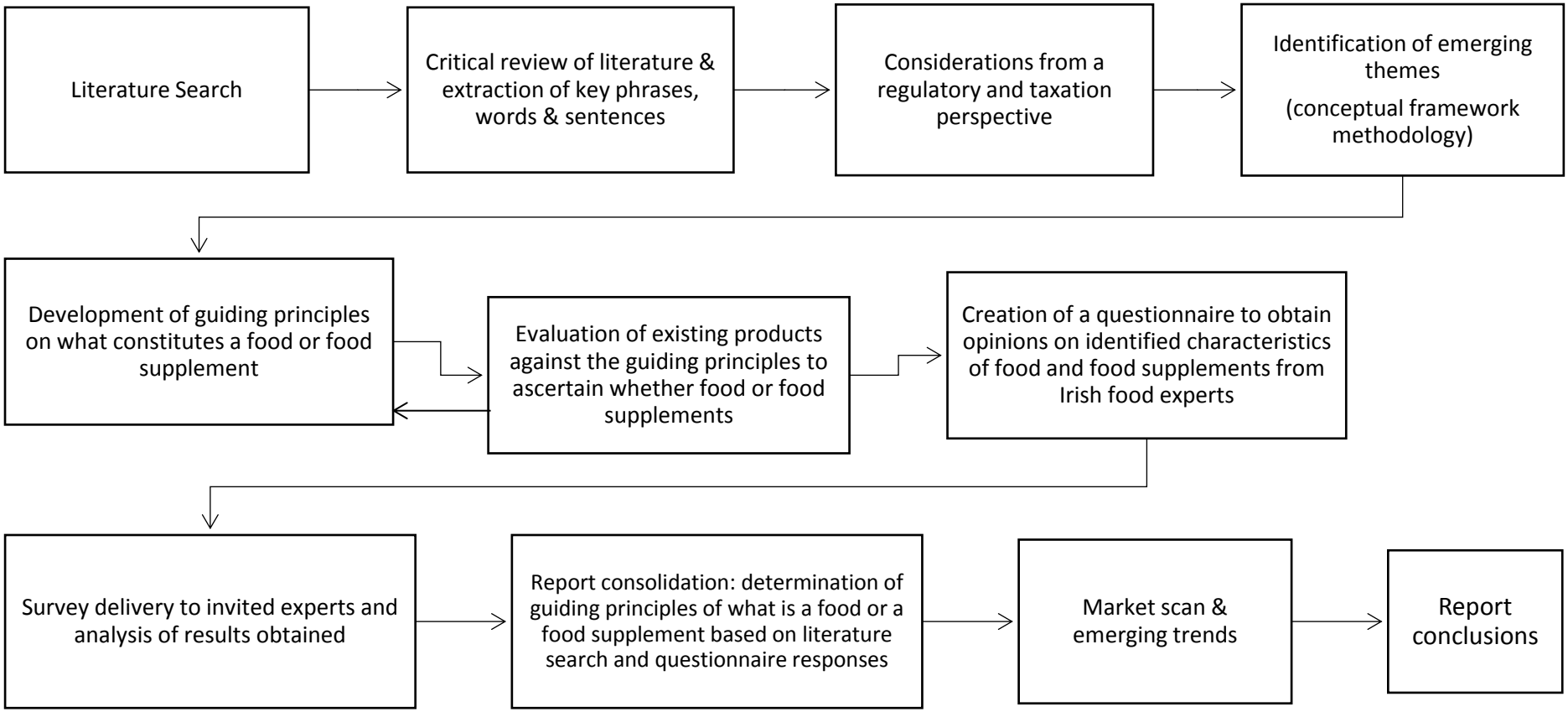
2.0 General introduction to methods employed in this Report

The methods used to inform this report include a review of the relevant academic and legislative literature and a survey of invited food experts in Ireland, with an overview provided in Figure 1.

In brief, chapter 3 employed a literature search to identify definitions of food and of food supplements, while chapter 4 focused specifically on the regulatory landscape, including examples of how food supplements are described from a taxation viewpoint. Emerging themes or principles as identified by the literature searches are described in chapter 5, along with the ability of such principles to distinguish between food and food supplements currently on sale. Chapter 6 details the development, delivery and results obtained from a survey of highly experienced academic food experts concerning their opinions of the characteristics of food and food supplements as identified by the literature search. Chapter 7 consolidates the information obtained and provides definitions and guidelines for food and food supplements. Chapter 8 details the market scan of 2017 offerings and potential future trends in food supplements for sale. Chapter 9 provides final conclusions and outcomes.

Throughout this report, the terms ‘food’ and ‘dietary’ supplement are equivalent, ‘food supplement’ the more commonly used term in Europe and ‘dietary supplement’ the more commonly used term in the US.

Figure 1. Overview of methodologies employed



3.0 Literature Review: Methodologies used

3.1 Search strategy

A multi-faceted approach was taken to identify what constitutes a food and whether supplements are food. The search was as systematic in style as possible and largely focused on i) academic and scientific literature (including grey literature), and ii) legislative documents and webpages of competent authorities in the food arena. It also surveyed the websites of major industry and consumer organisations. Search terms included 'food', 'food supplement', 'dietary supplement', 'food definition', 'what is food', 'define food', 'define dietary supplement', 'define food supplement'. Examples of scientific search engines used include PubMed, CinaHil Plus, Web of Science and the Cochrane Library. Websites of the following authorities were searched: World Health Organisation (WHO), the Food and Agriculture Organisation (FAO), Codex Alimentarius Commission (a joint venture between the WHO and FAO as part of their joint Food Standards Programme to protect consumer health and promote fair practices in food trade), The European Commission, European and Irish Food Safety Authorities. Also searched were science based information organisations (e.g. European Food Information Council) and large consumer organisations (e.g. BEUC, the European Consumer Organisation). Full details of the engines and websites searched and the numbers of documents retrieved are listed in Appendix A.

Details of all references which were considered relevant were recorded in a Microsoft Access® database and subsequently obtained through libraries and online searches and screened for relevance (Appendix B). The searches were conducted between February and April 2017. In total 22 references which provided definitions of food or guidance on general principles of what constituted foods or food supplements were identified for further review, 16 for food supplements. An electronic copy of this database is provided with a screenshot of the database pictured in Appendix B.

3.2 Data extraction and synthesis

From each of the identified references, key words, descriptors, phrases or sentences which provided definitions or guidance on what constitutes a food or food supplement were extracted. This extracted data and associated references was detailed in two Microsoft Excel® spreadsheets; one relating to 'food' and the second to 'food supplements'. Full details of the key words, phrases and sentences extracted from each reference are provided as electronic copies accompanying this report.

Subsequently, common words, phrases and contexts were identified across each of the references identified for 'food' and for 'food supplements'. The common words or phrases were extracted for both food and food supplements. Similar words/phrases were grouped together and an attempt made to name or describe each of these emerging groups or "themes" as per a conceptual framework[1]. For example, across the references identified for food, continued mention of 'nutrition', 'nutrients', 'nourishing', 'nourishment' and 'nutritive' led to an emerging theme called 'Nutritive'. This process was completed twice – once for all references identified for 'foods' and secondly for all references identified for 'food supplements'. Table 1 summarises, in alphabetical order, the 11 themes emerging for foods and 11 for supplements will full details of all supporting key words, phrases, descriptors and sentences identified listed in Appendix C. All references were given equal weighting or deemed to be of equal importance during this analysis.

Table 1 Alphabetical list of themes emerging for foods and for food supplements

Food	**Food Supplement**
Chemistry/Composition	Approved lists
Exemptions/Exclusion	Bioavailability
Function	Exemptions/Exclusion
Manner of Consumption	Function
Nutritive	Ingredients/Composition
Other	Other
Safety	Populations
Sensory Properties	Prescription/dosage
Social/Cultural	Presentation
Source	Proof of action
Structure/Physical Form	Safety

As evident from the descriptors for each theme, distinct descriptors for food related to:

- Nutritional properties of food
- Sensory properties of food
- Position as part of meals or snacks
- Role in social and cultural events
- Source material (e.g. plant, animal or insect)

[1] Conceptual frameworks are used in qualitative research and have been described as a written or visual presentation that: "explains either graphically or in narrative form, the main things to be studied – the key factors, concepts or variables and the presumed relationship between them" Miles & Huberman, 1994

- Physical form (e.g. liquid, solid, processed or semi-processed).

Discrete descriptors for food supplements were:

- Reference to lists of substances permitted as supplements (e.g. vitamins, minerals, botanicals)
- Bioavailability
- Population groups who may benefit from supplementation
- Suggested prescription or dosage
- Presentation e.g. capsule or dosage
- Proof of efficacy

Similar named themes included 'Exemptions/exclusion', 'Safety', 'Function', 'and 'Other'. There were broadly similar 'Exemptions/exclusion' for both food and food supplements e.g. tobacco, cosmetics, pharmaceuticals. However, an additional exemption for food supplements were that they were 'not a conventional food' or 'a substitute for a balanced diet'. Safety was a common theme, however, for supplements there was additional reference to safety standards and level of intake/avoidance of excessive intakes. The supporting text for 'Function' and 'Other' differed. For food, 'Function' included descriptors such as 'life', 'growth', 'repair' and 'health', whereas for supplements, it also included 'disease prevention', 'supplementing of normal diet', 'correction of nutrient deficiencies' and 'maintain an adequate intake of certain nutrients'. For the theme 'Other', supporting text for food was broad ranging from 'genetically modified', 'diet replacements' and 'novel' foods[2] to 'authenticity' and 'food labels'. For food supplements, supportive text focused mainly on US descriptions of multi-vitamin and multi-mineral supplements. Both food and food supplements had a theme which broadly described their composition. However, for foods, this ('Chemistry/composition') alluded to the chemicals and nutrients which may be present in food naturally or which may become present along the food chain ('nutrients', 'colours', 'toxicants', 'pesticides residues'). For food supplements, this theme ('Ingredient/composition') was more likely to mention lists of substances and nutrients permitted to be included in supplements as permitted for sale ('nutrients', 'botanicals', 'plant and plant preparations', 'herbs', 'foodstuffs'). Hence, while the two lists were broadly comparable in terms of nutrients and some non-nutrients, they were not identical.

At this point, all themes were given equal weighting or deemed to be equally relevant.

[2] Novel foods are foods not consumed to a significant degree in Europe prior to May 1997 and are defined in EU food law. Regulation (EC) No 258/97

3.3 Methodological Considerations

Advantages of the methods used in this search include the broad and objective nature of the search which was as systematic in style as possible and use of a conceptual framework approach to make sense of the literature and to identify any patterns or key themes emerging. Limitations include potential for personal bias during the pattern identification. All attempts were made to minimise any personal bias through periodic re-evaluation of the literature and themes to ensure robustness.

3.4 Summary and Conclusions

In summary, a literature search of scientific and academic literature and key regulatory documents identified definitions or descriptors of food and food supplements. Critical review of the sources highlighted common phrases or descriptors across the sources which were grouped together into themes. From the literature search, 11 themes were each identified for Food and for Food supplements. One theme (safety) was identical for both groups. There were 6 distinctly different themes arising for food and 6 for food supplements. The remaining 4 themes had broadly similar names, however, differences existed in the supportive text. This approach indicates that whilst there are some overlaps in what constitutes a food and a food supplement, they are not identical and can be distinguished as such. Such themes can be used to develop evidence-based principles to determine what constitutes a food or a food supplement in the ordinary and everyday meaning of the word.

4.0 Overview of regulatory and taxation perspectives

To this point, this Report has completed a critique of scientific literature and regulatory documents which provided specific definitions or descriptions of food and/or supplements. The purpose of this chapter is to describe other considerations regarding food, specific types of food and whether supplements are food from a food regulatory point and as identified from some taxation authority websites. It compares outcomes with the scientific literature where possible. In this manner, this chapter seeks to ensure context to the reader. However, it does not directly inform the final definitions of food and food supplements as derived in this report which were based on evidence-based definitions of 'food' in the everyday and ordinary meaning of the word.

4.1 Are food supplements food in a regulatory environment?

From the scientific literature (chapter 3.0), the question of whether food supplements are food is generally not directly addressed. The emphasis is usually on the safety or functional properties of the supplement or food, including any health effects.

In contrast, from a food regulatory affairs perspective, definitions are heavily influenced by Codex Alimentarius which defines food as *"any substance, whether processed, semi-processed or raw, which is intended for human consumption. It includes drink, chewing gum and other substances used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs"*. Hence, food supplements are not excluded from this definition and are therefore treated as food, albeit with their own discrete definitions. Therefore, food supplements could be viewed as a distinct type of food with their own defining criteria and associated legislation. In support of this, the definition of vitamin and mineral supplements by Codex states that such supplements are *"designed to be taken in measured small-unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet"*.

Within EU food law, food is similarly defined as *"any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment"*. The definition also includes water after a point of compliance but excludes feed, live animals unless they are prepared for placing on the market

for human consumption, plants prior to harvesting, medicinal product, cosmetics, tobacco and tobacco products, narcotic or psychotropic substances, residues and contaminants. Safety of food underpins the definition. (Regulation (EC) No 178/2002).

Food supplements are also defined as a type of food with their own distinct definition in EU law and are outlined in a guidance note by the Food Safety Authority of Ireland as *"foodstuffs, the purpose of which is to supplement the normal diet and which are concentrate sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities".* (Guidance Note No. 21 Food Supplements Regulations and Notifications (Revision 2)).

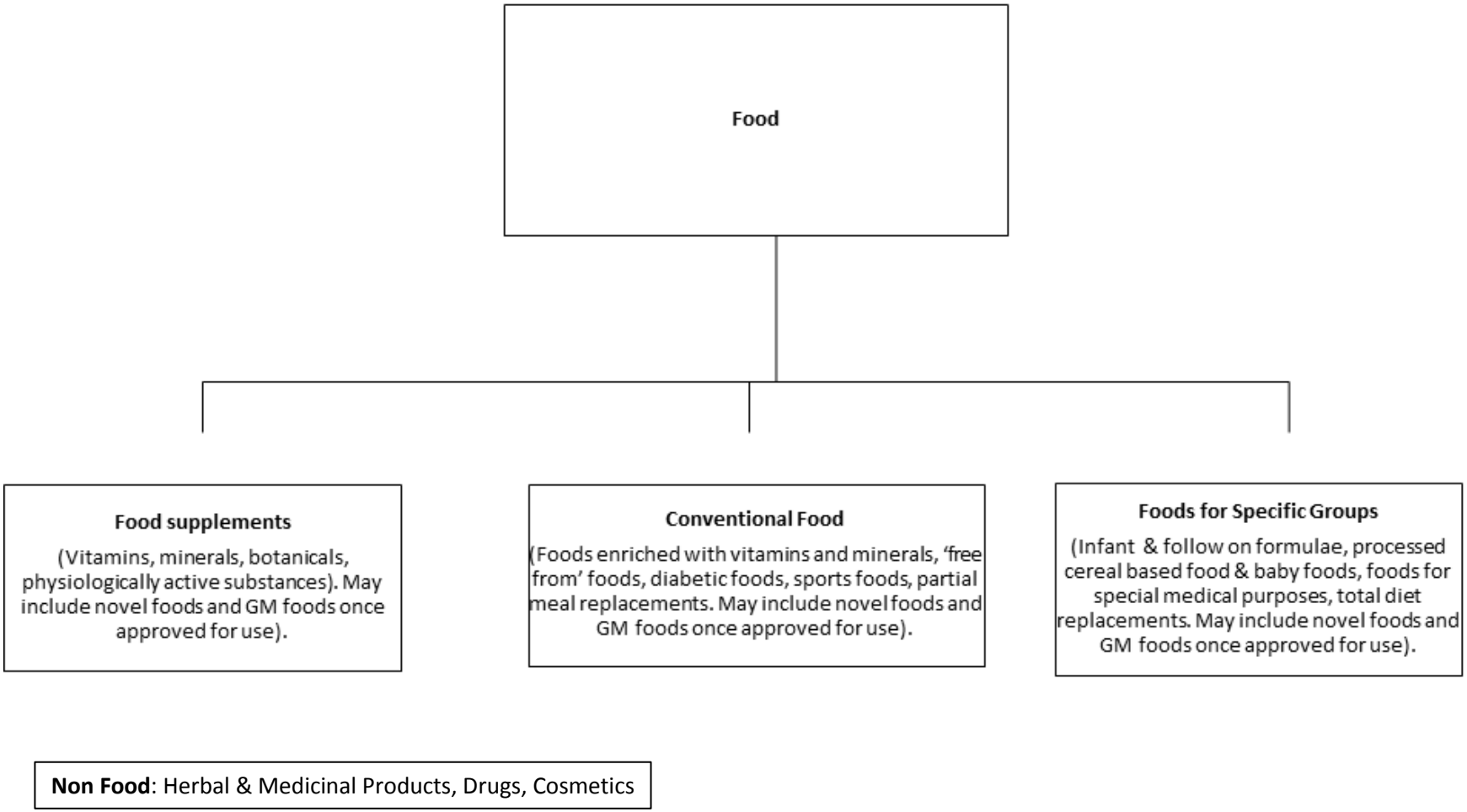
In Europe, discrete legislation exists for both food and food supplements regarding labelling and presentation, including nutritional claims. Such detail is not described here. However, specific requirements for food supplements are the inclusion of statements on-pack to the effect of:

- A warning not to exceed the stated recommended daily dose
- A statement to the effect that food supplements should not be used as a substitute for a varied diet
- A statement to the effect that the products should be stored out of the reach of young children.

4.2 What is food in a regulatory environment?

There are a number of categories of food within EU food law, each of which are describe briefly below and represented in Figure 2

Figure 2. Overview of classes of food as outlined in EU legislation. Also shown are some related non-food categories e.g. herbal medicines, cosmetics and medicines.



4.2.1 Food

In addition to regular foods (e.g. breads, meats) and food supplements, in regulatory documents, the term 'food' also makes reference to the following terms:

- 'Foods enriched with vitamins and minerals' (fortified foods)
- 'Free from foods' (e.g. gluten free)
- Foods for individuals with disorders of carbohydrate metabolism (diabetic foods)
- Sports foods
- Specially formulated foods presented as a replacement for one or more meals of the daily diet as part of energy-restricted (weight loss) diets
- Foods for Specific Groups
- Genetically modified foods (not readily evident for sale in Ireland currently)
- Novel foods (i.e. foods not consumed to a significant degree in Europe prior to May 1997 but once approved may be deemed regular food or ingredients in regular food, food supplements or foods for specific groups).

Specific legislation defines Food for Specific Groups and will be summarised below. For the remaining food types, while additional specific legislation may be in place for some of these foods, their production and presentation is underpinned by general food law and is subject to the same general (horizontal) food laws e.g. Nutrition and Health Claims (Reg. 1924/2006), Food Information to the Consumer (Reg. 1129/2011). Examples of such additional legislation include (but are not limited to): (i) specific lists of vitamins and/or minerals which can added to fortified foods; (ii) conditions of use for the claim 'gluten free'; or (iii) for partial meal replacement products, they must state that number of meals of the daily diet that they will replace and that other foodstuffs are necessary.

Below follows a brief description of foods for sports people, Food for Specific Groups as categories of food which may be of relevance to the current report. It will also briefly mention botanicals which may, or may not, be considered food.

4.2.2 Foods for sportspeople

In the scientific literature and food regulatory documents, products for sportspeople can be described as either 'foods' or 'food supplements'. In the scientific literature, there is no differentiation between the two, the emphasis is typically on safety, efficacy or functional outcome e.g. muscle recovery.

Current EU labelling legislation may interpret products for sportspeople as food or food supplements depending on their form and composition. For example, milk or a chocolate bar with added protein and vitamins is deemed 'food', as is a pure protein powder. However, presentation of the protein in a sachet or gel (i.e. small dosage form) or addition of botanicals or caffeine (i.e. physiologically relevant substances) may result in classification as a supplement. This appears to be completed on a 'case by case' basis by competent authorities e.g. the Food Safety Authority of Ireland (www.fsai.ie). Irrespective of form, any nutrition or health claims on foods for sportspeople must comply with the legislation pertinent to all other conventional food or food supplements.

4.2.3 Foods for Specific Groups

Within a regulatory environment, 'Foods for Specific Groups' are classed as 'food' but with their own definitions include 'infant and follow on formulae', 'processed cereal based food and baby food', 'foods for special medical purposes' and 'total diet replacement for weight control' (Regulation (EU) No 609/2013). Such groups are isolated in food law as they are considered to be well-established and defined categories of food that are essential for certain vulnerable groups of the population (previously called 'dietetic foods'). They are defined as:
"A limited number of categories of food constitute a partial or the sole source of nourishment for certain population groups. Such categories of food are vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements of certain clearly identified vulnerable population groups". (Regulation (EU) No 609/2013). A brief overview of each is provided below.

- Infant and follow-on formulae and infant foods have specific legislation given their significant/complete contribution to food and nutrient intake for young children. In contrast, young child formula (i.e. 'growing up milks') are described and treated as regular foods.

- Foods for special medical purposes are typically foods to be used under medical supervision to manage specific medical conditions, diseases or disorders. They are defined in legislation[3] as:
  "a category of foods for particular nutritional uses specifically processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or

[3] SI No 187 of 2009 giving full effect to Directive 1992/21/EC and as amended by Corrigendum of 5 Jan 2000 and Directive 2002/82/EC.

disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two". They must be clearly labelled for use under medical supervision. Examples include feeds prepared for individuals with metabolic disorders or enteral nutrition feeds, including sip feeds and oral nutrition supplements.

- Specially formulated foods, which when used as instructed by the manufacturer, replace the total daily diet (Total diet replacement for weight control). Statements to this effect must be labelled clearly on the products. Total diet replacements must also state that the product should not be used for more than three weeks without medical advice[4].

Within the scientific literature, reference to any of the above foods is typically with respect to their position within the legislation (Stipler et al. 2015) or with respect to function e.g. efficacy of weight loss (Gulati et al. 2017) or contribution to nutrient intakes (Kehoe et al. 2015).

4.2.4 Botanicals

Botanicals and derived preparations made from plants, algae, fungi or lichens are widely available on the EU market in the form of food supplements. There is no centralised authorisation procedure for the use of botanicals and derived preparations in food. In food, the use of botanicals and derived preparations has to comply with general principles and requirements of food law as regular food with the onus on the food business operator for product safety (e.g. Reg (EC) 178/2002). The European Food Safety Authority (EFSA) has compiled a 'Compendium of Botanicals' intended to guide it in any safety assessments of botanicals and their preparations intended for use in food and food supplements.

Some botanicals are considered as traditional herbal medicinal plants and are used both in medicinal products and in food supplements. The European Medicines Agency (EMA) is responsible for assessing both the safety and efficacy of herbal preparations when used as medicines. In Ireland, the Health Products Regulatory Authority (HPRA, www.hpra.ie) describes three categories of botanicals which

[4] SI 786 of 2007 giving effect to Directive (EC) 96/8/EC and Directive 2007/29/EC https://www.fsai.ie/legislation/food_legislation/foods_for_particular_nutritional_uses/energy_restricted_diets.html

can be herbal medicine products, herbal substances subject to prescription control when used in products for oral consumption and herbal substances for oral consumption or topical application which require market authorisation or certification of traditional use registration. These are not considered food.

4.3 Definitions of food and food supplements from selected taxation bodies globally.

A brief search for definitions of food and/or food supplements as produced by taxation bodies worldwide was also conducted. Definitions were identified for the UK and for several states in the US as part of 'sales and service tax'.

In the UK, description of a food product is *"food of a kind used for human consumption"* whereby: *"the average person, knowing what it is and how it is used, would consider it to be food or drink; and it is fit for human consumption. The term includes products eaten as part of a meal, or as a snack; and products like flour, which, although not eaten by themselves, are recognised food ingredients. The term would not usually include medicines and medicated preparations, dietary supplements, food additives and similar products, which, although edible, are not food".* Food supplements are described as *"dietary supplements of a kind not normally purchased and used as food are standard-rated"*. Specific examples of dietary supplements are provided not limited to vitamin and mineral supplements of all kinds, royal jelly products, charcoal biscuits, cod liver and fish oil supplements and certain tablets, pills, capsules, elixirs and tonics. Within this guidance are also listed types of foods deemed vatable and categories of foods including 'specialised products' such as invalid foods, diabetic and hypoallergenic (e.g. gluten free) foods and slimmer foods. Sports products are listed as a separate category, as are food and drinks that are used for religious and sacramental purposes.
(Vat 701/14. https://www.gov.uk/government/publications/vat-notice-70114-food/vat-notice-70114-food)

Definitions were identified in some States in the USA (e.g. Minnesota, Hawaii, Rhode Island) all of which broadly defined food and food ingredients as *"substances, whether in liquid, concentrated, solid, frozen, dried, or dehydrated form, that are sold for ingestion or chewing by humans and are consumed for their taste or nutritional value".* Lists of taxable and non-taxable food and food ingredients are provided with two examples being dietary supplements and candy. Dietary supplements were specifically defined as *"any product intended to supplement the diet required to be labelled as a dietary supplement, identifiable by the 'Supplemental Facts' box found on the label and as required pursuant*

to Federal Law". Additional detail for Minnesota State alluded to composition (e.g. vitamin, mineral, botanical), form (e.g. tablet, capsule, powder), differentiation from ordinary or conventional food ("is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet". For all US definitions, the requirement to label a product with a 'supplement facts' panel was a key determinant of whether the substance was taxable or not .i.e. a dietary supplement or not. (http://www.revenue.state.mn.us/businesses/sut/factsheets/FS102A.pdf and http://www.revenue.state.mn.us/businesses/sut/factsheets/FS102E.pdf)

4.4 Summary and Conclusion

This chapter describes how food and food supplements are considered from a food regulatory affairs perspective as well as by some taxation authorities. It is not intended as all-encompassing. Of note is the categorisation of food supplements as food under food law but not as conventional or tax-free foods (zero rated) under taxation laws. However, within food law, food supplements are just one category of food. Another distinct category are 'Foods for Specific Groups' which are clearly defined as at types of food that are essential for certain vulnerable population groups. In contrast, food supplements are not deemed essential and, while can play a role in the diet, are clearly listed as 'not a substitute for a healthy balanced diet'. Their labels must also state other warning statements. Policy recommendations exist for intake of two food supplements by two population subgroups in Ireland (folic acid for women of child bearing age and vitamin D for infants).

Other considerations relate to products for sportspeople which may be either food or food supplements under food law, and botanicals which are typically presented as food supplements or medicines. Uncertainties in either case are dealt with on a case-by-case basis by the FSAI.

Broadly comparable definitions of food and food supplements were identified from the websites of UK and US tax authorities. However, some differences existed, namely mention of specific compounds/products deemed to food or not food (e.g. flour, food additives, food ingredients) and definitive lists of products which were deemed food but taxable. Overall, they were generally comparable.

5.0 Emerging principles from literature for defining food and food supplements

After identification of the common themes emerging from the literature review (chapter 3), in an iterative process, attempts were made to establish principles which could be used to define food and food supplements in an ordinary and everyday meaning. The ability of these principles to determine whether a product was a 'food' or a 'food supplement' was first tested using a convenience sample of products traditionally classified as food supplements (n12) and in subsequent iterations also tested against additional supplements and a convenience sample of foods enriched with vitamins and/or minerals (fortified foods) and conventional foods (24 products in total). This process was completed three times yielding a final set of guiding principles based on the literature identified and described below.

5.1 Preliminary attempts to define attributes of a food or a food supplement based on literature search

Based on the themes identified from the literature search and on critical review of the results obtained, a series of 12 defining characteristics were first established for defining a food, 14 for defining a food supplement. All were given equal weighting in the first instance and are described in Table 2 below, including the rationale for their inclusion based on the emerging themes.

Table 2. Summary of initial attempt to define attributes of food and food supplements based on literature search

	Defining Characteristics:	**Rationale / Source**
	Food	
1	For human consumption	From review; 'Safety'
2	Understood as food by average consumer	Added on reflection; inferred from search
3	Must be primarily composed of material originating from plant, animal or similar kingdoms, or substances isolated thereof	From review: 'Source'
4	Contain a nutritive component(s)	From review: 'Nutritive'
5	Consumption helps achieve or maintain good health in addition to basic nutrition	From review: 'Function'
6	May be consumed native or following processing but with an inherent physical and chemical structure or matrix	From review: 'Manner of consumption' & 'Structure/physical form'
7	May contain non-nutritive food components, either intentionally or as a result of processing/manufacturing	From review: 'Chemistry / composition'

8	With inherent sensory attributes not limited to taste, smell, texture which are deemed desirable to the average consumer	From review: 'Sensory properties'
11	May play a role in social, cultural or religious contexts, either as meals, snacks or food ingredients	From review: 'Social / cultural' and 'other'
12	Is not a medicine, medicated preparation or tobacco product nor is a food ingredients in cosmetics, food supplements or similar	From review: 'Exemptions/ Exclusions '
	Food Supplements	
1	For human consumption	From review; 'Safety'
2	Designed to supplement a normal (healthy) diet	From review: 'Function'
3	Understood as a food supplement by the average consumer	Added on reflection; inferred from search
4	Contains bioavailable nutrients or substances with a nutritional or physiological effect	From review 'Bioavailable' and 'Ingredients/ composition'
5	Typically presented in pills, capsules, liquid form or similar	From review 'Presentation'
6	Clearly listed as a food supplement with clear dosage instructions	From review 'Prescription /dosage'
7	No hormones, drugs, tobacco or derivatives thereof	From review 'Exemptions/ exclusions'
8	Must not be presented as a substances which can prevent, treat or cure a human condition or properties thereof	Added on reflection; inferred from search
11	Must not be presented for use as a conventional food	From review; 'Exemptions/ exclusions'
12	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet	Added on reflection; inferred from search
13	Must be safe when consumed as recommended	From review 'Safety'
14	May make reference to populations	From review 'Populations'

Using a simple 'tick box' exercise, twelve products currently classified as food supplements under Irish VAT law were tested against each of these criteria to see whether they rated as 'food' or a 'food supplement. Example of how three of these supplements fare is illustrated below in Table 3 with the full results obtained displayed in Appendix D.

It was observed on screening that there was a lack of specificity with some of the criteria. For example, the third and fourth defining criteria for food ('must be primarily composed of material originating from plants, animals or similar kingdoms or substances isolated thereof' and 'contain a nutritive

component') could be applied to many food supplements as well as to food. For criterion number 6 for foods ('may be consumed native or following processing but with an inherent physical and chemical structure or matrix'), this was insensitive without inclusion of the word 'food'. Such overlaps are not surprising given some shared characteristics of food and food supplements. Criteria number 12 for food was devised based on the exclusions listed in the scientific and legislative documents ('is not a medicine, medicated preparation or tobacco product nor is a food ingredient in cosmetics, food supplements or similar'). The wording 'is not a food supplement or similar' was added on reverse of the definition for food supplements as listed by Codex Alimentarius (CAC/GL 55-2003) and in the US (US Dept. Health and Human Services, 2003) where food supplements are defined as "not being a conventional food". No such statement was listed in EU food law but the statement was retained given the global nature of this research and report objective to focus on foods in the everyday and ordinary meaning of the word. For food supplements, the merit of mentioning the word 'healthy' was unclear (criteria number 2; 'Designed to supplement a normal (healthy) diet').

In testing the individual products, there was a degree of ambiguity for a plant protein powder as to whether it would rate as a food or a food supplement. Although the product label stated 'Supplement Facts', it was not immediately obvious as to whether the product was a food or a food supplement given that protein was the sole ingredient, a relatively high dosage was recommended and the manner of consumption in a beverage. This highlighted the importance of factoring product presentation including labelling.

Table 3. Example of how three products traditionally classed as food supplements* rated in a simple tick box exercise to determine whether they were a food or food supplement based on all of the criteria identified from literature search. '?' indicates definitive 'yes' or 'no' answers could not be simply identified. Full details of all 12 products tested available in Appendix D.

	Criteria describing food	**Apple Extract Tablets**	**Plant Protein powder**	**Multi-vitamin & mineral tablet**
1	A food for human consumption		?	
2	Understood as food by average consumer		?	
3	Must be primarily composed of material originating from plants, animals or similar kingdoms, or substances isolated thereof	√	√	
4	Contain a nutritive component(s)	√	√	√
5	Consumption helps achieve or maintain good health in addition to basic nutrition	?	√	√
6	May be consumed native or following processing but with an inherent physical and chemical structure or matrix	√	√	√
7	May contain non-nutritive food components, either intentionally or as a result of processing/manufacturing		?	
8	With inherent sensory attributes not limited to taste, smell, texture which are deemed desirable to the average consumer			
11	May play a role in social, cultural or religious contexts, either as meals, snacks or food ingredients			
12	Is not a medicine, medicated preparation or tobacco product nor is a food ingredient in cosmetics, food supplements or similar	√	√	√
	Criteria describing a food (dietary) supplement			
1	For human consumption	√	√	√
2	Designed to supplement a normal (?healthy) diet	?	√	√
3	Understood as a food (dietary) supplement by the average consumer	√	√/?	√
4	Contains bioavailable nutrients or substances with a nutritional or physiological effect	?	√	√
5	Typically presented in pills, capsules, liquid form or similar	√	√	√
6	Clearly listed as a food (dietary) supplement with clear dosage instructions	√	√/?	√
7	No hormones, drugs, tobacco or derivatives thereof	√	√	√
8	Must not be presented as a substances which can prevent, treat or cure a human condition or properties thereof	√	√	√
11	Must not be presented for use as a conventional food	√	?	√
12	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet	√	√	√
13	Must be safe when consumed as recommended	√	√	√
14	May make reference to populations	√	?	√

* Illustrative descriptors rather than actual product names

5.2 Subsequent refinements of attributes

Based on this preliminary analysis, the attributes were refined, with attempts made to identify those which could be attributed as 'core' and those 'ancillary' or 'supportive' of what would constitute a food or a food supplement. Amendments included highlighting the safety of food and food supplements ('fit for human consumption') and factoring exclusion criteria as a core attribute of foods. For food supplements, mention was also given as to whether the product could be interpreted as a food by the consumer in the ordinary and everyday meaning of the word along with the product purpose (i.e. to supplement a normal diet and/or to achieve a particular aim beyond sustenance and a normal diet).

In a second checklist, 24 products (16 currently classified as supplements and 8 as food, including sports foods and foods enriched with vitamins and minerals, i.e. fortified foods) were tested against the criteria. Details of the criteria tested and a summary of the proportions of products which would be deemed as 'food' or 'food supplement' based on these attributes are listed in Table 4. Broadly speaking, these revised attributes were more appropriate for differentiating foods and food supplements and could form a basis for defining clear principles for determining whether a product is a food, however, some overlaps remained. For example, some attributes were common to both product types (e.g. 'is fit for human consumption' and 'must be nutritive in nature'). Analysis also revealed that additional consideration remained for wording concerning foods for sportspeople, specifically protein powders and shakes which could be considered as a food or a food supplement. In contrast, a hypotonic sports drink and a chocolate bar containing vitamins and protein would be considered 'food'. The screening also highlighted the value of capturing the details of product presentation (e.g. table, capsule, lozenge, powder) as a core attribute. Full details of how each product scored are listed in Appendix E.

.

Table 4. Comparison of products against the attributes of food and food supplements identified from literature review. 24 products (17 supplements, 7 foods (including fortified and sports foods) were scored against these attributes. Table details the number and proportion (%) of food supplements and foods which satisfied these attributes. Values in parenthesis represent products where the information was partially satisfied or unclear and therefore could not be excluded.

		Supplements (n16)			Regular foods (inc. sports foods & fortified foods) (n8)	
FOOD		**n**	**%**		**n**	**%**
Core attributes of a food (All 3 attributes mandatory)						
1	Is fit for human consumption	16	100		8	100
2	Is understood as food for human consumption by the average consumer	1 (1)	6 (6)		8	100
3	Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood as a food supplement by the average consumer	1	6		8	100
Comprises the following characteristics						
1	Primarily composed of plant or animal food or from similar kingdoms e.g. insects, (not including extracts or concentrated essences or analogous)	3 (5)	19 (31)		8	100
2	Must be nutritive in nature	9 (7)	56 (44)		8	100
3	Must contribute to basic nutrition and help achieve or maintain good health. Any nutrition and/or health claims provided must reflect those approved under appropriate EU food regulations (e.g. Regulations (EU) Nos. 1924/2006, 1169/2011)	3 (5)	19 (31)		8	100
4	May be consumed native or following processing but with an inherent physical and chemical food structure or food matrix*	(2)	(12)		8	100
5	With inherent sensory attributes characteristic of food, not limited to taste, smell and texture and which are deemed desirable to the average consumer				8	100
6	May play a role in social, cultural or religious contexts and may be consumed as a meal or snack.	(1)	(6)		8	100
FOOD SUPPLEMENT						
Core attributes of a food supplement (mandatory)						
1	Is fit for human consumption	16	100		8	100
2	Is understood as a food supplement, rather than food, by the average consumer	15 (1)	94 (6)		(1)	12
3	Is designed to help satisfy a normal, healthy balanced diet.	16	100		8	100
4	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet reflecting permitted claims and labelling as per appropriate EU food regulations (e.g. Regulation (EU) No. 1924/2006).	4 (12)	25 (75)		(8)	(100)
Comprises the following characteristics:						
1	Is a concentrated source of nutrients or other substances permitted for use in the EU (singly or in combination) and with a nutritional or physiological effect.	16	100		1 (6)	12 (75)
2	Typically presented in tablets, pills, capsules, liquid or powder form or similar	15 (1)	94 (6)		0	0
3	Is clearly listed as a food supplement with clear dosage instructions	15 (1)	94 (6)		0	0
4	Must not contain hormones, drugs, tobacco or derivatives thereof	16	100		8	100
5	Must not be presented as substances which can prevent, treat or cure a human condition or properties thereof	16	100		8	100
6	Must not be presented for use as a conventional food	15 (1)	94 (6)		0	0
7	Must list the following statements on labels: 1) a warning not to exceed the recommended daily dose; 2) a statement to the effect that food supplements should not be used as a substitute for a varied diet; 3) statement to the effect that the products should be stored out of the reach of young children;	14 (2)	88 (12)		(8)	(100)

*A food matrix may be described as the nutrient and non-nutrient components of foods and their molecular relationships, i.e. chemical bonds, to each other. (Source: United States Department of Agriculture, National Agricultural Library (2015))

5.3 Final determination of principles for determining whether a product is a food or food supplement based on scientific literature search.

Following this, a third and final attempt was completed to further refine the attributes, as derived from the literature search, to produce clear core principles for determining if a product was a food, or a food supplement. The word 'dietary' was listed alongside 'food supplement' reflecting US descriptions. These final principles are outlined below, with one principle relevant for both food and food supplements:

Food and food (dietary) supplements

All food and/or food supplements must be safe for human consumption

Food

1 Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood as a food (dietary) supplement presented in formats not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.

[1]Conventional food relates to foods or food ingredients primarily composed of plant or animal material (or similar) with an inherent food matrix or form (e.g. liquid, solid, frozen, dried, dehydrated, concentrated). Such foods are ingested or chewed for their nutritional value or for their sensory attributes not limited to taste.

Food (dietary) supplement

1 Is understood as a food supplement, rather than conventional food, by the average consumer and is presented and labelled as such. Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar.

2 Is composed of nutrients or other substances with a nutritional or physiological effect as defined in EU legislation. Food supplements are designed to supplement total dietary intakes with a view to satisfying a normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet

This final set of attributes or core principles were then tested against the above mentioned food and food supplement products. Table 5 provides summary details, with more specific details provided in Appendix F. Assuming the plant protein powder was a supplement as determined from the label (which is listed as 'Supplement facts'), there was 100% success in differentiating between the two groups. This indicates the value of factoring product presentation and intention of the food business operator to present the product as a supplement or not. It also indicates that the criteria identified from the literature search could form the basis of functional principles which could determine whether a product is food.

Table 5. Proportion of current marketplace products which classed as foods or food supplements according to the refined definitions and using a simple tick box exercise

Food and Food Supplements		**Food Supplements (n16)**	**Food including sports foods & fortified foods (n8)**
	All food and/or food supplements must be fit for human consumption	100	100
Food			
1	Is understood as conventional food for human consumption by the average consumer1 and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in formats not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.	0	100
Food supplement			
2	Is understood as a food supplement, rather than conventional food, by the average consumer and is presented and labelled as such. Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar.	100	0
3	Is composed of nutrients or other substances with a nutritional or physiological effect as defined in EU legislation. Food supplements are designed to supplement total dietary intakes with a view to satisfying a normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet	100	0
Outcome		Food Supplement	Food

5.4 Summary and conclusions

This chapter describes the development of principles for determining whether a product is a food or food supplement based on characteristics identified from a comprehensive literature search. The final characteristics were able to successfully differentiate the two food product types when tested against convenience samples of food products currently on sale.

6.0 Questionnaire: Development, administration and results obtained

6.1 Questionnaire development and administration

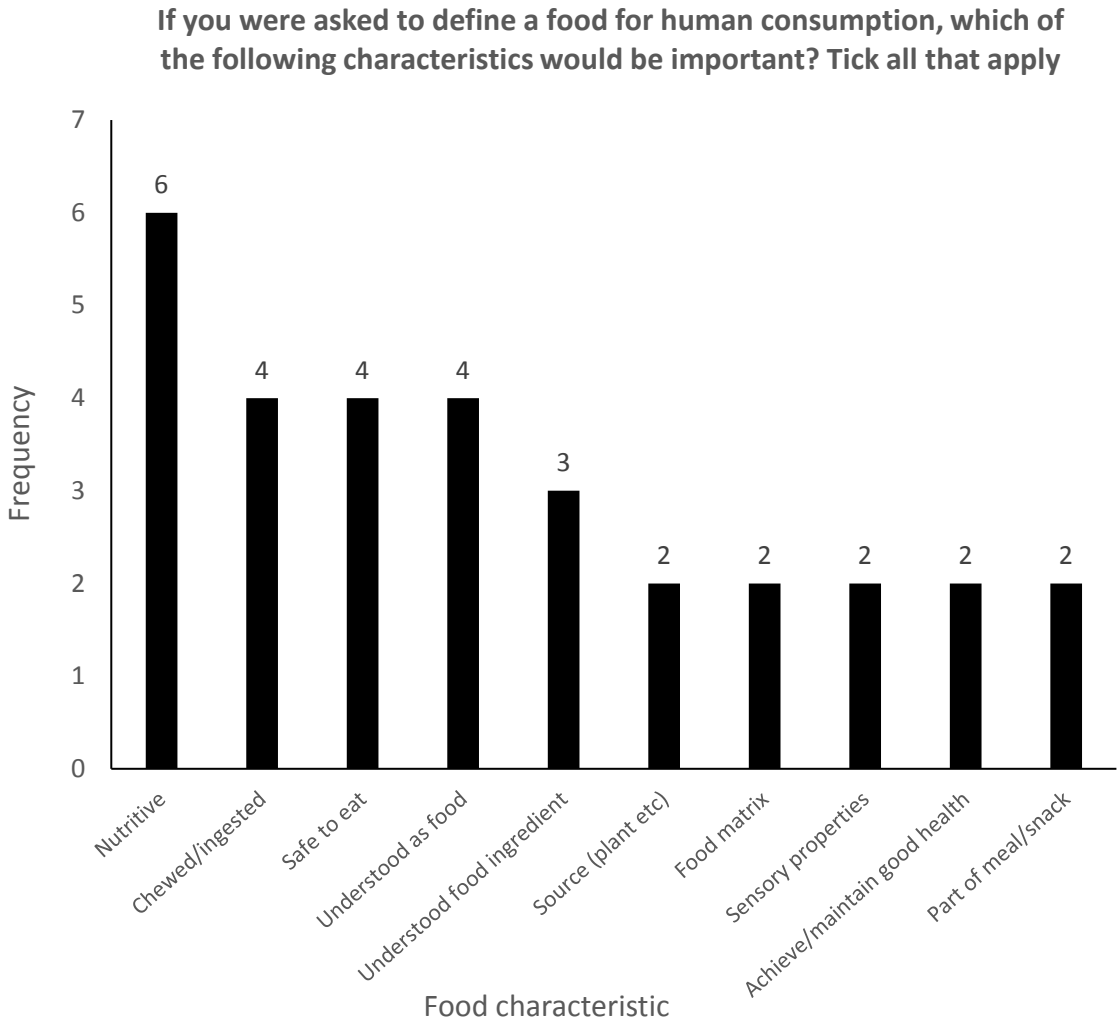
Based on the emerging themes arising from the literature search, a questionnaire was devised for administration to 11 experts in the field of food science, food safety and nutrition in Ireland. This group were highly qualified and experienced experts at the level of senior research fellow (academic), lecturer, senior lecturer or professor and each with 15 – 40+ years' experience in the field. The questionnaire assessed their opinions on whether the attributes of food and food supplements as identified from the literature review were valid and in agreement with their own learned views and experience. It also assessed whether they believed food supplements were food, whether a food matrix would help delineate between foods and food supplements and the extent of reliance on EU legislation. A series of 8 questions were constructed to include 'tick box' and open-ended questions for comment. The survey was completed using the 'surveymonkey' resource (www.surveymonkey.com) with respondents given two weeks for completion. Participants were asked to complete the survey based on their understanding of food and food supplements in an ordinary and everyday perspective rather than deferring to EU legislation. A reminder email was circulated two days before the end of the survey period. 6 respondents completed the questionnaire (55% response rate). A copy of the complete questionnaire and associated cover letter are included in Appendix G.

6.2 Questionnaire results

Characteristics of Food

From a choice of 10 options, the most frequently chosen characteristics of food were: 'has nutritive properties' (n6), 'can be chewed and ingested' (n4), is 'is safe for human consumption' (n4) and 'understood as food by the consumer' (n4) (Figure 2). The next common attributes were 'understood as a food ingredient by the consumer' (n3). Less common (n2) were mention of the source material (plant, animal, bacteria, fungi or insect material), a food matrix, sensory properties of food, a role for food in achieving and maintaining good health and consumption as part of a meal or snack. The characteristic 'may play a role in social, cultural or religious contexts' was not chosen.

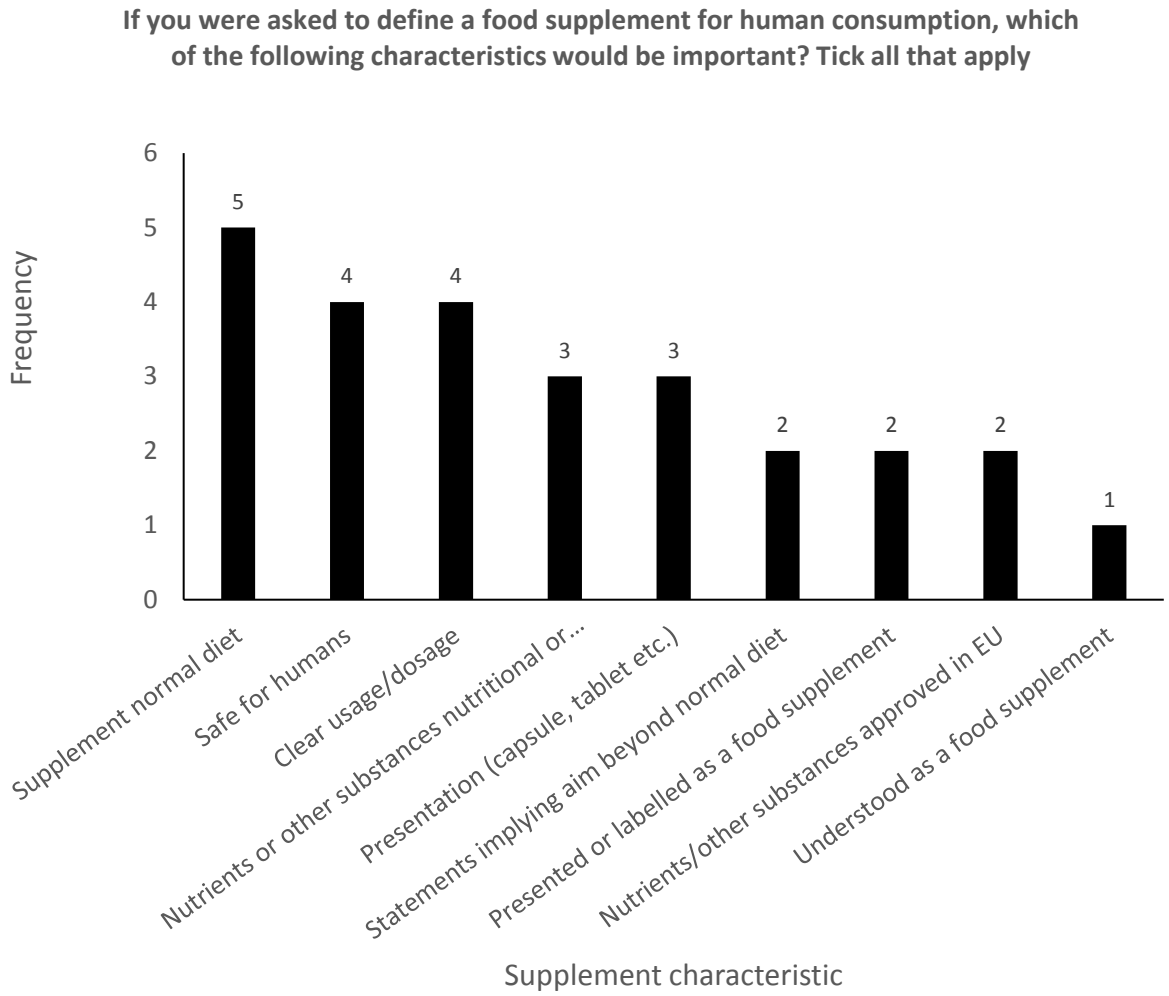
Figure 2 Frequency of response by food experts to characteristics of food as identified by literature



Characteristics of Food Supplements

From a list of 9 options (Figure 3), participants were most likely to list 'aims to supplement the normal diet' (n5), followed by 'is safe for human consumption' (n4), and 'has clear usage or dosage instructions' (n4). Other considerations were 'contains nutrients or other substances with a nutritional or physiological effect (n3), 'is presented as a tablet, pill, capsule, liquid, gel, powder or other product for the preparation of beverages or similar' (n3). Less popular options were: 'is accompanied by statements which imply achievement of a particular aim beyond supplementing a normal healthy balanced diet', 'is presented or labelled as a food supplement', 'contains nutrients or other substances approved for use in the EU' and 'is understood by the consumer as a food supplement rather than food'.

Figure 3 Frequency of response by food experts to characteristics of food supplements as identified by literature



Consideration of product types as food or food supplements

Participants were asked in two questions to indicate whether they considered particular product types as ‘food’ or ‘food supplements’. In general, all participants classed all options listed as foods, with particular products selected as food and/or supplements, namely ‘oral nutritional supplements’ (n4) (Table 8). The participants did not list any other product categories which could be considered as a food supplement.

Table 8 Summary of responses by food experts to types of food as to whether they believed they were foods and/or food supplements

	Food	Food Supplement
Foods enriched with vitamins and minerals	4	1
Infant and follow-on formulae	5	n/a
Young child formula (e.g. growing up milk)	4	n/a
Food supplement	4	n/a
Total diet replacements for weight control	5	3
Partial meal replacements for weight loss	5	3
Oral nutritional supplements	3	4
Other dietary foods for special medical purposes to be administered under medical supervision	2	2
Enteral and Parenteral Nutrition feeds	4	3
Food additives	1	0

The option to provide open ended answers was provided for these questions which indicated that in general, the respondents answered these questions from a food regulatory affairs perspective e.g. *"under EU law food supplements are food"* (chapter 4.0). Other comments referred to Codex Alimentarius or included:

"Foods (nutritional properties, ingested by mouth, to achieve and maintain good health) include food supplements (nutritional properties, (oral) supplement to normal diet)".

"I would see food ingredients as component of food rather than foods per se. With regard to oral nutritional supplements, I would see them as pharmaceutical rather than food"

"Total diet replacements for weight control, Partial meal replacements for weight loss, Other dietary foods for special medical purposes to be administered under medical supervision may be considered as foods that replace other foods in the normal diet, not food supplements. Enteral and Parenteral nutrition feeds are not consumed by mouth. Food additives e.g. artificial sweeteners or colours do not have any nutritional properties"

One participant defined food supplements as:
"*Small dose products providing concentrated amounts of nutrients and other substances with a physiological effect but not to the extent of being a medicine"*. This broadly reflects the EU food law definition of food supplements.

Overall, all respondents tended to defer to EU food law definitions, as outlined in chapter 4.0, although some inter-individual differences in responses were observed for each product type.

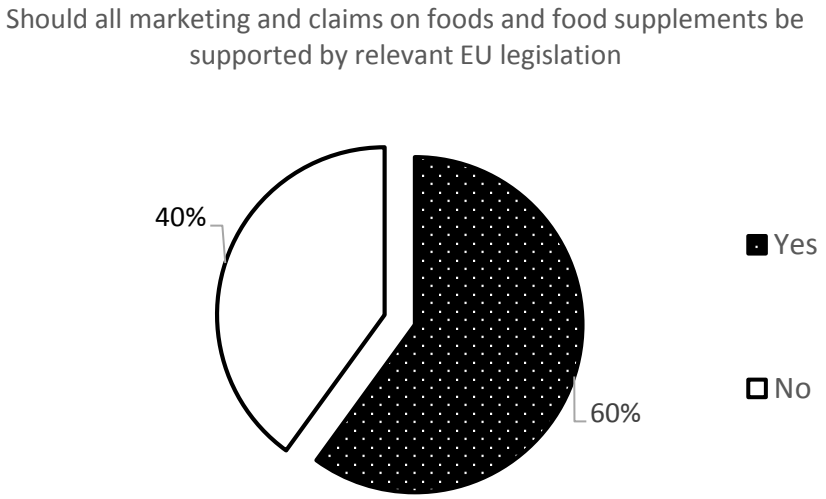
Role of a food matrix

Only one respondent believed that a 'food matrix' (defined by the USDA as the nutrient and non-nutrient components of foods and their molecular relationships i.e. chemical bonds, to each other) allowed differentiation of foods from food supplements. One comment included: "*food supplements are foods (have nutritional properties and ingested by mouth); food supplements may also have a food matrix, e.g. fish liver oils as vitamin D supplement compared to foods such as vegetable oil as salad dressing".*

Influence of legislation

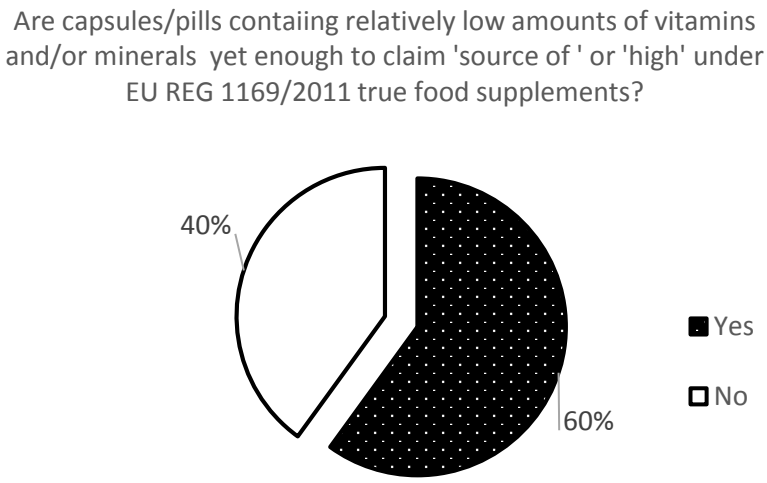
The majority (60%) of respondents believed that for a substance to be described as a food or food (dietary) supplement, all associated and marketing claims should be supported by relevant EU legislation

Figure 4 Influence of legislation



Respondents did not believe that there was any threshold for the amount of vitamins and/or minerals which should be present in food supplements, with one comment for this question *"I see food and nutritional supplements as two separate entities regardless of amount nutrients contained".* In contrast one comment suggested that was a greater need for maximal limits for the amount of nutrients in food supplements.

Figure 5



6.3 Summary and Conclusion

This short questionnaire of invited experts in the food arena in Ireland indicated that the experts broadly agreed with the characteristics of food and food supplements as identified from the literature search. While some of the characteristics were comparable (e.g. safe for consumption), others were specific for foods and for food supplements. No additional characteristic were proposed or identified by the experts suggesting that all relevant attributes had been identified. Hence, the identified characteristics could allow for the development of guidelines to distinguish conventional foods from food supplements.

This questionnaire also indicated that the experts, despite being asked to answer the questions on food and food supplements from an 'every day and ordinary meaning' and 'not relying on definitions

from EU food law or otherwise' did answer some questions from a food regulatory affairs perspective. Hence, any substance consumed by mouth bar a medicine, herbal medicine, tobacco or cosmetic/tincture was deemed a 'food', with open ended comments stating this. This reflects the current status under EU food law and as underpinned globally by Codex Alimentarius[5] as outlined in chapter 4. Therefore, food supplements were classified by the experts as a type or category of food, as were weight loss foods replacing all or part of the daily diet and foods for special medical purposes (formerly called 'dietetic foods').

The majority of questionnaire respondents also believed that while any marketing on foods and food supplements should adhere to EU food law, there was no minimum threshold for the amount of vitamins and minerals a supplement could contain. Currently, there are no minimum or maximum thresholds for the vitamin and mineral content of food supplements enshrined in law. Attempts to establish maximum levels remain stalled and at present this issue is not close to resolution (FSAI, Guidance Note 21, Revision 2, 2013).

In conclusion, the results from this questionnaire show that in a wider sense invited food experts in Ireland deem food supplements as food, albeit a specific type or category of food. Expert answers also indicated that they were informed by EU Food law in making this decision thereby illustrating the interplay between science and policy in modern society. This aside, experts were in agreement with the discrete defining characteristics of food and of food supplements as identified from the scientific literature. It is possible to conclude that while food supplements are food, they can be distinguished as a type of food which is distinct from conventional food.

[5] Regulation (EC) No 178/2002 and http://www.fao.org/docrep/w5975e/w5975e07.htm

7.0 Consolidation of literature review and questionnaire outcomes: defining food and key principles of food and food supplements.

This report commenced with a search of academic and relevant literature sources to identify definitions and descriptions of food and food supplements. It also described some definitions and interpretations from food regulatory affairs and taxation viewpoints. After extraction of descriptive text, attempts were made to determine key characteristics of foods and of food supplements and to see if food supplements were identical to conventional food. Products currently on sale in Ireland as food supplements or food were compared against these characteristics to see whether they would be classed as 'food' or 'food supplements'. Following this, a survey of highly qualified food experts was completed to ascertain if they agreed with these descriptors of foods and food supplements or could identify any other relevant characteristics. This chapter attempts to consolidate all of the information collected to date with a view to defining food, to determine key principles of food and food supplements and to examine whether food supplements are food. The final emphasis will be on the everyday and ordinary meaning of the word 'food' and 'food supplements'.

7.1 Key principles of food and food supplements

A literature search identified key characteristics of food and food supplements, some of which were common to food and to food supplements while others identified that food supplements were distinct from conventional food. Generally such principles were supported by the survey of experts. To provide some indicator of level of agreement between the literature search and the expert survey, tables 9 and 10 provide a consolidation of the key characteristics of foods and food supplements. This table was constructed by visually cross-checking mention of the characteristics between the two sources and subsequently indicating gauged level of agreement using the '+' symbol to show if there was strong (+++), medium (++) or some (+) agreement, or whether a characteristic was not specified. Cross-comparison with the outcomes from the critique of regulatory and taxation guidance is not included here due to this Report's emphasis on definitions in an ordinary and everyday sense.

Overall, the tables support the notion that while food and food supplements have some similar properties, there are clear differences in the characteristics of food and of food supplements. Key properties of both are that they are safe and are not medicines, drugs or tobacco or ingredients in cosmetics or tinctures. Both can also contribute to nutrition and therefore health. However, thereafter characteristics differ with those for foods tending to focus on the inherent properties and role of the food in the diet. In ordinary and everyday terms, the experts agreed strongly with results of the

literature search that foods should be chewed and ingested and should be understood as food or food ingredients by the average consumer. In other words, for a product to be food, it must be clearly identifiable as 'food' and consumed in a manner usual of foods. It must conform to more conventional notions of what a food may be. In contrast, for food supplements, both the literature and experts agreed strongly, that food supplements are presented in forms distinct from regular foods (i.e. pill, capsule etc.) with clear (dosage) usage instructions and should supplement or add to the normal or usual diet. They should also be labelled as such. Experts believed that food supplements were food (thereby echoing food regulatory definitions) but that they could be considered a distinct grouping of substances or type of food which sets them apart from regular food. They are not presented as a conventional food form.

There was moderately good agreement between the literature search and the experts regarding properties of food such as its composition (plant, animal etc.), its presentation (solid, liquid), sensory attributes, its importance in achieving good health and place as part of meals and snacks. Experts did not factor highly a role for food as part of social, cultural or religious contexts. However, based on their comments, it would appear that they placed greater emphasis on some characteristics which are reflected in EU food law definitions of food. Critically, they did not disagree with any of the characteristics listed.

There was higher agreement between the literature and survey regarding characteristics of food supplements which tend to focus more on the composition and purpose or function of the supplement, including its presentation. This is perhaps unsurprising as discussion of food supplements in the literature either tended to focus on legislative definitions of food supplements or to focus on individual supplements from a food science or nutrition perspective – e.g. kinetics of nutrient release following encapsulation, safety or efficacy of outcome on biochemical endpoints.

In summary, accepting that food supplements are a type of food, there was generally good agreement between the opinion of the experts with the outcomes of the literature search regarding key characteristics of food and of food supplements. Such characteristics can be used to underpin any definitions and associated guiding principles for food and food supplements

Table 11. Consolidation of the characteristics of food defined by the literature search and subsequent survey of food experts as completed in this report.

	Defining characteristic of a food	Literature Search	Expert Survey
1	Safe for human consumption	+++	+++
2	Understood as food by average consumer	+++	+++
3	Understood as food ingredient by average consumer	+++	++
4	Is not a medicine, medicated preparation or tobacco product nor is a food ingredient in cosmetics, food supplements or similar	+++	++ Food supplements considered food
5	Has nutritive properties	+++	+++
6	Must be chewed and ingested	+++	+++
7	Must be primarily composed of material originating from plants, animals, bacteria, fungi or insect material or similar	+++	++
8	Has a food matrix being presented in a solid, liquid, frozen, dehydrated, concentrated or dried forms	+++	++ (form only)
9	With inherent sensory attributes not limited to taste, smell, texture which are deemed desirable to the average consumer	+++	++
10	Consumption helps achieve or maintain good health	+++	++
11	May play a role in social, cultural or religious contexts	+++	not specified
12	Can be eaten as a meal or a snack	+++	++

+++ indicates strong agreement, ++ medium agreement, + some agreement. Not specified indicates lack of mention/reference

Table 12. Consolidation of the characteristics of food supplements defined by the literature search and subsequent survey of food experts as completed in this report.

		Literature Search	Expert Survey
	Criteria describing a food supplement		
1	Safe for human consumption	+++	+++
2	Understood as a food supplement by the average consumer rather than conventional food	++	++
3	Is presented and labelled as a food supplement	+++	++
4	Typically presented in pills, capsules, liquid, gel, powder or other product for the preparation of beverages or similar	+++	+++
5	Contains nutrients or other substances with a nutritional or physiological effect	+++	+++
6	Aims to supplement the normal diet	+++	+++
7	May imply achievement of a particular aim beyond supplementing a normal healthy balanced diet	++	++
8	Is not a medicine, medicated preparation or tobacco product	+++	+++
9	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet	++	+
10	Has clear usage or dosage instructions	+++	+++

+++ indicates strong agreement, ++ medium agreement, + some agreement. Not specified indicates lack of mention/reference

7.2 Are food supplements food?

The balance of evidence, to this point, suggests that food supplements are food insofar as they are consumed orally, can contribute nutritional properties and must be safe for use. However, they are considered as a distinct category or type of food with their own properties and descriptive characteristics. Hence, although food, they are not viewed as a 'conventional food form' or what could be called 'ordinary' or 'basic' food.

7.3 Are there other 'types' of food?

In a wider context, if food supplements are considered a 'type' of food, consideration should also be given to other foodstuffs which may be categorised as 'types' of food. Such categories are clearly defined in food law[6] (see chapter 4) but can also be clearly identified based on their everyday usage and purpose. Many were captured in the literature search for 'food' under the theme 'Other' hence discussed here. The experts were asked their opinion in an everyday sense, whether they considered these types as 'food' or 'food supplements'. This list included foods which are traditionally formulated for specific population groups, foods to be used under medical supervision, foods which provide some or all of total dietary intakes and in certain instances are essential to manage certain conditions or for clearly identified vulnerable population groups. In general, these products were all classed as 'food'. Some were also classed as 'food supplements', oral nutritional supplements and some foods to be administered under medical purposes (including tube feeding). Based on the literature search which identified many of these food categories as 'food' and on practical considerations of the purpose of these products in an everyday and ordinary sense, it is proposed to consider these products also as a 'type' of food. Many contain overlapping characteristics as for regular food (e.g. nutritive, chewed and ingested, presented in a food form). Furthermore, for the population groups involved, they are understood as food and essential to achieve and maintain good health.

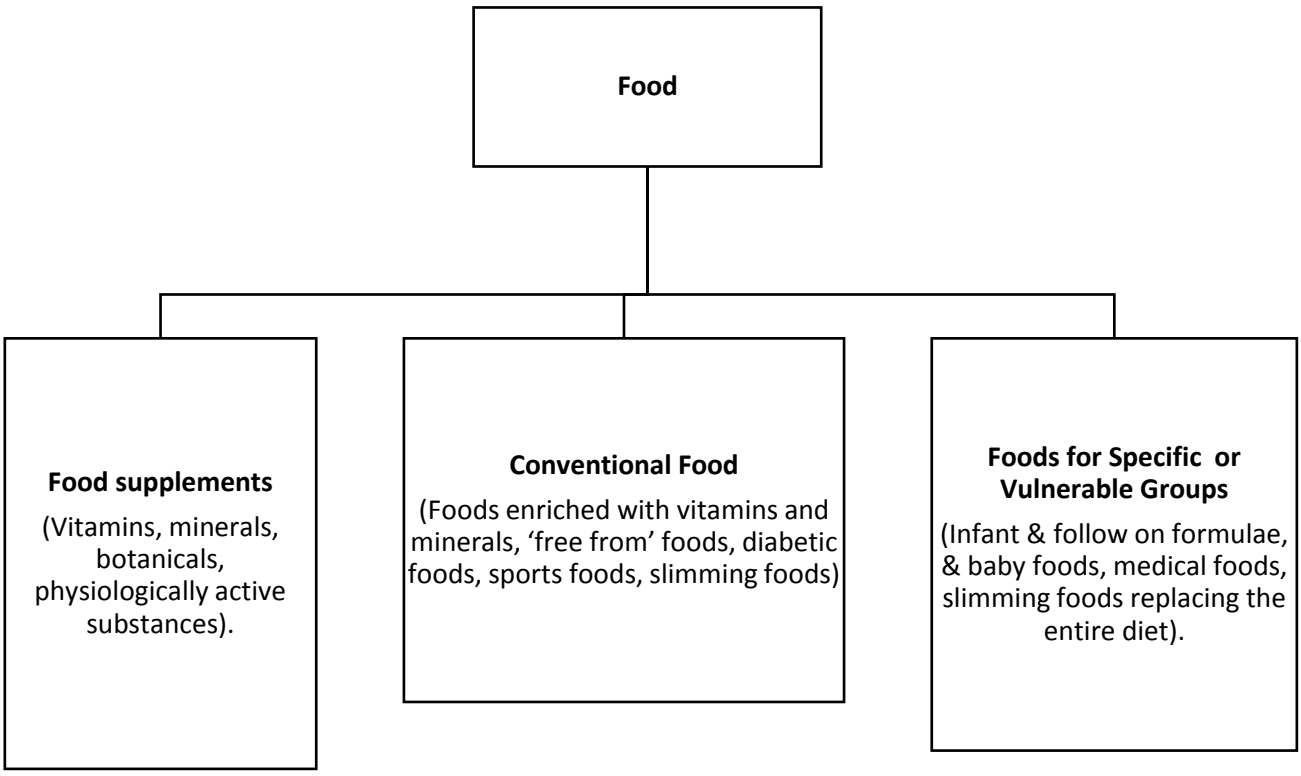
7.4 What is food?

On balance, on consideration of the totality of the evidence, the following graphical display (figure 6) is proposed to describe 'food' in an ordinary and everyday meaning. It reflects the general categorisation of foodstuffs in food regulatory affairs. Figure 6 therefore proposes that 'food' is an umbrella term. Within this banner are three components: i) regular or conventional food as identified by the literature search and supported by the experts; ii) food supplements as a distinct type of food, also readily identifiable from conventional food; iii) foods which are specific in focus and typically for use by specific and/or vulnerable population groups. This indicates that while the term 'food' is broad-reaching, within this category, conventional food is distinct from food supplements. Foods for

[6] Regulation (EU) No 609/2013

identified for specific groups are included for completeness but other than being formulated in purpose for specific or vulnerable groups, they are broadly equivalent to conventional food and should be considered equivalent.

Figure 6 Proposed description of food



7.5 Finalising definitions and guiding principles of food and food supplements

Based on the totality of the evidence to this point, definitions and associated guidelines of whether a product is a food or food supplement were finalised. The original characteristics of food as identified from the literature were amended to reflect any key considerations identified by the food exerts in the food survey, namely:

- Direct acknowledgement that food supplements are food, albeit not conventional or ordinary food
- Reference to dosage or usage instructions for food supplements

- Simplifying statements on food supplements that they are designed to supplement the normal diet rather than to supplement total dietary intakes with a view to satisfying a normal diet
- Removal of outright reference to EU legislation to supportive statements
- Inclusion of reference to role of foods in meals and snacks
- Removal of emphasis of food matrix.

The final guidelines were subsequently tested for the ability to differentiate between the convenience sample of products currently on sale and classed as foods or food supplements, with 100% success (Appendix H).

7.6 A definition of food and guiding principles for determining whether a product is a food or food supplement

7.6.1 Food

The following definition of food is proposed to describe 'food' in an ordinary and everyday meaning and to describe conventional food and food supplements as a type of food.

The term 'food' may relate to any substance that is edible except medicines, drugs, herbal medicines or tobacco. It includes food supplements, sports foods, medical foods, infant and follow on formulae, baby foods and slimming foods that replace all or part of the diet.

All food types must be safe for human consumption.

Within this, conventional, ordinary or basic food can be defined as:

"Substances that are understood as ordinary food[1] for human consumption by the average consumer and are presented and labelled as such. Ordinary food is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. It is not understood or presented as a food (dietary) supplement in forms not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar".

[1] Ordinary, basic or conventional food relates to foods or food ingredients typically in liquid, solid, frozen, dried, dehydrated or concentrated forms. Such foods are ingested or chewed at meals or snacks for their nutritional value or for their sensory attributes not limited to taste. Ordinary food is primarily composed of plant, animal, bacteria, fungi or insect material.

The following supportive guidelines are proposed to assist in determining what products fall within the scope of the definition of ordinary foods and what products fall outside of this.

Guiding principles for conventional, ordinary, or basic food proposed as:

1. Food that is safe for human consumption.
2. Is understood as ordinary food by the average consumer and is presented and labelled as such.
3. Is not a medicine, medicated preparation, tobacco or food ingredient in cosmetics, tinctures or similar.
4. Is not understood or presented as a food (dietary) supplement in forms not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.

Additional properties of an ordinary food are:

1. It is usually presented in liquid, solid, frozen, dried, dehydrated or concentrated forms
2. It is ingested or chewed
3. It is consumed at meals or snacks
4. It is consumed for nutritional purposes
5. It has inherent sensory properties characteristics of food, not limited to taste
6. It is primarily composed of plant, animal, bacteria, fungi or insect material.

7.6.2 Food Supplements

Food supplements are a type of food, however, they are not food in an everyday sense. The following definition of food supplements in an ordinary sense is proposed:

Food supplements, although edible, are not ordinary food. They may be defined as:

"Substances that are understood as a food (dietary) supplement, rather than ordinary food, by the average consumer and are presented and labelled as such. Food supplements are typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar and with clear usage or dosage instructions. Food supplements are composed of substances with a nutritional or physiological effect and are designed to supplement the normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet.

To extract guiding principles for food supplements from this, the following are proposed:

1. Food (dietary) supplements that are safe for human consumption
2. They are understood as a food (dietary) supplement, rather than ordinary food, by the average consumer
3. They are presented and labelled as food (dietary) supplements
4. They are not a medicine, medicated preparation, tobacco or food ingredient in cosmetics, tinctures or similar.

Additional properties of food supplements are as follows:

5. They are typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar
6. They have clear usage or dosage instructions
7. They are composed of substances with a nutritional or physiological effect
8. They are designed to supplement the normal diet
9. They may imply achievement of a particular aim beyond sustenance and supplementing a normal, healthy balanced diet.

7.7 Additional considerations and observations

This chapter has compared the results of the literature search on definitions and characteristics of food and food supplements with the views and feedback from highly experienced food experts in Ireland considered. It proposes a definition of food and defining principles of food and of food supplements. Methodological considerations at this point relate to the method used to compare the results which risked subjectivity. However, every effort was taken to be as objective as possible given the nature of this report which included results which were both qualitative and quantitative in nature.

Although consideration was given to food regulatory descriptions, in the final definitions and principles proposed, all references to legislation were removed. This was to reflect the ordinary and everyday viewpoint but the relevance of such legislation may arise should confusion arise for food supplements. For example, for the guideline 'presented and labelled as a food supplement'. Food legislation clearly lists statements which are specific to food supplements labels e.g. on-pack warnings about dosage exceedance or statements to the effect that supplements must not substitute for a varied diet (FSAI, Guidance Note No. 21, Revision 2, 2013). Such statements are not typically present or needed on foods.

Currently sports products can be classed as foods or food supplements. Supplements should be clearly identifiable from the product label (dosage/presentation) and if originating from the US through use of a 'Supplements Facts' box on the label. Foods for sports people are also clearly identifiable through their form and presentation e.g. isotonic sports drinks, milks or chocolate bars with added protein. For protein powders (e.g. whey, casein, soy or pea), unless clearly listed as a supplement on-pack they may be deemed a food. This situation arises as a result of the repositioning of sports food as regular food in law and their increasing use or normalisation as an everyday and normal product by the general population. Additional consideration to what is considered here may be required if desired to classify all products for sports persons collectively.

7.8 Summary and Conclusion

Based on a literature search and survey of experts, definitions of food have been provided. Food supplements, although a type of food, are distinct from normal, ordinary and conventional food. Clear defining principles based on the academic literature and the feedback from academic experts have been devised.

8.0 Market scan of food supplement offerings in 2017 and potential future trends

This chapter describes the current marketplace for food supplements and attempts to identify any emerging trends with respect to types, forms and presentation of food supplements for human consumption.

8.1 Background and Methodology

The marketplace for food supplements is significant in Ireland with an estimated value of 59m Eur in 2016 (Euromonitor, 2016). Such supplements are manufactured or sold by a mixture of companies, including national and multinational pharmaceutical companies, players in the packaged food and beverages industry, direct sales and private labels (Euromonitor, 2016). In 2016, the value of the global dietary supplement marketplace was estimated as USD 132.8 bn with significant inter-country sales (Zion Research, 2017).

Traditionally, the accepted role for dietary vitamin and mineral supplements were as aids to achieving a healthy balanced diet, helpful for those with inadequate dietary intakes or at particular stages of one's life to make sure adequate intake of individual nutrients (BNF, 2016).

National dietary survey data reveal that approximately 28% of the Irish adult population consume dietary or food supplements of any kind, this proportion increasing to 37% (31% men, 43% women) in those aged 65 years or over (IUNA, 2011). In this survey of 1500 Irish adults aged 18 years plus, 211 different supplements were consumed over 4 day survey periods. Supplement breakdown suggests that supplements consumed were largely vitamin and/or mineral combinations (30% were multivitamin/mineral combinations, 12% were multivitamins, 11% were single vitamins, 8% were single minerals, 5% were multi-minerals, 20% were fish oils, 9% were other oils (including primrose/starflower oils) and 5% were categorised as 'other'). Within this classification, vitamins and/or mineral supplements containing botanical ingredients were either classed as 'vitamin and/or mineral combinations' or 'other' depending on the product composition - i.e. the amount of vitamin and/or mineral present.

The aim of this chapter is to complete a search of current dietary (food) supplements on sale and to identify any future trends. To complete this work, the following searches were completed:

- Search of guidance by Irish health authorities.
- Search of regulatory authorities to identify any changes in legislation which may influence the type of food supplements on sale.
- Search of scientific literature.

- Search of market research data to identify any trends in consumer purchasing patterns e.g. Euromonitor.
- Search of online and physical manufacturers and retail outlets stores selling dietary supplements e.g. Holland and Barrett, Seven Seas, Pfizer, Sona.

The outcomes of the above searches are described below.

8.2 Search outcomes

8.2.1 Current guidance by health bodies in Ireland

In Ireland, there are currently two life stages where supplement use is strongly recommended as part of public health policy - vitamin D in early childhood (5 μg/day for 0-12 month old infants) and folic acid (400 μg/day) just before and during early pregnancy (FSAI, 2011). Beyond this, use of dietary or food supplements continues to relate to intake of particular vitamins and/or minerals when dietary intakes are inadequate to satisfy needs e.g. to enhance dietary iron intakes in strict vegetarians, to satisfy increased iron requirements during pregnancy or use of oral nutrition supplements by malnourished individuals (INDI, 2009). Such supplements are either recommended by a physician or health care provider or self-selected by the consumer. There is increasing acknowledgement of other supplement types e.g. supplements used as part of weight loss diets or sports nutrition supplements, albeit with the proviso that any health claims or benefits listed on these products should be approved legally, based on sound science and safe for use (INDI. 2016a, 2016b). Health authorities simply state there is a lack of scientific evidence regarding the efficacy of some supplements on sale.

Currently, there is one ongoing consultation regarding the content of vitamin D in supplements recommended for young children (FSAI, 2017). Whilst in 2011, a report from the FSAI recommended an expert working group be established to review whether all population groups required vitamin D supplementation (at levels of 5 or 10 μg/day depending on lifestage) (FSAI, 2011), this has not materialised and there is no indication of any plans for extension of such supplementation to other population groups, or to other nutrients.

8.2.2 Current regulatory guidance and emerging trends

8.2.2.1 Current regulatory guidance

In Europe and the US there are complex regulatory frameworks governing the composition, sale and marketing of dietary supplements. While broadly similar between the two regions, they are not

identical. In general, food supplements are described as concentrated sources of vitamins and/or minerals or other substances with physiological effects, not limited to botanicals, amino acids, prebiotics, fibres etc,. Of relevance to this report is the differing level of guidance available for vitamins and/or minerals relative to botanical products.

Clear guidance exists for supplements containing a single dose or multiple combinations of vitamin and/or mineral supplements (FSAI Guidance Note No. 21). It is less clear for other substances, including botanical products and extracts (e.g. herbs, plants, fungi, algae and extracts), or other bioactive substances (e.g. fatty acids, amino acids, pre- and pro-biotics, lutein, carnitine or enzymes such as co-enzyme Q10 or papain). In Ireland, food supplements should only be on sale following notification to the relevant competent authorities (e.g. Food Safety Authority of Ireland), with the onus of proving safety of the product placed at the manufacturer or food business operator. Complexities arise for botanicals as some may be deemed as herbal medicines and require registration with the Health Products Regulatory Authority (www.HPRA.ie) i.e. they are deemed a medicine and not a food supplement per se. This is completed on a case-by-case basis. Further, what may be deemed a food or food supplement in one European country may be a medicine in another and vice versa.

8.2.2.2 Predicted future trends

Botanicals

There is significant growth in the number of notifications of food supplements containing botanicals to the FSAI (personal communication 2017). This can also be evidenced in three manners.

1. The increasing number of botanical products approved for sale in Europe as ingredients in food supplements through the novel foods regulation (a novel food being a food not traditionally consumed to a significant degree in Europe before May 1997) (Regulation (EC) No 258/97).
2. The creation of a database or compendium of botanicals by the European Food Safety Authority (https://www.efsa.europa.eu/en/data/compendium-botanicals). This compendium is not a definitive list per se; it is intended to guide EFSA in any safety assessments of botanicals and their preparations intended for use in food and food supplements. However, it does broadly illustrate the breath of botanical which have arisen in regulatory circles for potential use in the EU food chain.
3. In parallel, as part of a broader consultation, the European Commission are evaluating the suitability of current processes used to assess the scientific robustness of health claims on foods and food supplements, with botanical ingredients selected for particular consideration. Outcome of this consultation period is due towards the end of 2017 / early 2018

(https://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en). It is anticipated that this consultation will provide clarity to food business operators, including those who make or supply food supplements containing botanicals. It is reasonable to assume that once this process is clarified it will open the door for additional botanical containing supplements. To give an indication of the potential future growth in this area, in 2010, 500 health claims on botanicals had been rejected by EFSA with review of a further 2000 claims paused awaiting guidance from the European Commission and as addressed in the current consultation. It is also likely that there will be greater clarity as to whether individual products are supplements or medicinal products.

Collectively, the available evidence would suggest further increases in the sale of food supplements containing botanicals and other substances with physiological effects (e.g. carnitine), either singly or in combination with more traditional ingredients e.g. vitamins/ minerals etc.

Sustainable food supplements

Producing food sustainably is a key part of national (Food Wise 2025; https://www.agriculture.gov.ie/foodwise2025/) and international agri-food policies (FAO 2014). Reducing reliance on animal products is highlighted as significant, including dietary intakes of meat and dairy produce and their inclusion in food supplements (e.g. protein products and supplements) (FAO/WHO 2017). Reduced reliance on red and processed meat is also recommended as part of cancer prevention strategies (WCRF 2017) and general dietary guidelines (FAO 2016). In addition to greater consumption of vegetables, grains, eggs and meats from smaller animals, insects are viewed as an alternative sources of protein, containing high levels of vitamins and minerals (Meyer & Reguant-Closa, 2017). It is highly probable that insects and/or insect extracts will feature more strongly in the human food chain, including future food supplements. (EFSA, 2015). Also present will be increased numbers of protein powders derived from a range of plant sources (e.g. soy, peas or other legumes). Although not currently featuring as part of EU food supplies, the use of genetically modified food and food ingredients are likely to be revisited. Any strict definitions of food supplements should factor inclusion of insects and genetically modified foods as part of future diets.

8.3 Scientific literature

Scientific literature relating to food supplements focused mainly on the safety, efficacy and delivery of individual supplements. In general, the literature suggests that adverse effects arising from the consumption of supplements, particularly plant food supplements are scarce (Restani et al. 2016).

There is increasing focus on the delivery of supplement ingredients and/or encapsulation technologies – e.g. delivery to particular sites along the gastrointestinal tract or slow, sustained ingredient release. The usefulness of nanotechnology as an aid to enhance ingredient delivery is also explored albeit to a lesser degree than with pharmaceuticals e.g. using transdermal delivery systems (skin patches) for release of vitamins and/or minerals (Madhaiyan et al. 2013). Scientific research relating to the efficacy of inhalation routes for successful delivery of vitamins and/or minerals is lacking.

Absolute data on research spend on food supplements is lacking for Europe, but in the US, the available evidence shows that in the period 2009 – 2011, $855m of federal funds was spent on dietary supplement related research funding, with 22% of this studying botanicals; this is more than for any other nutrient or food ingredient [vitamins (20% of funding), lipids (14%) or minerals/trace elements (10%)]. Collectively this also suggests future growth in the plant (botanical) food supplement sector.

8.4 Market trends

8.4.1 Global market trends

The value of the worldwide market for food supplements is predicted to grow from USD 132.8bn in 2016 to USD 220.3bn by 2022 (Zion market research, 2017). Globally, consumer insight indicates a shift in consumer interest and rationale for purchasing such supplements. Such insight suggests that consumers increasingly view supplements as part of preventative care or to provide 'health and wellness', particularly in an ageing population. In response, food supplement manufacturers have responded with the launch of a wider array of new and affordable dietary supplements (Euromonitor, 2012, 2016). As part of this 'preventative care', purported consumer benefits associated with dietary supplement intakes are to help offset high healthcare costs and to be associated with vitality and longevity. Such analysis also suggests:

- Further increases in sales given increased consumer engagement with health and wellness
- Further new product launches
- Increased consumer access through various distribution channels (e.g. the internet) (Euromonitor 2017).

The most recent analysis of the dietary supplements marketplace re-emphasises this significant shift in traditional presentation and distribution channels, mainly driven by changes in consumer expectations. The notion of 'connected consumers' is proposed whereby consumers are actively engaged in their health. They go beyond consuming supplements to prevent ill-health and promote vitality, insofar as they consume tailored or personalised supplements as part of regimes which

monitor their real-time health and provide feedback (so called connected health) (Euromonitor 2017). Such consumers are typically educated and frequent users of the internet and social media.

An example of such a personalised approach would be that a consumer completes an online survey or questionnaire and is returned personalised feedback on certain aspects of their diet and lifestyle which could be improved. It could also offering suitable supplements to help achieve these diet and lifestyle goals, often for direct purchase online. On a more advanced level, a consumer could post a dried blood spot, saliva or urine sample to a supplement manufacturer. The manufacturer quantifies levels of specific biomarkers in their laboratory and a tailored dietary supplement is recommended to the consumer based on the outcomes of the lab tests. This can be repeated at intervals to provide feedback as to the success of the supplement and options are available for the consumer to link in to online services provided by the company e.g. lifestyle coaches, dietary advice, personal fitness advice or access to membership programmes. Hence, the traditional distribution routes for food supplements, and the range of products available would differ somewhat as to what currently exists today.

Currently, the sale of personalised dietary supplements based is more popular in the US (to a lesser degree the UK) with a number of companies providing such services (e.g. www.ixcela.com ; https://vitl.com ; www.multiplylabs.com ; www.weilvitaminadvisor.com ; www.customvite.com). The biofluid of choice may vary, as may account for attributes such as age, gender, weight, physical activity, genetic tests, blood tests, microbiome tests (i.e. a profile of bacteria resident in the gut), dietary restrictions and health records. A screen of such companies also reveals a common trait of providing a product based on the connected consumers unique design and preference (e.g. GM free, 'natural', organic).

There is no evidence of a slow-down in the market and sales of sports nutrition products, including supplements. Market research indicates additional delivery routes, to include energy drinks prepared with egg and whey protein to augment dietary supplements. Also predicted are increases in the worldwide market for dietary supplements with the every growing awareness of tackling obesity and in an attempt at calorie reduction and weight loss (Zion Market Research, 2017).

8.4.2 National market trends

Market analysis specific to Ireland, suggests that Irish consumers still prefer nutrition from foods rather than supplements with emphasis on natural and fortified foods and on reading labels (Euromonitor 2016). However, in a global context, it is likely that Ireland will follow global trends, particularly in an ageing population. Currently, older Irish adults consume more supplements than younger generations

and females more than males (IUNA, 2011). There is well-documented predicted growth in the proportion of the population deemed as 'older' or 'elderly' whereby, it is anticipated that by 2040, 22% of the Irish population (1.4m people) will be >65 years of age, with just under half a million of these aged >80 years (CSO, 2013). Increasing supplement use by this ageing population is likely (Bord Bia, 2013).

In Ireland, dietary supplements are still sold mainly through retail and online channels, being primarily manufactured by large pharmaceutical manufacturers, through private labels or direct sales. Supplements are typically personalised only to the level of gender, life stage or lifestyle, e.g. supplements for males or females at various life stages or levels of physical activity. Market analysis in relation to sports supplements, indicates that for Irish consumers traits such as 'efficacy', 'safety' 'taste', 'accessibility', 'trusted advice' and 'education' remain important (Bord Bia 2011) .

It is unclear to what extent the Irish consumer will engage with personalised dietary supplements as emerging from the US. However, the emergence of Irish companies such as Nuritas is noted (www.nuritas.com). Nuritas uses data analytical techniques to identify molecules and compounds in food and food byproducts with health properties. Such molecules can then be extracted and concentrated in foods and food supplements. Hence, it is likely that the Irish consumer will have opportunity to purchase tailored supplements in the near future.

8.5 Current supplements on-sale in retail and online outlets

A scan of the categories of dietary supplements on sale in Ireland was conducted by searching online websites and instore audits. Rather than provide an exhaustive list of products and product types, the search indicated that, in general, the categories of food supplements on sale were reflective of those covered in regulatory documents, i.e.

1. Vitamins and/or mineral preparations
2. Essential fatty acids or lipids (including cod liver oil, krill oil, algal products)
3. Botanicals and botanical extracts
4. Other substances with a physiological effect, not limited to :
    a. Probiotic and prebiotic supplements
    b. Enzymes
    c. Amino acids
    d. Protein powders (dairy, soy, pea)

As mentioned, many vitamin and/or mineral preparations are broadly tailored by gender and lifestage e.g. supplements for pregnancy or for teenagers. Some are also tailored to account for lifestyle e.g. sports or leisure. Of note, is the growing number of botanical-containing supplements available.

In terms of supplement presentation, in addition to the well characterised forms of capsules, tablets, pills, elixirs etc., the advent of vitamin, mineral and/or botanical containing skin patches is noted (e.g. https://www.patchmd.com/). Also noted are vaping products (akin to ecigarettes). Although not strictly food supplements per se, they do contain botanicals, vitamins and minerals (e.g. https://vitaciggroup.com/). Hence, it is likely that Irish consumers may be exposed to food supplements with non-traditional delivery routes.

8.6 Conclusion

In conclusion, this chapter suggests that as part of an ageing population, supplement use will increase but that changes in how supplements are marketed/presented may appeal to younger generations as part of real time feedback on their health. In terms of composition, significant growth is predicted in terms of botanical containing supplements with no evidence to suggest a slowdown in demand for sports nutrition or weight loss supplements. The available evidence also suggests growth in online sales and in the advent of a 'connected consumer, a potential shift from generic supplements sold in retail outlets to tailored or personalised supplements supplied directly online. Finally, additional presentation routes may include skin patches and inhalation pieces, albeit that these remain to be scientifically substantiated presently.

9.0 Conclusions and recommendations

In conclusion, this report provides an evidence based approach to defining characteristics of food and food supplements based on a review of scientific and academic literature, relevant definitions and a survey of internationally acclaimed academic food experts. Using an iterative approach it has defined characteristics of food and food supplements and tested those against existing food products. It concludes that food supplements are a type or category of food (akin to food regulatory descriptions) but that they are not food in a conventional form as understood by the consumer. On this basis it was possible to define distinct characteristics of both food types.

Alongside this, a scan of current and potential future markets for food supplements has identified future growth in the food supplement sector, greater diversity in supplement composition and presentation and the advent of more tailored or personalised supplements rather than the more generic forms currently sold.

10.0 References

Andersen R. (2010) Food in History. Berkshire Encyclopaedia of Sustainability. Berkshire Publishing Group. eEdition 2016.

Bender DA (2014) Dictionary of food and nutrition (4th ed). Oxford University Press. eEdition http://www.oxfordreference.com/view/10.1093/acref/9780191752391.001.0001/acref-9780191752391 (date accessed 17.07.2017).

Bord Bia (2013) Heathy Ageing. The Seniors Market. http://www.bordbia.ie/industry/manufacturers/insight/publications/bbreports/Documents/Healthy%20Ageing%20Seniors%20Market%202013.pdf (accessed 16.8.2017).

Bord Bia (2011) Sports Nutrition: The European Market. http://www.bordbia.ie/industry/manufacturers/insight/publications/bbreports/Documents/Sports%20Nutrition%20-%20The%20European%20Market.pdf (date accessed 16.8.2017).

Briggs D & Wahlqvist M (1988) Food Facts: the complete no fads - plain facts guide to healthy eating (2nd edn). Ebook Visionary Voyager ebook available from: http://apjcn.nhri.org.tw/server/info/books-phds/books/foodfacts/html/maintext/main1a.html .

British Nutrition Foundation, BNF (2016) Nutrients, Food and Ingredients (pg 13) https://www.nutrition.org.uk/nutritionscience/nutrients-food-and-ingredients/vitamins.html?limit=1&start=12 (date accessed 16.08.2017).

Central Statistics Office, CSO (2013) Population and Labour Force Projections 2016- 2046. Dublin: The Stationery Office.

Codex Alimentarius (CAC/GL) (2005) Guidelines for vitamin and mineral food supplements. CAC/GL 55-2005. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/ (date accessed 17.07. 2017).

Codex Alimentarius Commission. Definitions for the purposes of the Codex Alimentarius. Definitions of risk analysis terms related to food safety. Procedural Manual 2016 25th edn. Joint FAO/WHO Food Standards Programme. Rome. http://www.fao.org/docrep/w5975e/w5975e07.htm (date accessed 17.07.2017).

Cohen PA, Venhuis BJ & Brandt SD (2016) Advancing supplement science: challenges and solutions. Drug Testing and Analysis 8, e1-e3.

Comerford KB (2013) Recent developments in multivitamin/mineral research. Advances in Nutrition 4(6):644-56.

Coultate T & Davies J (1994) Food: The Definitive Guide. Royal Society of Chemistry Ebook Collection.

Coultate T (2002) Food: The Chemistry of its components: 4th edn. Royal Society of Chemistry.

Council for Responsible Nutrition Supplement owl: The Dietary Supplement Product Registry. Available from https://www.crnusa.org/resources/supplement-owl-dietary-supplement-product-registry . Date accessed (17.07.2017).

Euromonitor (2012) The Art of Positioning dietary supplements http://www.euromonitor.com/the-art-of-positioning-dietary-supplements/report (Date accessed 16.08.2017).

Euromonitor (2016) Vitamins and Dietary Supplements in Ireland. http://www.euromonitor.com/vitamins-and-dietary-supplements-in-ireland/report (date accessed 16.08.2017)

Euromonitor (2017) Vitamins and Dietary Supplements. Trends and Prospects 2017. http://www.euromonitor.com/vitamins-and-dietary-supplements-vds-trends-and-prospects-2017/report (date accessed 16.08.2017).

European Advisory Services. (2007) The use of substances with nutritional or physiological effect other than vitamins and minerals in food supplements. SANCO/2006/E4/018. https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-2007_a540169_study_other_substances_en.pdf (date accessed 17.07.2017).

European Food Safety Authority. Food Supplements https://www.efsa.europa.eu/en/topics/topic/food-supplements. (date accessed 17.07.2017).

European Food Safety Authority (2015) Risk profile of insects as food and feed. EFSA Journal 13 (10) 4257.

FAO (2014) Building a common vision for sustainable food and agriculture. Principles and Approaches. Rome http://www.fao.org/3/a-i3940e.pdf

FAO (2016) Plates, pyramids, planet. Developments in national healthy and sustainable dietary guidelines: a state of play assessment. FAO and the Environmental Change Institute & The Oxford Martin Programme on the Future of Food. The University of Oxford. http://www.fao.org/3/a-i5640e.pdf (Date accessed 15.8.2017)

FSAI (2007) Functional Food. https://www.fsai.ie/assets/0/86/204/667b54fe-972c-4c04-a6f8-9a0c5c92f886.pdf (date accessed 17.07.2017).

Food Safety Authority of Ireland, FSAI (2011) Scientific Recommendations for Health Eating Guidelines in Ireland. FSAI. Dublin. Can be downloaded from www.fsai.ie (date accessed 16.08.2017).

Food Safety Authority of Ireland, FSAI (2013) Guidance note No. 21. Food Supplements Regulation and Notifications (Revision 2). FSAI. Can be downloaded from www.fsai.ie (date accessed 16.08.2011).

Food Safety Authority of Ireland, FSAI (2017) Consultation on criteria for 5ug vitamin D only supplements to be listed as suitable for infants in Ireland. https://www.fsai.ie/news_centre/press_releases/vitamin_D_consultation_28062017.html (Date accessed 11th August 2017)

International Food Information Council (2006) Food Science: The bridge between health and consumer taste preference. Food insight March/April issue. http://ific.org/foodsight (date accessed 17.07.2017).

Irish Nutrition and Dietetic Institute, INDI (2009) Position Paper: Oral Nutrition Supplements https://www.indi.ie/images/public_docs/1083_ons.pdf

Irish Nutrition and Dietetic Institute, INDI (2016a). The Facts about Detox diets https://www.indi.ie/news/1048-the-facts-about-detox-diets.html

Irish Nutrition and Dietetic Institute, INDI (2016b) A Guide to Sports Nutrition Supplements https://www.indi.ie/fact-sheets/fact-sheets-on-sports-nutrition/550-a-guide-to-sports-nutrition-supplements.html

Irish Universities Nutrition Alliance, IUNA (2011) National Adult Nutrition Survey, Summary Report. http://www.iuna.net/wp-content/uploads/2010/12/National-Adult-Nutrition-Survey-Summary-Report-March-2011.pdf (date accessed 16.08.2011).

Kapoor A & Sharfstein JM (2016) Breaking the gridlock: regulation of dietary supplements in the US. Drug Testing and Analysis 8, 424-430.

Kohn I (2012) Research World 2012. Food Microbiology, 1st Edition.

Larsen LL & Berry JA (2003) the Regulation of Dietary Supplements. Journal of the American Academy of Nutrition Practitioners 15 (9), 410414.

Madhaiyan K, Sridhar R, Sundarrajan S et al. (2013) Vitamin B12 loaded polycaprolactone nanofibers: a novel transdermal route for the water soluble energy supplement delivery.
Int J Pharm. 444(1-2):70-6.

Maixent JM (2012) Opinion paper food supplements: the European regulation and its application in France. Thoughts on safety of food supplements. Cellular and Molecular Biology (Noisy-le-grand). 58 Suppl:OL1720-9.

Marcus DM (2016). Dietary supplements: what's in a name? what's in the bottle? Drug Testing and Analysis 8, 410-412.

Meyer N & Reguant-Closa A (2017) 'Eat as if you could save the planet and win!' Sustainability integration into Nutrition for Exercise and Sport. Nutrients 9 (4); 412

Miles MB & Huberman MA (1994) Qualitative data analysis: an expanded sourcebook. (2nd edition). Beverly Hills, Sage.

Nordström K, Coff C, Jönsson H, Nordenfelt L, Görman U (2013) Food and health: individual, cultural, or scientific matters? Genes and Nutrition. 8(4):357-63.

Pereira C, Barros L, Ferreira IC (2017) Current Pharmaceutical Design. Dietary supplements: foods, medicines, or both? A controversial designation with unspecific legislation. Jan 17 Epub ahead of print.

Restani P, Di Lorenzo C, Garcia-Alvarez A et al. (2016) Adverse effects of plant food supplements self-reported by consumers in the Plant LIBRA survey involving six European countries. PLOS One11 (2) E0150089

Rogers PJ (2017) Food and drug addictions: similarities and differences. Pharmacology, Biochemistry and Behaviour 153, 182 – 90.

Synadiet. Food Supplements. http://www.synadiet.org/les-complements-alimentaires/quest-ce-que-cest (date accessed 17.07.2017).

US Department of Health and Human Services, Officer of the Inspector General. (2003) Dietary Supplement Labels: key elements. https://oig.hhs.gov/oei/reports/oei-01-01-00120.pdf (date accessed 17.07.2017).

Value Added Tax Consolidation Act 2010 http://www.irishstatutebook.ie/eli/2010/act/31/enacted/en/html (date accessed 17.07.2017).

Wahlqvist ML (2016a) Food structure is critical for optimal health. Food and Function 7:1245-50.

Wahlqvist ML (2016b) Future Food. Asia Pacific Journal of Clinical Nutrition 25(4), 706 – 15.

Ward E (2014) Addressing nutritional gaps with multivitamin and mineral supplements Nutrition Journal. 13:72 – 82.

World Cancer Research Fund Limit red meat and avoid processed meat. https://www.wcrf-uk.org/uk/preventing-cancer/cancer-prevention-recommendations/limit-red-meat-and-avoid-processed-meat [date accessed 11th August 2018].

Yetley EA (2007) Multivitamin and multimineral dietary supplements: definitions, characterisation, bioavailability, and drug interactions. American Journal of Clinical Nutrition 2007, 85 (Suppl): 269-76S.

Zion Research (2017) Dietary Supplements Market by Ingredients (Botanicals, Vitamins, Minerals, Amino Acids, Enzymes) for Additional Supplements, Medicinal Supplements and Sports Nutrition Applications – Global Industry Perspective, Comprehensive Analysis and Forecast, 2016 – 2022. https://www.zionmarketresearch.com/report/dietary-supplements-market (date accessed 16.08.2017)

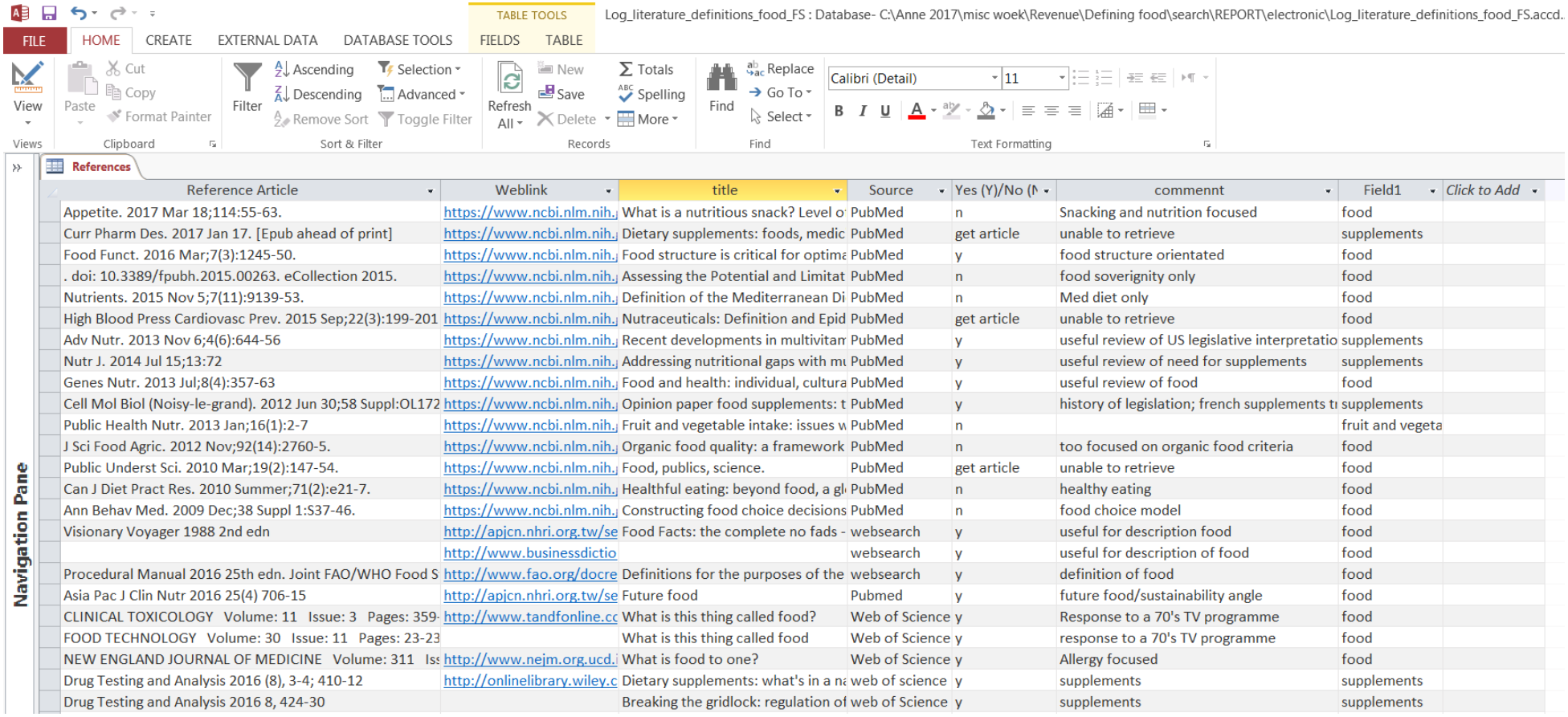
List of Appendices

Appendix A: Details of literature search strategy: summary of search engines and websites checked and documents retrieved using the terms 'food', 'food supplements', 'food definition', 'what is food' and 'define food'.

Search engine and Websites	**Area covered by search**	**Number of documents retrieved**
Academic and Scientific Literature		
Pub Med (www.ncbi.nlm.nih.gov/PubMed)	Access to the US National Library of Medicine's database of indexed citations and abstracts for medical, nursing, dental, veterinary, health care and preclinical sciences journal articles (Medline)	3,026
Web of Science (www.webofknowledge.com)	Multi-disciplinary research	11,131
Embase (https://www.elsevier.com/promo/rd-solutions/embase?p2=embase&term=embase&pscid=cm_ps_100000188)	Database of biomedical data	3,645
CinaHil Plus https://health.ebsco.com/products/cinahl-plus	Database of nursing and allied health journals	1,105
Cochrane Review http://www.cochranelibrary.com/	The Cochrane Library (ISSN 1465-1858) is a collection of six databases that contain different types of high-quality, independent evidence to inform healthcare decision-making.	1,603
Ebooks at UCD library (www.ucd.ie/library)	Electronic books and textbooks as available in University College Dublin library.	117
OpenSigle (Greynet; http://www.greynet.org/opensiglerepository.html)	Search of grey literature	1,103
Legislative websites and competent authorities in the food area		
Codex Alimentarius (http://www.fao.org/fao-who-codexalimentarius/en/); World Health Organisation (www.who.int) ; Food Safety Authority of Ireland (www.fsai.ie);	Global, European and national competent authorities and organisations	6

European Food Safety Authority (www.efsa.europa.eu); European Commission Website (www.europa.eu)		
Other websites		
European Food Information Council (EUFIC; www.eufic.org)	Non-profit organisation, which stands up for science-based information on food and health.	0
BEUC, (www.beuc.eu)	European Consumer Organisation	0
International Food Information Council (www.foodinsight.org)	Not for profit organisation communicating science-based information on health, nutrition and food safety	1
British Nutrition Foundation (www.nutrition.org.uk)	Not for profit organisation communication science based information on food and nutrition	0
Council for Responsible Nutrition (https://www.crnusa.org/resources/supplement-owl-dietary-supplement-product-registry)	Trade association representing dietary supplement and functional food manufacturers and ingredient suppliers	1
Synadiet, Syndicat National des Compléments Alimentaires (http://www.synadiet.org/qui-sommes-nous/presentation-et-missions)	French Food Supplements Association	1
Dictionary.com/Business Dictionary	Online dictionaries	2

Appendix B. Details of references identified as relevant: screengrab of the Microsoft Access Database used to screen all identified literature for relevance.



Log_literature_definitions_food_FS : Database- C:\Anne 2017\misc woek\Revenue\Defining food\search\REPORT\electronic\Log_literature_definitions_food_FS.accd.

FILE | HOME | CREATE | EXTERNAL DATA | DATABASE TOOLS | TABLE TOOLS FIELDS | TABLE

References

Reference Article	Weblink	title	Source	Yes (Y)/No (N	commennt	Field1	Click to Add
Appetite. 2017 Mar 18;114:55-63.	https://www.ncbi.nlm.nih.j	What is a nutritious snack? Level o	PubMed	n	Snacking and nutrition focused	food	
Curr Pharm Des. 2017 Jan 17. [Epub ahead of print]	https://www.ncbi.nlm.nih.j	Dietary supplements: foods, medic	PubMed	get article	unable to retrieve	supplements	
Food Funct. 2016 Mar;7(3):1245-50.	https://www.ncbi.nlm.nih.j	Food structure is critical for optima	PubMed	y	food structure orientated	food	
. doi: 10.3389/fpubh.2015.00263. eCollection 2015.	https://www.ncbi.nlm.nih.j	Assessing the Potential and Limitat	PubMed	n	food soverignity only	food	
Nutrients. 2015 Nov 5;7(11):9139-53.	https://www.ncbi.nlm.nih.j	Definition of the Mediterranean Di	PubMed	n	Med diet only	food	
High Blood Press Cardiovasc Prev. 2015 Sep;22(3):199-201	https://www.ncbi.nlm.nih.j	Nutraceuticals: Definition and Epid	PubMed	get article	unable to retrieve	food	
Adv Nutr. 2013 Nov 6;4(6):644-56	https://www.ncbi.nlm.nih.j	Recent developments in multivitam	PubMed	y	useful review of US legislative interpretatio	supplements	
Nutr J. 2014 Jul 15;13:72	https://www.ncbi.nlm.nih.j	Addressing nutritional gaps with mu	PubMed	y	useful review of need for supplements	supplements	
Genes Nutr. 2013 Jul;8(4):357-63	https://www.ncbi.nlm.nih.j	Food and health: individual, cultura	PubMed	y	useful review of food	food	
Cell Mol Biol (Noisy-le-grand). 2012 Jun 30;58 Suppl:OL172	https://www.ncbi.nlm.nih.j	Opinion paper food supplements: t	PubMed	y	history of legislation; french supplements t	supplements	
Public Health Nutr. 2013 Jan;16(1):2-7	https://www.ncbi.nlm.nih.j	Fruit and vegetable intake: issues w	PubMed	n		fruit and vegeta	
J Sci Food Agric. 2012 Nov;92(14):2760-5.	https://www.ncbi.nlm.nih.j	Organic food quality: a framework	PubMed	n	too focused on organic food criteria	food	
Public Underst Sci. 2010 Mar;19(2):147-54.	https://www.ncbi.nlm.nih.j	Food, publics, science.	PubMed	get article	unable to retrieve	food	
Can J Diet Pract Res. 2010 Summer;71(2):e21-7.	https://www.ncbi.nlm.nih.j	Healthful eating: beyond food, a gl	PubMed	n	healthy eating	food	
Ann Behav Med. 2009 Dec;38 Suppl 1:S37-46.	https://www.ncbi.nlm.nih.j	Constructing food choice decisions	PubMed	n	food choice model	food	
Visionary Voyager 1988 2nd edn	http://apjcn.nhri.org.tw/se	Food Facts: the complete no fads -	websearch	y	useful for description food	food	
	http://www.businessdictio		websearch	y	useful for description of food	food	
Procedural Manual 2016 25th edn. Joint FAO/WHO Food S	http://www.fao.org/docre	Definitions for the purposes of the	websearch	y	definition of food	food	
Asia Pac J Clin Nutr 2016 25(4) 706-15	http://apjcn.nhri.org.tw/se	Future food	Pubmed	y	future food/sustainability angle	food	
CLINICAL TOXICOLOGY Volume: 11 Issue: 3 Pages: 359-	http://www.tandfonline.cc	What is this thing called food?	Web of Science	y	Response to a 70's TV programme	food	
FOOD TECHNOLOGY Volume: 30 Issue: 11 Pages: 23-23		What is this thing called food	Web of Science	y	response to a 70's TV programme	food	
NEW ENGLAND JOURNAL OF MEDICINE Volume: 311 Iss	http://www.nejm.org.ucd.i	What is food to one?	Web of Science	y	Allergy focused	food	
Drug Testing and Analysis 2016 (8), 3-4; 410-12	http://onlinelibrary.wiley.c	Dietary supplements: what's in a na	web of science	y	supplements	supplements	
Drug Testing and Analysis 2016 8, 424-30		Breaking the gridlock: regulation of	web of Science	y	supplements	supplements	

Appendix C. Detailed description of common themes emerging for Food (table i) and for Food Supplements (table ii) and supportive text as identified from the literature search

Table i Detailed description of common themes emerging for **Food** and the supportive text.

Emerging themes	**Supportive text**
Chemistry/ Composition	Complicated set of chemicals…which can be changed by storage, preservation and cooking / macronutrients, micronutrients, colours, flavours, pharmacologically active substances (e.g. caffeine), natural toxicants, additives, contaminants (e.g. pesticides) / phytonutrients / peptides / lipids / oligosaccharides / nucleotides / polyphenols which may be monomeric or polymeric / pre- and pro-biotic foods / "to satisfy a nutritional need a foodstuff must be acceptable, and to be acceptable it must first look and then taste 'right'. This is where 'non-nutrients' become important. These are substances that occur in our food but are in no way necessary for our normal biological functions". Gives examples e.g. I) substances naturally present in raw material (e.g. flavour compounds, pigments); ii) toxins secreted by contaminating microorganisms (e.g. botulinum); iii) contaminants from agricultural practices (e.g. pesticide residues); iv) contaminants from processing and related procedures (e.g. metals, packaging migrants); v) commercially or domestically applied permitted additives (e.g. colours, flavours, emulsifiers); vi) by-products of processing & cooking (e.g. flavour, toxins and brown pigments from heated carbohydrates and fats). Bioavailable.
Exemptions/ Exclusions	Tobacco, pharmaceuticals, cosmetics
Function	Life / growth / energy / maintenance / health of the body / makes your body work, grow and repair itself / survival / fuel for biological functioning / nutrition / supply energy and build and replace tissue / conventional food eaten as part of normal diet with natural components in foods that would not normally supply them to have targeted function beyond simple nutrition, enhance well-being and health or reduce risk of disease or provide health benefits so as to improve quality of life (functional foods) / functional properties to ensure consistency, freshness etc. / achieve or maintain good health in addition to basic nutrition (functional food).

Manner of consumption	Eat / drink / edible / potable / edible
Nutritive	Nutrition / nourishing / nourishing / nutritive / nutrient (carbohydrate, fat, protein, essential mineral and vitamins) / right balance of nutrients / essential nutrients / satisfy biological needs for nutrients
Other	Availability / labels / ritual marking formal and informal life stages / trust / power / gender / authenticity / food cues / natural / genetically modified food / novel food / food for special medical purpose / diet replacements / convenience / affordability / religious beliefs/ philosophy / specific dietary-related disorders/ food can be morally unacceptable due to production and marketing aspects.
Safety	Must not be harmful / must be suitable for human consumption
Sensory properties	Taste / sensory properties / smell / touch / sound (e.g. crunch on eating) / mouthfeel/pre- and post-ingestive food cues / ability to influence taste receptors and memory / pre- and post-ingestive features of food/human need for food that tastes, smells, looks and feels good
Social/cultural	Social context, cultural values and identities / cultural, social, ethical and sensual relationships to food / social role / sensory, cognitive choices / cultural formation / role in social discourse
Source	Animal / plant / confectionary / microbiological / insect / water / soil / animal / plant / micro-organisms / fungi / algae or substances isolated from them / organisms obtained through GM techniques
Structure/Physical form	Solid/liquid/production/size of food/food particles / raw / pastes / ground / milled / processing / acid /alkaline / Structure / mouth feel / bioavailabilities / biological relevance of structure (matrix) / production / structure e.g. mouth feel / impact of nutrients and structure in influencing memory/level of manufacturing / solid or liquid / processed, semi-processed, raw / substance used in manufacture, preparation, or treatment of food / products intended for human consumption in an unprocessed, processed or mixed state / including chewing gum / understand the effects, good or bad, of operations such as cooking and preservation

Table ii Description of common themes emerging for **Food Supplements** and the supportive text.

Emerging Themes	**Supportive text**
Approved lists	Approved lists of vitamins and minerals
Bioavailability	Bioavailability / bioavailabilities / bioavailability and how it lacks standard scientific and regulatory definitions. Concepts include absorption and/or utilisation (e.g. availability for use or storage). Highlights problems where there are beneficial functions of unabsorbed nutrients (e.g. binding of bile salts by calcium in gut). Also mentions bioequivalence & influence of host factors e.g. life stage, physiologic state, homeostasis. Concept of utilisation rate as a component of bioavailability. Cross-references two categories of product formulation factors that affect bioavailability and bioequivalence: factors that affect product dissolution or release from the dosage form and factors related to excipients or inactive ingredients that may affect stability, absorption and metabolic processes
Exemptions/ Exclusion	No herbs, hormones or drugs / lack of efficacy / tobacco / not represented for use as a conventional food or as the sole item of a meal or diet / not in a conventional food form / exempt from drug approval standards / must not attribute properties that they can prevent, treat or cure a human disease or properties thereof / must not imply that a healthy balanced diet cannot provide appropriate quantities of nutrients in general / no substances with pharmacological, immunological or metabolic action or which can make a medical diagnosis.

Function	Improve health and prevent chronic disease / improve nutrient intakes / in times of shortfall / maintain a food health, complement their diet, avoid deficits, meet the needs of the body, create a source of well-being, reduce health care expenditures / purpose is to supplement the intake of vitamins and/or minerals from the normal diet / to supplement the normal diet/ correct nutritional deficiencies or maintain an adequate intake of certain nutrients. / These products are intended to be used as supplements to, not substitutes for, a well-balanced diet and healthy lifestyle. When used properly, dietary supplements can help promote overall good health, fill nutrient gaps, and in some cases, reduce the risk of certain diseases. "Food supplements are not a substitute for a well-balanced diet. Rather, they are designed to support the daily diet, helping to ensure that the levels of intake of vitamins, minerals and other nutrients are maintained at an optimum level, particularly on the days where temptation rules and our diet might be less balanced. Supplements may be used to correct nutritional deficiencies or maintain an adequate intake of certain nutrients. / To supplement the nutrient intake in a normal diet".

Ingredients/ Composition	Nutrients / vitamins / minerals / botanicals / amino acids / fatty acids / constituents from food (e.g. omega-3 fatty acids, lutein) / substances with a nutritional or physiological effect / vitamins, minerals, plants and plant preparations, other ingredients (e.g. unpurified animal ingredients (chemically undefined) e.g. royal jelly or shark cartilage or novel foods / herbals / protein powders, botanical extracts / vitamin, mineral, herb or other botanical, an amino acid, dietary substance for use by man to supplement the diet by increasing total dietary intake, or a concentrate, metabolite, constituent, extract or combination of these ingredients / can contain one or more vitamins and minerals or a combination of such / concentrated sources of nutrients or other substances with a nutritional or physiological effect / amino acids, enzymes, pre and pro-biotics, essential fatty acids, botanicals and botanical extracts, miscellaneous bioactive substances. Botanicals include herbs, plants, fungi, algae and extracts thereof / must state names of categories of substances that characterise the product. / Dietary supplements include vitamins, minerals, herbs and botanicals, amino-acids, sports nutrition supplements, weight management products and specialty supplements. / Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect. / In the United States, dietary supplements may contain multiple ingredients, including vitamins, minerals, herbs or other botanicals, and amino acids; dietary substances for use by humans to supplement the diet by increasing the total dietary intake; concentrates, metabolites, constituents, and extracts; or combinations of one or more of these ingredients / foodstuffs
Other	Although multivitamin-multimineral (MVM) and similar terms (e.g., multis or multiples) are commonly used, they have no standard or defined meaning and can refer to products with widely varied compositions and characteristics. Categorizations varied from systems that focused on the product's intended use (e.g., body building, weight loss), ingredients (e.g., vitamin and mineral content), sources of ingredients (e.g., antacids as a source of calcium), disease perspectives (e.g., antioxidants and cancer), or consumer behaviours (e.g., herbal versus MVM users)". "No regulatory definitions exist for MVMs".
Populations	May be for special populations/ may need to account for age, gender, family history, life stage, presence or absence of disease.

Prescription/Dosage	Frequency of intake/dosage / % of daily reference values / concentrated source / designed to be taken in measured small unit quantities / concentrated sources / correct dosage and avoidance of exceedance of recommended dose / 'one a days'/ specialised products (e.g. for men, senior women, menopause, daytime or night-time, performance, energy, menopause, hair).
Presentation	Pill / capsule / table / liquid form / labelled as a food supplement / labelled as a dietary supplement / concentrated / capsules, tablets, powders, solutions etc./ but are not in a conventional food form / marketed in dose form / ampoules of liquids, drop dispensing bottles and other similar forms of liquids and powders designed to be taken in measured small quantities / appropriate labelling (presentation, advertising, % reference doses, approved lists, correct units, statements of compliance e.g. out of reach children, doses and avoidance of exceedance of doses, compliance with general food labelling, names of active substances) / food supplements are marketed as pills, tablets, capsules or liquids in measured doses etc.
Proof of Action	Testing health outcome / proof of efficacy / pre-market scrutiny / proven scientific background / synthetic or natural but with proven purity
Safety	Potential for harm if not used correctly / conform quality standards / safety checks / safe within recommended doses / excessive intakes may be harmful or cause unwanted side effects/ maximum safe levels

Appendix D. Initial testing of food products against characteristics defined for food and for food supplements from literature search

Table illustrates in a simple checklist how 12 products rated against the checklist for 'food' and for 'food supplement' using criteria identified from the literature review. All criteria were given equal weighting. '?' indicates inability to definitively answer 'yes' or 'no' using simple checklist criteria.

	Defining characteristics of Food	**Apple Extract Tablets**	**Multi-vitamin & mineral with plant extracts**	**Sugar Cane wax tablets**	**Plant extract tablet**	**Rice yeast extract tablet**	**Zinc gluconate capsule**
1	A food for human consumption						
2	Understood as food by average consumer						
3	Must be primarily composed of material originating from plants, animals or similar kingdoms, or substances isolated thereof	√			√	√	
4	Contain a nutritive component(s)	√	√	?	?	?	√
5	Consumption helps achieve or maintain good health in addition to basic nutrition	?	?	?	?	?	?
6	May be consumed native or following processing but with an inherent physical and chemical structure or matrix	√	√	√	√	√	√
7	May contain non-nutritive food components, either intentionally or as a result of processing/manufacturing		√	√	√	?	?
8	With inherent sensory attributes not limited to taste, smell, texture which are deemed desirable to the average consumer						
11	May play a role in social, cultural or religious contexts, either as meals, snacks or food ingredients						
12	Is not a medicine, medicated preparation or tobacco product nor is a food ingredient in cosmetics, food supplements or similar	√	√	√	√	√	√

	Defining characteristics of a Food Supplement	Apple Extract Tablets	Multi-vitamin & mineral with plant extracts	Sugar Cane wax tablets	Plant extract tablet	Rice yeast extract tablet	Zinc gluconate capsule
1	For human consumption	√	√	√	√	√	√
2	Designed to supplement a normal (?healthy) diet	?	?	?	?	?	?
3	Understood as a food supplement by the average consumer	√	√	√	√	√	√
4	Contains bioavailable nutrients or substances with a nutritional or physiological effect	√	√	√	√	√	√
5	Typically presented in pills, capsules, liquid form or similar	√	√	√	√	√	√
6	Clearly listed as a food supplement with clear dosage instructions	√	√	√	√	√	√
7	No hormones, drugs, tobacco or derivatives thereof	√	√	√	√	√	√
8	Must not be presented as a substances which can prevent, treat or cure a human condition or properties thereof	√	√	√	√	√	√
11	Must not be presented for use as a conventional food	√	√	√	√	√	√
12	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet	√	√	√	√	√	√
13	Must be safe when consumed as recommended	√	√	√	√	√	√
14	May make reference to populations	√	√	√	√	√	√

	Defining Characteristics of food:	**Glucosamine chondroitin tablet**	**Plant protein Powder**	**Multi-vitamin & mineral tablet**	**Garlic oil capsules**	**Glucosamine sulphate tablet**	**Vegan ubiquinione tablet**
1	A food for human consumption		?				
2	Understood as food by average consumer		?				
3	Must be primarily composed of material originating from plants, animals or similar kingdoms, or substances isolated thereof		√		√	√	?
4	Contain a nutritive component(s)		√	√		?	
5	Consumption helps achieve or maintain good health in addition to basic nutrition	?	√	√	?	?	?
6	May be consumed native or following processing but with an inherent physical and chemical structure or matrix	√	√	√	√	√	√
7	May contain non-nutritive food components, either intentionally or as a result of processing/manufacturing	?	?		?	?	?
8	With inherent sensory attributes not limited to taste, smell, texture which are deemed desirable to the average consumer						
11	May play a role in social, cultural or religious contexts, either as meals, snacks or food ingredients						
12	Is not a medicine, medicated preparation or tobacco product nor is a food ingredient in cosmetics, food supplements or similar	√	√	√	√	√	√

	Defining Characteristics of food supplement:	**Glucosamine chondroitin tablet**	**Plant Protein Powder**	**Multi-vitamin & mineral tablet**	**Garlic oil capsules**	**Glucosamine sulphate tablet**	**Vegan ubiquinione tablet**
1	For human consumption	√	√	√	√	√	√
2	Designed to supplement a normal (?healthy) diet	?	√	√	√	√	√
3	Understood as a food supplement by the average consumer	√	√/?	√	√	√	√
4	Contains bioavailable nutrients or substances with a nutritional or physiological effect	√	√	√	√	√	√
5	Typically presented in pills, capsules, liquid form or similar	√	√	√	√	√	√
6	Clearly listed as a food supplement with clear dosage instructions	√		√	√	√	√
7	No hormones, drugs, tobacco or derivatives thereof	√	√	√	√	√	√
8	Must not be presented as a substances which can prevent, treat or cure a human condition or properties thereof	√	√	√	√	√	√
11	Must not be presented for use as a conventional food	√	?	√	√	√	√
12	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet	√	√	√	√	√	√
13	Must be safe when consumed as recommended	√	√	√	√	√	√
14	May make reference to populations		?	√		√	√

Appendix E. Second testing of 24 food products against characteristics identified for food and for food supplements.

FOOD							
Core attributes of a food (All 3 attributes mandatory)		**Apple Extract Tablets**	**Multi-vitamin & mineral with plant extracts**	**Sugar Cane wax tablets**	**Plant extract tablet**	**Rice yeast extract tablet**	**Zinc gluconate capsule**
1	Is fit for human consumption	√	√	√	√	√	√
2	Is understood as food for human consumption by the average consumer						
3	Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood as a food supplement by the average consumer						
Comprises the following characteristics							
1	Primarily composed of plant or animal food or from similar kingdoms e.g. insects, (not including extracts or concentrated essences or analogous)	√		?	?	?	
2	Must be nutritive in nature	√	√	?	?	?	√
3	Must contribute to basic nutrition and help achieve or maintain good health. Any nutrition and/or health claims provided must reflect those approved under appropriate EU food regulations (e.g. Regulations (EU) Nos. 1924/2006, 1169/2011)						
4	May be consumed native or following processing but with an inherent physical and chemical food structure or food matrix*						
5	With inherent sensory attributes characteristic of food, not limited to taste, smell and texture and which are deemed desirable to the average consumer						
6	May play a role in social, cultural or religious contexts and may be consumed as a meal or snack.						

FOOD SUPPLEMENT							
Core attributes of a food supplement (All 4 attributes mandatory)		**Apple Extract Tablets**	**Multi-vitamin & mineral with plant extracts**	**Sugar Cane wax tablets**	**Plant extract tablet**	**Rice yeast extract tablet**	**Zinc gluconate capsule**
1	Is fit for human consumption	√	√	√	√	√	√
2	Is understood as a food supplement, rather than food, by the average consumer	√	√	√	√	√	√
3	Is designed to help satisfy a normal, healthy balanced diet.	√	√	√	√	√	√
4	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet reflecting permitted claims and labelling as per appropriate EU food regulations (e.g. Regulation (EU) No. 1924/2006).	?	?	?	?	?	?
Comprises the following characteristics:							
1	Is a concentrated source of nutrients or other substances permitted for use in the EU (singly or in combination) and with a nutritional or physiological effect.	√	√	√	√	√	√
2	Typically presented in tablets, pills, capsules, liquid or powder form or similar	√	√	√	√	√	√
3	Is clearly listed as a food supplement with clear dosage instructions	√	√	√	√	√	√
4	Must not contain hormones, drugs, tobacco or derivatives thereof	√	√	√	√	√	√
5	Must not be presented as substances which can prevent, treat or cure a human condition or properties thereof	√	√	√	√	√	√
6	Must not be presented for use as a conventional food	√	√	√	√	√	√
7	Must list the following statements on labels: 1) a warning not to exceed the recommended daily dose; 2) a statement to the effect that food supplements should not be used as a substitute for a varied diet; 3) statement to the effect that the products should be stored out of the reach of young children;	√	?	√	√	√	√
*A food matrix may be described as the nutrient and non-nutrient components of foods and their molecular relationships, i.e. chemical bonds, to each other. (Source: United States Department of Agriculture, National Agricultural Library (2015))							

FOOD							
Core attributes of a food (All 3 attributes mandatory)		**Glucosamine chondroitin tablet**	**Plant protein Powder**	**Multi-vitamin & mineral tablet**	**Garlic oil capsules**	**Glucosamine sulphate tablet**	**Vegan ubiquinione tablet**
1	Is fit for human consumption	√	√	√	√	√	√
2	Is understood as food for human consumption by the average consumer		?				
3	Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood as a food supplement by the average consumer		?				
Comprises the following characteristics							
1	Primarily composed of plant or animal food or from similar kingdoms e.g. insects, (not including extracts or concentrated essences or analogous)		√		?		
2	Must be nutritive in nature	?	√	√	?	?	?
3	Must contribute to basic nutrition and help achieve or maintain good health. Any nutrition and/or health claims provided must reflect those approved under appropriate EU food regulations (e.g. Regulations (EU) Nos. 1924/2006, 1169/2011)		?	√			
4	May be consumed native or following processing but with an inherent physical and chemical food structure or food matrix*		?				
5	With inherent sensory attributes characteristic of food, not limited to taste, smell and texture and which are deemed desirable to the average consumer						
6	May play a role in social, cultural or religious contexts and may be consumed as a meal or snack.						

FOOD SUPPLEMENT							
Core attributes of a food supplement (Mandatory)		**Glucosamine chondroitin tablet**	**Plant protein Powder**	**Multi-vitamin & mineral tablet**	**Garlic oil capsules**	**Glucosamine sulphate tablet**	**Vegan ubiquinione tablet**
1	Is fit for human consumption	√	√	√	√	√	√
2	Is understood as a food supplement, rather than food, by the average consumer	√	?	√	√	√	√
3	Is designed to help satisfy a normal, healthy balanced diet.	√	√	√	√	√	√
4	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet reflecting permitted claims and labelling as per appropriate EU food regulations (e.g. Regulation (EU) No. 1924/2006).	?	?	√	?	?	?
Comprises the following characteristics:							
1	Is a concentrated source of nutrients or other substances permitted for use in the EU (singly or in combination) and with a nutritional or physiological effect.	√	√	√	√	√	√
2	Typically presented in tablets, pills, capsules, liquid or powder form or similar	√	?	√	√	√	√
3	Is clearly listed as a food supplement with clear dosage instructions	√	?	√	√	√	√
4	Must not contain hormones, drugs, tobacco or derivatives thereof	√	√	√	√	√	√
5	Must not be presented as substances which can prevent, treat or cure a human condition or properties thereof	√	?	√	√	√	√
6	Must not be presented for use as a conventional food	√	?	√	√	√	√
7	Must list the following statements on labels: 1) a warning not to exceed the recommended daily dose; 2) a statement to the effect that food supplements should not be used as a substitute for a varied diet; 3) statement to the effect that the products should be stored out of the reach of young children;	√	√	√	√	√	√
*A food matrix may be described as the nutrient and non-nutrient components of foods and their molecular relationships, i.e. chemical bonds, to each other. (Source: United States Department of Agriculture, National Agricultural Library (2015))							

FOOD							
Core attributes of a food (All 3 attributes mandatory)		**Powdered vitamins & mineral formula**	**Rice-based powdered vitamins & mineral formula**	**Liquid fulvic acid**	**Liquid multi-vitamin and mineral**	**Nutrition drink with added vitamins and minerals**	**Chocolate bar with protein, vitamins and minerals**
1	Is fit for human consumption	√	√	√	√	√	√
2	Is understood as food for human consumption by the average consumer					√	√
3	Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood as a food supplement by the average consumer					√	√
Comprises the following characteristics							
1	Primarily composed of plant or animal food or from similar kingdoms e.g. insects, (not including extracts or concentrated essences or analogous)		√		?	√	√
2	Must be nutritive in nature	√	√	√	√	√	√
3	Must contribute to basic nutrition and help achieve or maintain good health. Any nutrition and/or health claims provided must reflect those approved under appropriate EU food regulations (e.g. Regulations (EU) Nos. 1924/2006, 1169/2011)	√	√		?	√	√
4	May be consumed native or following processing but with an inherent physical and chemical food structure or food matrix*		?			√	√
5	With inherent sensory attributes characteristics of food, not limited to taste, smell and texture and which are deemed desirable to the average consumer				?	√	√
6	May play a role in social, cultural or religious contexts and may be consumed as a meal or snack.					√	√

FOOD SUPPLEMENT		Powdered vitamins & mineral formula	Rice-based powdered vitamins & mineral formula	Liquid fulvic acid	Liquid multi-vitamin and mineral	Nutrition drink with added vitamins and minerals	Chocolate bar with protein, vitamins and minerals
Core attributes of a food supplement (Mandatory)							
1	Is fit for human consumption	√	√	√	√	√	√
2	Is understood as a food supplement, rather than food, by the average consumer	√	√	√	√	?	
3	Is designed to help satisfy a normal, healthy balanced diet.	√	√	√	√	√	√
4	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet reflecting permitted claims and labelling as per appropriate EU food regulations (e.g. Regulation (EU) No. 1924/2006).	√	√	?	√	√	√
Comprises the following characteristics:							
1	Is a concentrated source of nutrients or other substances permitted for use in the EU (singly or in combination) and with a nutritional or physiological effect.	√	√	√	√	√	?
2	Typically presented in tablets, pills, capsules, liquid or powder form or similar	√	√	√	√	?	√
3	Is clearly listed as a food supplement with clear dosage instructions	√	√	√	√		
4	Must not contain hormones, drugs, tobacco or derivatives thereof	√	√	√	√	√	√
5	Must not be presented as substances which can prevent, treat or cure a human condition or properties thereof	√	√	√	√	√	√
6	Must not be presented for use as a conventional food	√	√	√	√		
7	Must list the following statements on labels: 1) a warning not to exceed the recommended daily dose; 2) a statement to the effect that food supplements should not be used as a substitute for a varied diet; 3) statement to the effect that the products should be stored out of the reach of young children;	√	√	?	√	partially	partially
*A food matrix may be described as the nutrient and non-nutrient components of foods and their molecular relationships, i.e. chemical bonds, to each other. (Source: United States Department of Agriculture, National Agricultural Library (2015))							

FOOD							
Core attributes of a food (All 3 attributes mandatory)		**Fortified corn flakes**	**Yogurt drink with plant sterols**	**Orange juice with probiotics**	**Black Pudding**	**Fortified yogurt (solid)**	**Isotonic sports drink**
1	Is fit for human consumption	√	√	√	√	√	√
2	Is understood as food for human consumption by the average consumer	√	√	√	√	√	√
3	Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood as a food supplement by the average consumer	√	√	√	√	√	√
Comprises the following characteristics							
1	Primarily composed of plant or animal food or from similar kingdoms e.g. insects, (not including extracts or concentrated essences or analogous)	√	√	√	√	√	√
2	Must be nutritive in nature	√	√	√	√	√	√
3	Must contribute to basic nutrition and help achieve or maintain good health. Any nutrition and/or health claims provided must reflect those approved under appropriate EU food regulations (e.g. Regulations (EU) Nos. 1924/2006, 1169/2011)	√	√	√	√	√	√
4	May be consumed native or following processing but with an inherent physical and chemical food structure or food matrix*	√	√	√	√	√	√
5	With inherent sensory attributes characteristics of food, not limited to taste, smell and texture and which are deemed desirable to the average consumer	√	√	√	√	√	√
6	May play a role in social, cultural or religious contexts and may be consumed as a meal or snack.	√	√	√	√	√	√

FOOD SUPPLEMENT							
Core attributes of a food supplement (Mandatory)		**Fortified corn flakes**	**Yogurt drink with plant sterols**	**Orange juice with probiotics**	**Black Pudding**	**Fortified yogurt (solid)**	**Isotonic sports drink**
1	Is fit for human consumption	√	√	√	√	√	√
2	Is understood as a food supplement, rather than food, by the average consumer						
3	Is designed to help satisfy a normal, healthy balanced diet	√	√	√	√	√	√
4	May imply achievement of a particular aim beyond sustenance and supplementing a normal diet reflecting permitted claims and labelling as per appropriate EU food regulations (e.g. Regulation (EU) No. 1924/2006).	√	√	√	?	√	√
Comprises the following characteristics:							
1	Is a concentrated source of nutrients or other substances permitted for use in the EU (singly or in combination) and with a nutritional or physiological effect.	?	?			?	?
2	Typically presented in tablets, pills, capsules, liquid or powder form or similar						
3	Is clearly listed as a food supplement with clear dosage instructions						
4	Must not contain hormones, drugs, tobacco or derivatives thereof	√	√	√	√	√	√
5	Must not be presented as substances which can prevent, treat or cure a human condition or properties thereof	√	√	√	√	√	√
6	Must not be presented for use as a conventional food						
7	Must list the following statements on labels: 1) a warning not to exceed the recommended daily dose; 2) a statement to the effect that food supplements should not be used as a substitute for a varied diet; 3) statement to the effect that the products should be stored out of the reach of young children;	partially	partially	partially	partially	partially	partially
*A food matrix may be described as the nutrient and non-nutrient components of foods and their molecular relationships, i.e. chemical bonds, to each other. (Source: United States Department of Agriculture, National Agricultural Library (2015))							

Appendix F. Third testing of 24 food products against characteristics identified for food (FP and for food supplements (FS).

		Apple Extract Tablets	Multi-vitamin & mineral with plant extracts	Sugar Cane wax tablets	Plant extract tablet	Rice yeast extract tablet	Zinc gluconate capsule
	All food and/or food supplements must be fit for human consumption	√	√	√	√	√	√
Food							
1	Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in formats not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.						
Food supplement							
2	Is understood as a food supplement, rather than conventional food, by the average consumer and is presented and labelled as such. Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar.	√	√	√	√	√	√
3	Is composed of nutrients or other substances with a nutritional or physiological effect as defined in EU legislation. Food supplements are designed to supplement total dietary intakes with a view to satisfying a normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet	√	√	√	√	√	√
Outcome		FS	FS	FS	FS	FS	FS

		Glucosamine chondroitin tablet	Plant protein Powder	Multi-vitamin & mineral tablet	Garlic oil capsules	Glucosamine sulphate tablet	Vegan ubiquinione tablet
	All food and/or food supplements must be fit for human consumption	√	√	√	√	√	√
Food							
1	Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in formats not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.						
Food supplement							
2	Is understood as a food supplement, rather than conventional food, by the average consumer and is presented and labelled as such. Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar.	√	√	√	√	√	√
3	Is composed of nutrients or other substances with a nutritional or physiological effect as defined in EU legislation. Food supplements are designed to supplement total dietary intakes with a view to satisfying a normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet	√	√	√	√	√	√
Outcome		FS	FS	FS	FS	FS	FS

		Powdered vitamins & mineral formula	Rice-based powdered vitamins & mineral formula	Liquid fulvic acid	Liquid multi-vitamin and mineral	Nutrition drink with added vitamins and minerals	Chocolate bar with protein, vitamins and minerals
	All food and/or food supplements must be fit for human consumption	√	√	√	√	√	√
Food							
1	Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in formats not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.					√	√
Food supplement							
2	Is understood as a food supplement, rather than conventional food, by the average consumer and is presented and labelled as such. Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar.	√	√	√	√		
3	Is composed of nutrients or other substances with a nutritional or physiological effect as defined in EU legislation. Food supplements are designed to supplement total dietary intakes with a view to satisfying a normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet	√	√	√	√		
Outcome		FS	FS	FS	FS	F	F

		Fortified corn flakes	Yogurt drink with plant sterols	Orange juice with probiotics	Black Pudding	Fortified yogurt (solid)	Isotonic sports drink
	All food and/or food supplements must be fit for human consumption	√	√	√	√	√	√
Food							
1	Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in formats not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.	√	√	√	√	√	√
Food supplement							
2	Is understood as a food supplement, rather than conventional food, by the average consumer and is presented and labelled as such. Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar.						
3	Is composed of nutrients or other substances with a nutritional or physiological effect as defined in EU legislation. Food supplements are designed to supplement total dietary intakes with a view to satisfying a normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet						
Outcome		F	F	F	F	F	F

[1]Relates to foods or food ingredients primarily composed of plant or animal material (or similar) with an inherent food matrix or structure (e.g. liquid, solid, frozen, dried, dehydrated, concentrated). Such foods are ingested or chewed for their nutritional value or for their sensory attributes not limited to taste.

Appendix G. Copy of email and questionnaire administered to food experts

Dear XXX,

I am approaching you in relation to a review on the definition of 'food' that Revenue is undertaking. The purpose of this review is to define 'food' and to define clear principals for determining whether a product is a 'food' in the everyday and ordinary meaning of the word. It does not rely on definitions from EU food law or otherwise. The output from this analysis will inform national policy on determining different VAT rates which are applicable to food, foodstuffs and food supplements.

To this end, we are conducting a survey and your confidential input, as an expert in the field, would be appreciated. Please complete the survey based on your expert opinion. The survey contains 8 questions and should take no longer than fifteen minutes to complete. None of the information you provide will be shared with third parties, and your responses will be anonymous. I would be grateful if you could complete the questionnaire by 30 June 2017. Click the link below to start the survey.

Thank you for your participation and time and for completing this survey in confidence.
Yours sincerely,
XXXXX

Questionnaire

1. If you were asked to define a FOOD for human consumption, which of the following characteristics would be important? Please tick as many of the below criteria as you believe relevant.

a) Is safe for human consumption
b) Is understood as food by the consumer
c) Is understood as a food ingredient by the consumer e.g. flour
d) Is derived from plant, animal, bacteria, fungi or insect material
e) Has a food matrix being presented in a solid, liquid, frozen, dehydrated, concentrated or dried forms
f) Has sensory properties not limited to taste, smell and texture
g) Has nutritive properties
h) Must be chewed or ingested
i) Consumption of which helps achieve and maintain good health
j) May play a role in social, cultural or religious contexts
k) May be consumed as part of a meal or snack
l) Other

If Other, please specify: _____.

2. If you were asked to define a FOOD SUPPLEMENT for human consumption, which of the following characteristics would be important? Please tick as many of the below criteria as you believe relevant.

a) Is safe for human consumption
b) Is understood by the consumer as a food supplement rather than food
c) Is presented or labelled as a food supplement
d) Contains nutrients or other substances with a nutritional or physiological effect
e) Contains nutrients or other substances approved for use in the EU
f) Aims to supplement the normal diet
g) Is accompanied by statements which imply achievement of a particular aim beyond supplementing a normal healthy balanced diet
h) Is presented as a tablet, pill, capsule, liquid, gel, powder or other product for the preparation of beverages or similar
i) Has clear usage or dosage instructions
j) Other (please specify) _____

3. Do you consider the following to be food? Tick all that apply.

a) Food supplement
b) Foods enriched with vitamins and minerals
c) Total diet replacements for weight control
d) Partial meal replacements for weight loss
e) Infant and follow-on formulae
f) Young child formula (e.g. growing up milk)
g) Oral nutritional supplements
h) Enteral and Parenteral Nutrition feeds
i) Other dietary foods for special medical purposes to be administered under medical supervision
j) Food additives e.g. artificial sweeteners or colours

If you do not consider any of the above a food, please explain why?

---

4. Do you consider the following to be a food supplement? Tick all that apply.

a) Foods enriched with vitamins and/or minerals
b) Total diet replacements for weight control
c) Partial meal replacements for weight loss
d) Oral nutritional supplements
e) Enteral and Parenteral Nutrition feeds
f) Other dietary foods for special medical purposes to be administered under medical supervision
g) Food additives e.g. artificial sweeteners or colours

If you do not consider any of the above a food supplement, please explain why?

---

5. Are there any other substances that you consider to be a food supplement?

_____

6. Do you believe for a substance to be described as a food or food (dietary) supplement, all associated marketing and claims should be supported by relevant EU legislation?
Yes

No

7. Do you believe that a food matrix (defined by the USDA as the nutrient and non-nutrient components of foods and their molecular relationships i.e. chemical bonds, to each other) is a key feature which allows differentiation of foods from food supplements?

Yes

No

Please provide a rationale for your answer:

_____

8. Do you believe that capsules or pills (or similar) which contain relatively low amounts of vitamins and/or minerals, yet enough to claim 'source of' or 'high' (i.e. 15% or 30% of the labelling Nutrient Reference Value under EU Reg 1169/2011) are true food supplements?

Yes

No

Please provide a rationale for your answer

_____

Appendix H. Efficacy of final guidelines to identify food deemed to be ordinary, conventional or basic (F) or a food supplement (FS).

		Apple Extract Tablets	Multi-vitamin & mineral with plant extracts	Sugar Cane wax tablets	Plant extract tablet	Rice yeast extract tablet	Zinc gluconate capsule
	All food and/or food supplements must be fit for human consumption	√	√	√	√	√	√
Food							
1	Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in forms not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.						
Food supplement							
2	Is understood as a food (dietary) supplement, rather than conventional or ordinary food, by the average consumer and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or food ingredient in cosmetics, tinctures or similar.	√	√	√	√	√	√
3	Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar and having clear usage or dosage instructions. Is composed of nutrients or other substances with a nutritional or physiological effect. Food supplements are designed to supplement the normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet	√	√	√	√	√	√
Outcome		FS	FS	FS	FS	FS	FS

[1]Relates to foods or food ingredients typically in liquid, solid, frozen, dried, dehydrated or concentrated forms. Such foods are ingested or chewed at meals or snacks for their nutritional value or for their sensory attributes not limited to taste. Ordinary food is primarily composed of plant, animal, bacteria, fungi or insect material.

		Glucosamine chondroitin tablet	Plant protein Powder	Multi-vitamin & mineral tablet	Garlic oil capsules	Glucosamine sulphate tablet	Vegan ubiquinione tablet
	All food and/or food supplements must be fit for human consumption	√	√	√	√	√	√
Food							
1	Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in forms not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.						
Food supplement							
2	Is understood as a food (dietary) supplement, rather than conventional or ordinary food, by the average consumer and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or food ingredient in cosmetics, tinctures or similar.	√	√	√	√	√	√
3	Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar and having clear usage or dosage instructions. Is composed of nutrients or other substances with a nutritional or physiological effect. Food supplements are designed to supplement the normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet	√	√	√	√	√	√
Outcome		FS	FS	FS	FS	FS	FS

[1]Relates to foods or food ingredients typically in liquid, solid, frozen, dried, dehydrated or concentrated forms. Such foods are ingested or chewed at meals or snacks for their nutritional value or for their sensory attributes not limited to taste. Ordinary food is primarily composed of plant, animal, bacteria, fungi or insect material.

		Powdered vitamins & mineral formula	Rice-based powdered vitamins & mineral formula	Liquid fulvic acid	Liquid multi-vitamin and mineral	Nutrition drink with added vitamins and minerals	Chocolate bar with protein, vitamins and minerals
	All food and/or food supplements must be fit for human consumption	√	√	√	√	√	√
Ordinary or Conventional or Basic Food							
1	Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in forms not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.					√	√
Food Supplement							
2	Is understood as a food (dietary) supplement, rather than conventional or ordinary food, by the average consumer and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or food ingredient in cosmetics, tinctures or similar.	√	√	√	√		
3	Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar and having clear usage or dosage instructions. Is composed of nutrients or other substances with a nutritional or physiological effect. Food supplements are designed to supplement the normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet	√	√	√	√		
Outcome		FS	FS	FS	FS	F	F

[1]Relates to foods or food ingredients typically in liquid, solid, frozen, dried, dehydrated or concentrated forms. Such foods are ingested or chewed at meals or snacks for their nutritional value or for their sensory attributes not limited to taste. Ordinary food is primarily composed of plant, animal, bacteria, fungi or insect material.

		Fortified corn flakes	Yogurt drink with plant sterols	Orange juice with probiotics	Black Pudding	Fortified yogurt (solid)	Isotonic sports drink
	All food and/or food supplements must be fit for human consumption	√	√	√	√	√	√
Food							
1	Is understood as conventional food for human consumption by the average consumer[1] and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or a food ingredient in cosmetics, tinctures, or similar. Is not understood or presented as a food supplement presented in forms not limited to: tablets, pills, gels, capsules, lozenges, liquids, powders or other products for the preparation of beverages or similar.	√	√	√	√	√	√
Food supplement							
2	Is understood as a food (dietary) supplement, rather than conventional or ordinary food, by the average consumer and is presented and labelled as such. Is not a medicine, medicated preparation, tobacco or food ingredient in cosmetics, tinctures or similar.						
3	Is typically presented as tablets, pills, gels, liquids, lozenges, capsules, powders or other products for the preparation of beverages or similar and having clear usage or dosage instructions. Is composed of nutrients or other substances with a nutritional or physiological effect. Food supplements are designed to supplement the normal diet. Food supplements may imply achievement of a particular aim beyond sustenance and supplementing a normal healthy balanced diet						
Outcome		F	F	F	F	F	F

[1]Relates to foods or food ingredients typically in liquid, solid, frozen, dried, dehydrated or concentrated forms. Such foods are ingested or chewed at meals or snacks for their nutritional value or for their sensory attributes not limited to taste. Ordinary food is primarily composed of plant, animal, bacteria, fungi or insect material.