Dietary supplements, 'functional' and 'super' foods: Science, regulations and roles in the diet". Royal Society of Medicine, London, 29 November 2022

Meeting Summary:

"Dietary supplements, 'functional' and 'super' foods: Science, regulations and roles in the diet". Royal Society of Medicine, London, 29 November 2022

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Abstract

A meeting on "Dietary supplements, 'functional' and 'super' foods: Science, regulations and roles in the diet" was held at the Royal Society of Medicine in London on 29 November 2022. Eight invited speakers drawn from academic, public health, clinical and commercial backgrounds addressed different aspects of the topic from scientific, legislative and commercial perspectives. This document provides an informal summary of the individual presentations and discussions with the audience.

Introduction

Confusion exists amongst the general public and healthcare professionals regarding the safety, legal status and utility of food supplements, "functional foods" and "superfoods". Recognising this, the Food and Health Forum of the Royal Society of Medicine hosted a meeting on "Dietary supplements, 'functional' and 'super' foods: Science, regulations and roles in the diet", in London on 29 November 2022. The event explored these topics from scientific, legislative and commercial perspectives. The primary objective of the event was to provide a balanced perspective so participants would be better informed and able to understand and offer knowledgeable, evidence-based advice and guidance about the roles and use of these products.

A unique aspect of the programme was that it addressed the topic matter in a sequential way, from how these get on the market (evaluation and approval) and potential claims, to the evidence and guidance on their use, benefits and risks. This was delivered by authoritative speakers with directly relevant experience from academic research, public health, clinical care and industry.

Key learning objectives of the event were to enable participants to:

- Understand the general regulatory environment for foods and ingredients, including assessment, approval of safety and claims;

- Confidently advise patients and consumers about food supplements, "functional" and "super" foods;
- Be aware of current guidance on food supplements in public health and clinical practice, including possible risks and benefits in their use.

The one-day meeting was organised into a morning and afternoon session, with 4 speakers each, and a panel discussion with audience participation following each pair of presentations. The full programme is included here as an Appendix.

Morning session

Welcome and introduction

The meeting was opened by Dr Leigh Gibson, President of the Food and Health Forum, Royal Society of Medicine.

Mr Patrick Coppens: "An overview of the regulatory environment"

Considerable order has been brought to this subject over the last two decades and Mr Coppens took us through the relevant legislation. He then highlighted some public health aspects of the use of supplements, concluding with a recent evaluation of the potential economic impact of appropriate use of supplements.

- Legislation
  Up to the year 2002 food supplements were regulated under individual national laws. There was wide diversity in the rules and approaches and this posed considerable barriers to trade. The European Union (EU) Food Supplements Directive of 2002 (2002/46/EC) established a category under food law to include non-vitamin and mineral ingredients. However, detailed rules were laid down only for vitamin and mineral supplements. The Directive provided the following definition: *"'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated 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 or 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"* (Article 2(a)). The Directive also provided rules for labelling, a list with permitted nutrient sources, and a statement that Member States may require notification to the relevant authorities of the intention to market a specific product. This latter point has become mandatory in all EU Member States except Austria, the Netherlands, Slovenia and Sweden.

  The use of food supplements is also legislated under EU horizontal rules which are applicable to foods in general. National specific rules of Member States and rules on mutual recognition within the EU are also included. Whilst the United Kingdom is no longer in the EU, general EU food law still applies, with the primary objective of upholding a high standard of safety and consumer protection (https://www.food.gov.uk/business-guidance/how-the-fsa-has-prepared-for-the-uk-leaving-the-eu-and-the-end-of-the-transition).

The EU legal framework applicable to food supplements includes: General Food Law (Reg EC 178/2002); Food Supplements (Dir 2002/46/EC); Food Hygiene (Reg EC 852/2004); Labelling (Reg EU 1169/2011); Health Claims (Reg EC 1924/2006); Additives (Reg EC 1333/2008); Irradiation (Dir 1999/2/EC); Contaminants (Reg EC 1881/2006); Official Controls (Reg EU 2017/625); Extraction Solvents (Dir 2009/32/EC); Pesticides Residues (Reg EC 396/2005); Fortification (Reg EC 1925/2006) and Novel Foods (Reg EU 2015/2283). All details can be found via the official EU website: https://eur-lex.europa.eu/browse/directories/legislation.html.

Those seeking to market food supplements have an overall responsibility to ensure the safety of their product which, of course, includes complying with all relevant legislation. Pre-market authorisation is required for food additives, nutritional substances and novel foods, and safety assessments are carried out by the European Food Safety Authority (EFSA). General labelling requirements are specified in EU Regulation 1169/2011 and all health claims are subject to pre-market authorisation (Regulation EC 1924/2006) as detailed below. Article 6 of the Food Supplements Directive (2002/46/EC) states that: *"The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties."*

Since 2020 work has been ongoing in Europe to harmonise the maximum permitted levels for vitamins and minerals. The upper tolerable intake levels of vitamins A, D, E and B6, folic acid, iron, manganese, selenium and fluoride are currently under evaluation by EFSA. The place of botanicals in food legislation has long been the subject of debate and the EU is aware of the need to further consider how the use of plants should be harmonised, including the safety aspect.

- Role in public health
  Food supplements have an important role in public health, primarily for specific sub-groups of the population. Troesch et al (2012) reviewed vitamin intakes in Germany, the UK, The Netherlands and the USA compared with their respective national recommendations. Although there were inter-country differences, intakes of several vitamins were below recommendations in a significant part of the population in all the countries studied. The most critical vitamin appeared to be vitamin D whilst the least critical was niacin. In 2022 the EFSA NDA Panel published a scientific opinion related to nutrient profiling (https://www.efsa.europa.eu/en/efsajournal/pub/7259). In this report they concluded that intakes of EPA and DHA may be inadequate for primary CVD risk prevention in Member States with low consumption of fish/seafood and products thereof. The Panel also noted that "*intakes of calcium, vitamin D, folate, iodine and iron may also be inadequate in certain subgroups of European populations […]. Inadequate intakes of these nutrients are usually addressed by national nutrition policies (e.g. supplementation, food fortification) in Member States and/or individual advice."*

- Economic implications
  Mr Coppens presented a summary of a recent report on healthcare cost savings which could be accrued from the appropriate use of food supplements. Taking into account the role of omega-3 fatty acids, phytosterols, calcium/vitamin D, lutein and B-vitamins the savings to healthcare costs over a 5 year period were estimated to be 125 billion Euros in total (https://foodsupplementseurope.org/wp-content/themes/fse-theme/documents/value-of-supplementation/hccs_booklet-single-page.pdf).

  The www.foodsupplements.org website provides detailed information on a wide range of subjects relevant to dietary supplements in Europe.

In concluding, Mr Coppens reiterated that the development of legislation covering the legal use of food supplements in Europe has been the subject of intense activity during the last two decades. In addition to the publication of a specific directive, supplements fall under the remit of general food law. Supplements clearly have a useful role to play, particularly when individuals are not consuming a balanced diet.

Professor Hans Verhagen: "Risk assessment and risk-benefit assessment in food safety and nutrition"

Professor Verhagen presented an overview of risk assessment and risk-benefit assessment, which are important elements in the pre-market evaluation of food supplements and, as noted above, are applicable to all food ingredient authorisations.

- Hazard versus risk
  Professor Verhagen began by citing Paracelsus (1493-1541) *"All substances are poisons. There is none which is not a poison. The right dose differentiates a poison from a remedy".*

  There is an important difference between "hazards" and "risks". EFSA defines a hazard as: *A substance or activity which has the potential to cause adverse effects to living organisms or environments* (https://www.efsa.europa.eu/en/glossary-taxonomy-terms), whilst the EU defines risk as: *A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard* (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20090807:EN:PDF). A hazard doesn't pose a risk until there is exposure.

  The dose-responses of living organisms to food components follow sigmoidal curves. At the higher end are dose levels with clear (adverse) effects, while at the lower end is the so-called no-observed-adverse-effect-level (NOAEL). From a point-of-departure such as the NOAEL, safe levels of intake (Health-Based Guidance Values, HBGVs) are derived by application of safety factors (uncertainty factors) to cover variation between and within species.

  Chronic health-based guidance values (HBGVs) such as the acceptable daily intake (ADI), tolerable daily intake (TDI) or tolerable weekly intake (TWI) are estimates of the amount of a chemical, expressed on a body weight basis, that may be ingested regularly (e.g. daily, weekly) over a lifetime without appreciable risk. As an example, the ADIs of some intense sweeteners in the EU are such that these would equate to an intake of 1.67 to 4.33 litres of sweetened beverages daily over a lifetime without appreciable risk of harm.

  The following elements comprise the risk-assessment paradigm:

  Hazard identification: What health problems are caused by the chemical?

  Hazard characterisation: Absorption, distribution, metabolism and excretion of the entity (ADME), acute to chronic toxicity, human data, genotoxicity, reproductive toxicity, etc. Derivation of a health-based guidance value such as the ADI.

  Exposure assessment: Levels in food, dietary exposure, relevant food groups, relevant populations, time trends.

  Risk characterisation: Relating exposure to the Hazard characterisation.

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The results of the risk assessment including the scientific advice and analysis will then be passed to the risk managers for regulation and control. The third aspect in the process is risk communication.

- Risk-benefit assessment
  Normally the focus of research into the health impact of food is either only on risks/hazards or on benefits, and on one food and one health effect. However, food and food constituents can be associated with both benefits and risks, and an integrated approach is mandated. This is known as risk-benefit assessment. As such, future dietary reference values could take into account not only basic needs but also other health affects related to risks and (additional) benefits, in order to inform the risk managers (Verhagen et al. 2021).

  As an example, the risk-benefit analysis for the intake of nicotinic acid (vitamin B3) could take into account the daily requirement for meeting nutritional needs, as well as flushing (reddening of cheeks), cholesterol lowering effects and risk of hepatotoxicity at higher levels. Another good example of an integrated risk-benefit analysis is the case of the fortification of flour with folic acid. Hoekstra et al (2008) considered the benefit of reducing neural tube defects, the risk of masking vitamin B12 deficiency, the benefit of overcoming folate deficiency and the risk and benefit of the impact on colorectal cancer. The overall health impact of fortifying bread with folic acid in the Netherlands was assessed in terms of Disability Adjusted Life Years (DALY), which combines morbidity and mortality and so serves as a common health measure. The research estimated that, per year, folic acid fortification resulted in a 37% reduction in the incidence of neural tube defects (-5474 DALYs), 1% increase in masking vitamin B12 deficiency (+53 DALYs) and 4.1% reduction in colorectal cancer (-2217 DALYs).

  It was emphasised that risk-benefit assessment requires the comparison of effects with effects. It does not compare effects with the absence of effects nor does it assess safe dose levels to see if there is anything left for benefits. Rather, it defers to safety calculations to allow for an overall increased net health benefit. Many groups have been working on risk-benefit assessment for the past 20 years. Methods have been developed and the EU funded the BRAFO project which was coordinated by the European branch of the International Life Sciences Institute. This project has developed a tiered approach to risk-benefit assessment (Hoekstra et al, 2012).

In summary, the science of risk-benefit assessment has developed apace during the last two decades. The objective is to make foods and food components safe for human consumption taking into account risks whilst seeking an increased net health benefit.

Panel discussion (audience questions) with Mr Patrick Coppens and Professor Hans Verhagen

The formal presentations were followed by a lively discussion on a range of subjects:

- Risk versus benefit
  Professor Verhagen was asked to comment on the fact that, in risk assessment, the individual facing the risk isn't necessarily the individual likely to benefit. This may be seen primarily as a problem of the policy maker but doesn't the risk assessor also have a role? The example of folic acid was discussed whereby the beneficiaries are babies whilst, with universal fortification, the elderly risk vitamin B12 deficiency. It was pointed out that risk-benefit occurs at a population level rather than at the level of individuals. Professor Verhagen re-emphasised the role of the policy maker.

- Tolerable upper levels for vitamins and minerals
  An audience member asked whether safety margins are applied to nutrients in the same way as they are for chemicals or high potency sweeteners (a factor of 100 or more). Professor Verhagen noted that this is not possible for nutrients. He cited the example of vitamin C where the minimum dose for an adverse effect is in the region of 3000 mg/day. If a safety factor of 100 were to be applied the resulting dose of a mere 30 mg/day would be inadequate.

- Optimal intake versus intake to alleviate deficiency
  The questioner cited the example of vitamin D where the level required to alleviate rickets or osteomalacia may not be the optimal level for other aspects such as immune function. Mr Coppens commented that EFSA have not been requested to consider optimal intakes, rather the focus has been on preventing deficiency. However, he noted that intakes within the upper tolerable intake level would mediate less tangible benefits such as immune effects.

- Grey areas
  A questioner cited the example of gummies for gamers, containing caffeine and other ingredients, marketed as providing energy. The question was whether there are grey areas between supplements and fortified foods. Mr Coppens commented that indeed there are grey areas. The example could be considered as a supplement or a fortified food. However, both categories have a legal framework and it is the responsibility of the manufacturer to apply the appropriate legal framework. Another example is supplements versus foods for special medical purposes. "Legal shopping", i.e. taking benefits from an inappropriate legal framework, and taking parts of different rules for a single product, are not permitted.

- Packaging
  The question was whether packaging is taken into account when assessing risk. It was noted that packaging regulations are in place which address the question of migration on storage. Product stability studies are also an essential element of assessment.

- Polyphenols
  There was a question regarding whether EFSA will be evaluating a possible dietary recommendation for polyphenols. Mr Coppens pointed out that the work of EFSA is largely mandated by the EU Commission and Member States. Polyphenols will have been evaluated in the context of the health claims dossiers. However, with over 3,000 of these evaluated the panel could not call to mind the specifics.

Professor Harry J McArdle: "Assessing potential health and nutrition claims; what evidence is required?"

Professor Mc Ardle summarised the legislation and evidence required to establish health and nutrition claims on foods including food supplements. He began his presentation by citing data from the World Health Report of 2002, highlighting the many leading mortality risk factors that are modifiable by diet.

He then introduced the European Food Safety Authority and its role in evaluating health claim applications, finally focusing on the operation of the nutrition and health claims regulation, first published in 2006.

- Risks and controversies
  Modifiable risk factors include high blood pressure, elevated cholesterol, underweight, sub-optimal fruit and vegetable intake, high body mass index, high alcohol consumption, iron deficiency, zinc deficiency and vitamin A deficiency (https://www.who.int/publications/i/item/9241562072).

  Intense interest in diet and health has led to many myths and controversies. As an example, the marketing of spinach by Popeye initiated in the 1930's was based on an iron content ten times the actual level due to a misplaced decimal point. (This entertaining story is reviewed in Sutton, 2010.) Misleading health claims abounded on food products prior to the introduction of legislation. "Helps strengthen your body's defences" and "clinically proven to improve attentiveness" are just two unproven examples.

- Establishment of the European Food safety Authority
  The European Food Safety Authority (EFSA) was set up in January 2002 following several food crises in the late 1990s. It is an independent source of scientific advice and communication on risks associated with the food chain. As the risk assessor, EFSA produces scientific opinions and advice which provide a sound foundation for European policies and legislation. The European Commission, European Parliament and EU Member States can then take effective and timely risk management decisions. Opinions are published in the EFSA journal and on the EFSA website (http://www.efsa.europa.eu/). Since January 2021 risk assessment for health claims in the UK is undertaken by the UK Nutrition and Health Claims Committee (UKNHCC).

- Novel foods
  Novel foods are the subject of EU Regulation 2015/2283. One of the criteria for a food to be considered a novel food is the absence of use for human consumption to a significant degree within the Union before the 15 of May 1997. Thus, a newly developed food supplement would come under the auspices of the novel foods legislation.

- Health claims
  Health claims on foods within the EU (including food supplements, "functional" and "super" foods) fall under the remit of EU Regulation (EC) No 1924/2006 of the European parliament and of the council of 20 December 2006 on nutrition and health claims made on foods (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1924-20141213). This Regulation lays out in detail the criteria for the establishment of a nutrition or health claim within the EU. The core principle is a scientific assessment of the highest possible standard. The substantiation of a claim involves reviewing generally accepted scientific evidence, evaluating the totality of the available scientific data, and weighing the evidence. Dossiers are submitted for consideration to EFSA's Panel on Nutrition, Novel Foods and Food Allergens (NDA). Scientific substantiation of a positive effect requires a favourable outcome to all three of the following questions:

1. Is the food/constituent characterised?,
2. Is the claimed effect based on the essentiality of a nutrient? Or is the claimed effect defined and is it a beneficial physiological effect, and can it be measured *in vivo* in humans? and
3. Is a cause and effect relationship established between the consumption of the food/constituent and the claimed effect?

Relevant human efficacy studies are at the top of the required evidence hierarchy and are central to a successful claim application. They may be supported by efficacy studies in animals, non-efficacy studies in humans and animals and *in vitro* mechanistic studies. Claims cannot refer to a disease or to the reduction of the risk of a disease and subjects with a disease cannot be the target population for claims made on foods. However, the reduction of a risk factor for a disease is a legitimate target for a claim (Regulation (EC) No 1924/2006 and (EU) No 1169/2011). Examples of such risk factors include:

Disease	**Surrogate endpoint (risk factor)**
Cardiovascular disease	Serum low-density lipoprotein cholesterol, Total cholesterol
Stroke	Blood pressure
Osteoporosis	Bone mineral density
Colon/rectal cancer	Adenomatous polyps
Type 2 diabetes	Elevated blood sugar concentrations, Insulin resistance
Dementia	Mild cognitive impairment
Inflammatory diseases	Cytokines (e.g. hsCRP, IL-6)

Detailed requirements for the establishment of a reduction of disease risk claim are given in Regulation EC 1924/2006, Article 14. It should be noted that not all of these risk factors are accepted as definitive risk factors.

To date 30 nutrition claims and 267 health claims have been authorised by the European Union for use in foods. Nuala Collins and Hans Verhagen provide an excellent summary of the situation as of September, 2022: https://www.raps.org/RAPS/media/news-images/Feature%20PDF%20Files/22-9_Verhagen-Collins.pdf.

Examples of positive health claim opinions include:

> "**Calcium (and vitamin D)** may reduce the loss of bone mineral in post-menopausal women. Low bone mineral density (BMD) is a risk factor in the development of osteoporotic bone fractures". Conditions of use include "…at least 1200 mg of calcium from all sources or at least 1200 mg of calcium and 800 I.U. of vitamin D from all sources to be consumed daily should be considered for the purpose of setting conditions of use for a risk reduction claim on the loss of BMD, which may contribute to a reduction in the risk of bone fracture. The target population is women 50 years and older" (EFSA Panel, 2010a).
>
> "**Oat beta-glucan** has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease". Conditions of use: "…in order to bear the claim, foods should provide at least 3 g of oat beta-glucan per day The amount can reasonably be consumed as part of a balanced diet. The target population is adults who want to lower their blood cholesterol concentrations" (EFSA Panel, 2010b).

NOTE: Reduction in disease risk (Article 14) claims have two parts, namely 1. The effect of the food on a risk factor, and 2. The relationship between the risk factor and disease (Regulation (EC) No 1924/2006).

On a global basis there are several different approaches to the establishment and authorisation of nutrition and health claims on foods. For example, in the USA there is a category for **Significant scientific agreement (SSA)** claims which include:

- Disease risk biomarkers (similar to the UK and EFSA), and
- Disease incidence claims

Claims relating to structure or function for dietary supplements are allowed without pre-assessment by the US Food and Drug Administration (FDA). Companies must however have scientific substantiation and notify FDA within 30 days of first marketing, and the products must include a mandatory disclaimer statement. The permitted US claim for calcium is “Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.” The permitted claim relating to whole grain is: “diets rich in whole grain food and other plant food and low in total fat, saturated fat, and cholesterol, may reduce the risk of heart disease and some cancers”.

- Future challenges
  Much progress has been made during the last two decades to bring order to the complex subject of establishing nutrition and health claims on foods. However, further challenges lie ahead:

  - The requirement for evidence for the establishment of health claims to be obtained from healthy individuals presents a challenge, particularly in older populations. In addition, there may be greater benefits from foods with certain health claims for individuals at higher risk on the health-disease continuum.
  - Nutrient profiling and the situation of botanicals are still under discussion some 16 years after the publication of the Nutrition and Health Claims Regulation (EC 1924/2006).
  - The current status of legislation has little utility in the spectrum of personalised and precision nutrition, where much research remains to be done, and
  - There is potential for specialised products for groups of individuals who are currently healthy but may have higher or lower nutrient requirements such as folate for individuals with a methylenetetrahydrofolate reductase (MTHFR) mutation or those with elevated cholesterol.
  - Identification of new biomarkers will be important in establishing new health claims.

  A recent publication provides an excellent summary of the nature of the evidence base and strengths, challenges and recommendations in the area of nutrition and health claims (Ashwell et al*,* 2022).

In summary, excellent progress has been made during the last two decades in bringing order to the acceptance of nutrition and health claims on foods in the European Union and the United Kingdom. Consumers can be reassured that foods legally on the market, including food supplements, will have been evaluated to the highest possible standard. However, there is still work to be done in bringing clarity to some areas such as botanicals and nutrient profiling, and enforcement agencies have a vital role to play.

Mr Frans van der Sman: "Using authorized health and nutrition claims: Examples of use and mis-use in the market"

Mr van der Sman built on the previous presentations, focusing on how authorised health and nutrition claims on foods and thus also food supplements, are applied in the market. He highlighted examples of good practice as well as examples which fail to meet current high standards. The latter can only be considered as a short term expedient and do not form part of the strategy of a reputable food company wishing to grow and prosper.

- Objectives of the nutrition and health claims regulation
  Mr van der Sman firstly re-emphasised key aspects of the Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December, 2002 on nutrition and health claims made on foods:

  - The objective is to protect consumers from false and misleading claims,
  - Health claims are not allowed unless a specific claim is listed as an authorised claim in the EC register of health claims,
  - The European Food Safety Authority (EFSA) is responsible for the scientific substantiation of health claims in the EU. EFSA assesses a claims dossier and publishes an opinion. Subsequently the European Commission decides upon the formal authorisation of a health claim
  - The 'force field' between science and consumers

  Following this, he focused on the 'force field' operating to convert the science around claims on foods into language understandable to consumers. Elements in this force field which spans the EC/EFSA, food and beverage producers and consumers include:

  - Conditions of use
  - Interpretation
  - EU versus Member States
  - Marketing Departments
  - Consumer understanding – focusing on the average consumer
  - Flexibility of wording, and
  - Supplements

  It was pointed out that nutritional benefits cannot be tasted thus communication is necessary and this is achieved via claims. A claim explains the unique benefits of a product and is a voluntary statement. In contrast, ingredient declarations and nutrition tables are not claims and are mandatory.

- The role of EU Member States
  Once a claim has been approved by the European Commission based on the evaluation and opinion of EFSA, it is delegated to individual EU Member States (MS) to agree on the wording appropriate for consumers in that MS. Harmonisation of wording throughout Europe may seem desirable but consumer understanding will vary from MS to MS and translation into local languages may lose meaning for consumers. Individual MS are then responsible for local enforcement.

  Conditions of use are defined for each approved health claim. For example:

Claim: Iron contributes to the reduction of tiredness and fatigue
Conditions of use: Only for food which is at least a source of iron (=2.1 mg/100g)

Encouragingly, conditions of use are almost always correctly implemented by food producers and challenges on incorrect use are hardly ever seen. However, one could debate whether the average consumer is deficient in a particular nutrient or vitamin. The regulation allows the claim when the conditions of use are met regardless of the nutritional status of the individual consumer.

- Marketing considerations
  Multinational food producers will position the same product differently in different markets based on the local regulatory environment and consumer preferences. As an example, a yoghurt marketed in France on the basis of its taste and natural ingredients, is marketed in Italy based on the presence of *bifidus* probiotics with implications for the balance of intestinal flora. The other attributes are also included in the marketing of this product in Italy. Marketing departments, proud of their products, are quick to seize opportunities to set themselves apart from competitors.

  A further example of interpretation in action is that of inulin:

  > The authorised claim for inulin and bowel function has the following conditions of use: "…*at least a daily intake of 12g of native chicory inulin…"*. This requirement is *daily* and not necessarily in a single serving. One breakfast cereal incorporating chicory inulin provides 5.4g per serving whilst another provides just 2.0g per serving. Both products provide the requisite explanation of the effect on bowel function. In the case of the first of these products 100g of the breakfast cereal would provide the daily amount whilst in the other the amount of product needed to meet the target would be 360g, which is not feasible. However, the latter product still makes a contribution to the daily amount.

  Marketing departments are most likely to push the envelope on claims, with attenuation from scientists and legislators. The example of a tea was given. This is marketed on the basis of 'immunity' on the front of the pack, repeated on the back of pack with the authorised functional claim: "*Contains vitamin C that contributes to the normal function of the immune system".* Most probably this claim is in line with the legislation, based on the presence of vitamin C in the product. However, it does beg the questions: Why vitamin C in tea? Is it still present at 100^{o}C? Is the consumer deficient? Has the vitamin C been added just for the purposes of making the claim?

  In a similar vein an oat drink and other products which claim *'daily immunity'* based on their vitamin C content also highlight the presence of extracts of echinacea (for which no claim is authorised), and the latter may be the point that resonates with consumers. The claim based on vitamin C is valid, but the product may not be exempt from negative publicity due to the possibility of misleading consumers. For example, Foodwatch Netherlands publish a yearly list of "Gouden Windei" nominees for the award for misleading food marketing. Ice teas marketed on the basis of '*good energy', 'feel immune'* or *'inner beauty'* have been on the list. Again the products comply with legislation, but have been the subject of negative publicity.

In conclusion, it is evident that translating science into attractive consumer messaging can be fraught with difficulty. A responsible company will ensure that all the necessary details are considered. Even if a product complies with the law it may be problematic for consumers to understand what lies behind the claim(s). Marketing must understand that there is no such thing as a quick opportunistic win when using health claims in consumer communication. The

EC Regulation on nutrition and health claims in foods (EC 1924/2006) has been crucial in protecting consumers from being misled. Producers have a complex task in communicating with consumers but marketing will find a way. Understanding the force field allows producers to take a responsible position.

Panel discussion (audience questions) with Professor Harry McArdle and Mr Frans van der Sman

The presentations again prompted an interesting range of questions:

- Quality of the data for evaluation of a claim
  A questioner asked how those undertaking evaluations could be sure of the quality of the data. Professor McArdle replied that all data have to comply with good laboratory practice (GLP) and if there are any doubts original lab books can be requested. High quality scientists evaluate the data and it is extremely unlikely that anything less than high quality data would be accepted.

- Tiredness and tea
  The panel confirmed that if a dose of iron complying with the conditions of use of the authorised claim on iron and reduction of tiredness is present in the tea, then the claim can be made. No caveat about iron deficiency is necessary.

- How is the 'healthy population' defined?
  The questioner highlighted the issue where a benefit might be demonstrated for an overweight population which may not be manifest in individuals of normal weight. The panel acknowledged that this can be a difficult point to address. Individuals in a 'pre-disease' state such as overweight and hypertension could be included whilst those with frank diseases could not. However, the data must be generated on a population representative of the target population for the claim/product. There is a category of foods for special medical purposes, in which case the population for studies would need to be representative of the medical condition under consideration.

- Labelling requirement for potential harm?
  In the case of pharmaceuticals, warnings about possible side effects are required. Is this the same for foods and supplements? Mr Coppens confirmed that in the case of supplements, conditions of use are determined at the national level and in certain cases statements about use levels and warning statements are indeed required.

- If EFSA is there to protect consumers, why are claims allowed on unhealthy products?
  The example given was a claim for enhanced immune function based on the addition of vitamins to products high in sugar. Are these legal but not protecting the consumer? The questioner also raised a point about bioavailability. In the case of tea does preparation destroy the vitamins? EFSA's evaluation will have covered the conditions of use so the question of bioavailability would have been addressed. However, the individual Member State enforcement authorities would be responsible for ensuring that the prescribed conditions of use are being complied with. It was noted that the original Nutrition and Health Claims Regulation included a clause relating to nutrient profiling which was specifically designed to ensure that 'unhealthy' products cannot be the subject of a nutrition or health claim. However, due to the complexity of the subject the question of how to implement nutrient profiles is still under discussion.

- "Superfoods"
  The questioner wanted to know the panel's perspective on "superfoods". The panel suggested deferring the response until the afternoon session, when the topic would be specifically addressed by Dr Mela.

Afternoon session

Professor Julie Lovegrove: "The potential role of food supplements in public health and restrictive diets"

Professor Lovegrove started by noting that poor diet was reported to be the single largest risk factor for global disability-adjusted life years (GBD 2015 Risk Factors Collaborators, 2016), and that a substantial proportion of the UK population fails to adhere to current dietary guidance (Scheelbeek et al., 2020). A very large volume of vitamin and mineral supplements are sold in the UK although current public health advice emphasises that, with a few exceptions, these generally are not needed.

The first part of the presentation focused on 2 nutrient supplements specifically advised in current UK public health guidance: folic acid and vitamin D

- Folic Acid
  All women planning a pregnancy are advised to take a 400 µg/day supplement of folic acid 12 weeks pre-conceptually and until week 12 of pregnancy (SACN, 2017). This level of folic acid intake has been shown to reduce the risk of Neural Tube Defects (NTD) by half. Unfortunately, uptake of the recommended supplement is low in many parts of the population and many pregnancies are also unplanned. Furthermore, there are indications that in the target population, folate status is often low and has been declining since 2008. Mandatory fortification of foods in many countries has proven successful in reducing NTD prevalence, and the UK is now exploring the implementation of this, following a series of assessments and recommendations from the Scientific Advisory Committee on Nutrition.

- Vitamin D
  The general population from age 4 is advised to consume 10 µg/day of vitamin D throughout the year, from all dietary sources (SACN, 2016). However, there is a high prevalence of low vitamin D status within the UK population, and the desired intake level is difficult to achieve from foods alone. The use of a 10 µg/day vitamin D supplement is therefore advised. Professor Lovegrove noted that there had been considerable debate about the possible efficacy of (higher doses of) vitamin D during the recent COVID-19 pandemic. However, nutrition interventions or improved nutritional status beyond current dietary recommendations, including vitamin D, do not appear to either prevent this infection nor reduce its severity.

The second part of the presentation considered nutrient needs for individuals following restricted diets, particularly those with low intakes of animal products. Vitamin B-12, iron and long chain n-3 polyunsaturated fatty acids (PUFA) were highlighted as particular nutrients of concern.

- Vitamin B-12
  About 5% of the UK population follows a vegetarian or vegan diet, and there is growing interest in meat-free diets, especially from younger individuals. These dietary patterns provide limited sources of vitamin B-12, a nutrient which is also a concern for older

individuals due to an increased risk of vitamin B-12 malabsorption. Therefore, vitamin B-12 supplementation is advised for these populations.

- Iron
  Iron supplements may be advised for women aged 11-50 years, and individuals following a vegetarian or vegan diet, where iron intakes and/or status are a particular concern. Although plant-based diets may appear to contain iron in adequate amounts, the bioavailability of the iron from these diets may be relatively poor.

- Long chain n-3 PUFA
  Current guidance is for consumption of 2 portions of fish per week, one of which is oily fish. However, only 25% of the UK population consumes any oily fish and less than 17% adhere to the current guidance. In order to achieve the benefits of long chain n-3 PUFA (found mainly in oily fish) for reduction of cardiovascular disease risks, consumption of supplements may be advised.

Professor Lovegrove concluded her presentation by reiterating that dietary supplements (excluding vitamin D & folate pre-conceptually) are generally not required by individuals consuming a balanced diet. However, in addition to recommended folic acid and vitamin D supplements (and recommended supplements for infants and young children), supplements of vitamin B-12, iron and long chain n-3 PUFA may be advised for those with restrictive diets and other situations where the intakes or bioavailability of these nutrients are limited.

Professor Ian Young: "Guidance and experience on supplement use in clinical practice"

Professor Young began his presentation with evidence that although use of nutrient supplements is very high, they tend to be used by people who are healthier, and the added health benefits of their use (in general, or specific nutrients) may be difficult to discern. He speculated on a number of possible reasons why individuals may choose to use supplements, and expressed the view that there is good evidence of benefits for a minority of supplements but limited or no evidence for a large majority of these.

The presentation focused around 3 headings:

- Areas where guidelines and evidence support benefit
  While many clinicians do not ask about supplement use, this should be part of every consultation. Reiterating points made by Professor Lovegrove, Professor Young emphasised where preventive use of supplements is clearly recommended in the UK: Vitamin D from age 4, folic acid for pregnancy and Healthy Start vitamins for infants and young children. Appropriate supplements may also be advised for individuals with restricted (e.g. vegan) or extreme diets.

  Oral nutrition supplements (ONS) may be regarded as medicines and prescribed in a wide range of clinical situations where patients present with or are at risk of malnutrition. This includes compromised gastro-intestinal function or inborn errors of metabolism, as well as where attempts to improve nutrition through diet have failed. There are also examples of supplements specifically formulated e.g. to support individuals in alcohol withdrawal, and to reduce the rate of progression of age-related macular degeneration.

- Areas where there is little evidence, or evidence is equivocal or negative
  Professor Young noted that there is limited or uncertain support for benefits of non-nutrients, or nutrient intakes much higher than required to prevent deficiencies. One

example was the proposed use of B-vitamins to reduce cardiovascular disease via homocysteine-lowering. While the overall results of many trials tend to indicate no benefit for key endpoints, there remains a possibly of a small reduction in stroke risk. Another example is the use of coenzyme Q10 to relieve the muscle ache experienced by many statin users. While meta-analyses indicate no efficacy for this purpose, his own personal experience has been that many patients self-report a benefit which may facilitate continued compliance with their statin prescription. On that basis, he continues to recommend use of the supplement in some cases, whilst acknowledging this could be a placebo effect.

- Areas where guidelines and evidence indicate risk of harm
  There is an obvious risk of toxicity from over-consumption of supplements (or anything else), but also risks of supplements interacting with drugs, or resulting in other adverse events. Examples were given of known interactions between certain herbal preparations and medications, and increased mortality associated with high vitamin E intakes, or with high beta-carotene intakes in smokers and ex-smokers.

Professor Young concluded by advising “food first”, i.e. that a good balanced diet is the preferred advice. However, he recognised that many patients will not follow that guidance. In recommending supplements, clinicians are advised to follow the available evidence and guidelines. At the same time, it is important to consider potential for harm, including hidden harms such as affordability, or patients using supplements in place of making appropriate dietary choices or as an alternative to conventional evidence-based treatments. Finally, he expressed his personal view that patient-initiated use of supplements may produce benefits, or at least increase sense of autonomy and self-control. The mechanism of any benefit is less important than the existence of a benefit. Clinician-initiated supplements may also lead to benefits, some of which are likely to be placebo effects.

Panel discussion (audience questions) with Professors Lovegrove and Young

Questions from the audience allowed further discussion along several lines.

- Nutrition education in medical training
  Both speakers recognised this is still not at the desired level, and there is continued effort needed to highlight why and how this can be improved. Professor Lovegrove suggested this might be better accomplished by incorporating nutrition into existing subject areas, rather than it being a separate, additional module in an already full curriculum.

- Benefits and harms of nutrient supplements
  An audience member pointed out that a distinction should be made between herbal (botanical) preparations and nutrient supplements, and that evidence of adverse events causing hospital admissions from supplements was markedly lower than for medicines. In addition, it should be acknowledged that the evidence of increased mortality from vitamin E supplements was largely derived from the specific vitamer α-tocopherol, and so may not apply to other forms of the vitamin. Professor Young agreed with these points, and that while harm (but also clinical benefit) from nutrient supplements was generally unlikely, physicians should nevertheless be aware of the possibility. He also noted that α-tocopherol was still the most prevalent form of vitamin E in supplements. He further clarified that his presentation and views were focused on evidence of clinical benefits, as opposed to intermediate markers other than established risk factors. Professor Lovegrove added that nutrient supplements will, of course, usually have a benefit for individuals deficient in specific nutrients due to inadequate intakes, but there was little evidence for

benefits from intakes above that. For vitamin D specifically, both speakers reiterated support for the recommended 10 µg/day supplement, but currently did not see evidence for benefits of intakes above this.

- What are clinicians saying to their patients and the public about health claims?
  It's uncertain what individual clinicians know and say about specific health claims to their patients. However, Professor Young noted that there are a number of medical and other regulated professionals active on social media, and not all of what is said is evidence-based or in line with his personal views. There is a diversity of opinions on many aspects of nutrition, and limited areas where the evidence leads to a clear consensus.

  Professor McArdle added that the EU (and current UK) nutrition and health claims regulations limit what can be said by registered professionals in support of products. Mr Coppens pointed out that companies are not permitted to refer to recommendations by health care professionals [HCP] in their commercial marketing, an exception being advice coming from official medical or public health bodies. [In correspondence after the meeting, this discussion was further clarified. Mr Coppens advised that HCPs should be cautious about endorsing a food within a commercial context and using their professional credentials in such wider communication to consumers. Authorities may investigate if an HCP has a financial or other gain from such communications.]

- The placebo effect
  An audience member expressed the view that a placebo effect is a belief, and belief can be part of treatment. Professor Young repeated his view that use of the placebo effect can be a perfectly legitimate approach in medical practice. He acknowledged that for example, coenzyme Q10 may act as a placebo in patients with muscle pain from statin use, but patients will benefit if that belief facilitates their continued use of an effective medicine.

- The term "nutraceutical"
  Professor Lovegrove was not in favour of the term, and felt it implied high amounts of nutrients used for a clinical benefits. However, the term perhaps also acknowledges that, like medicines, excessive amounts of nutrients can be harmful. Professor Young had a more neutral view of the term, but felt it has the potential to be misused. If it referred to a high level of a nutrient being used to achieve a pharmacological effect, then in that context they should be regulated and prescribed like other pharmaceuticals.

Dr Hayley A Young: "Who uses supplements and why? Consumer understanding, expectations, and behaviour"

Dr Young took a consumer-oriented perspective on the use of supplements. Based on the EFSA definition of food supplements (which includes nutrients as well as -biotics and herbal extracts), she drew on academic literature where available, but also data from market research, the UK Food Standards Agency and the US National Health and Nutrition Examination Survey (NHANES).

- Who uses supplements and why?
  About 60% of UK adults report using a dietary supplement in the past year, with a recent boost in intakes associated with the COVID-19 pandemic. In the US and UK, the top 3 supplements are multivitamins, ω-3 fatty acids and vitamin D. NHANES data indicate usage prevalence is higher in older individuals, females, non-Hispanic whites, and those with a higher income and educational attainment. A majority of users are at normal weight, and report very good health status and greater food security, suggesting that users in general have a better diet quality. Other, specific groups such as the military, sports

professionals, vegans and people with eating disorders also report higher use of supplements.

The main reported reasons for using supplements are to maintain or improve health, and fill perceived gaps in nutrient intakes. Further evidence from qualitative research indicates this is underpinned by a desire to have control over their health (as an insurance), and supplements offer an easily accessible way to do this without needing to see a doctor. A smaller group uses supplements just as a habit to attain specific goals such as improved appearance or sports performance. Whilst consumers express some doubts about the effectiveness of supplements, they generally do not perceive any associated risks, except for some niche products (e.g., fat burners). There is also a view that supplements may enhance the therapeutic effectiveness or relieve side effects of medicines. However, consumers are generally unaware of potential interactions between dietary supplements and medications, and very few worry about the risk of consuming too much of a particular nutrient.

- Consumer understanding of regulations and claims
  Consumers in general don't give much thought to the regulations relating to dietary supplements, and may infer assurance of safety and efficacy from their legal sale, even where disclaimers are present on the label. While many express interest in health-related claims and symbols, there is nevertheless low trust in claims which may be seen as pure marketing.

  Dr Young noted that there are a number of aspects to consider in relation to how different claims, labels and symbols may be understood and their potential influences on consumer behaviours. It is a challenge for wording to be easily understood but yet justified, and also limit the potential for consumers to make inaccurate inferences about product health benefits. There is also a risk that the information may have unintended consequences on food intake or perceptions of product quality. An EU-funded project, CLYMBOL (Role of health-related claims and symbols in consumer behaviour) found that consumers did not tend to think about or categorise claims in the same way as regulators. Furthermore, attention to claims was often limited, and a function of individual health goals (relevance) and nutrition knowledge.

- Where do consumers get their information?
  A majority of consumer access the internet for health-related information. This includes targeted searches, but also social media endorsements. Most looked for information, particularly on efficacy and side effects, before buying dietary supplements. Recommendations (e.g., from healthcare or fitness professionals and/or friends and family) were also a key driver.

In summary, Dr Young presented a general framework of how information interacts with individual and product characteristics and the purchase context, to drive consumer understanding and inferences about safety and effectiveness, and ultimately behaviour. A number of gaps and challenges and gaps in consumer understanding were highlighted. These include shortcomings in the quality and timeliness of data on the number and nature of dietary supplements, and a lack of consistency and depth in the available consumer research.

Overall, there is an apparent disconnect between likely effectiveness and consumption rates: those most likely to take supplements are the least likely to benefit. Particular concerns were noted around the assumption that supplements are benign, lack of understanding about potential interactions with medications, and use of more 'risky' supplements or combinations.

Most related research has focused on packaged foods not supplements, but this shows that consumers struggle to understand claims.

The presentation ended with a future outlook and recommendations. A key point is the need for education to increase consumer nutrition knowledge and understanding. This may be facilitated by increased availability of accessible and reliable information, such as the National Institutes of Health Office of Dietary Supplements. There are also new supplements emerging where consumer understanding is limited, such as the growing market for products containing cannabidiol (CBD), and few consumers are aware that it is classified as a 'novel food'.

Dr David Mela: "'Functional' and 'super' foods: Land of hopes and stories?"

Dr Mela began with a general scheme outlining the concepts of "superfoods" and "functional foods", noting that these terms have no agreed definitions. "Superfoods" are usually whole foods or ingredients deemed (by someone) to be beneficial for health because of their naturally high levels of particular nutrients or other bioactive components. In contrast, "functional foods" is usually describing manufactured foods that have been specifically formulated to contain added nutrients or other putative bioactive components ("functional ingredients") intended to enhance the health benefits of the product.

- Superfoods
  While there is no standard or defining criteria for a "superfood", the designation is often underpinned by the presence of antioxidants, minerals, vitamins, fibres, flavonoids or 'healthy' fats. Examples were shown of lists of "top 10 superfoods" from different sources. These lists typically included berries, seeds/nuts and cruciferous vegetables, but there was limited overlap and no single food appeared on every list.

  Dr Mela showed where there may be inconsistencies and potential sources of consumers confusion around "superfoods". Although popular media, social influencers and blogs may promote specific foods as "superfoods", the UK Advertising Standards Agency has determined this would be a (regulated) general health claim if used by companies to market commercial products. The term can therefore only be used in that commercial context if it is accompanied by an authorised, specific health claim (see Article 10(3) under Regulation (EC) No 1924/2006 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1924-20141213). The example was shown of popular media calling black pudding a "superfood", while the same term was not permitted to be used on a commercial brand of ready-to-eat salad. This limitation would not apply to non-commercial uses, such as recipes for a "superfood salad". Examples were also given of commercial products that were not specifically marketed as "superfoods" but claimed to be *made from* "superfoods", or were being sold under a general "Superfood" heading or category by (e-)retailers. In short, the term "superfood" seems to be flexible in application, and its use driven more by popular opinion and promotion than clearly grounded science.

- Functional foods (FF)
  Dr Mela gave his own definition of FF as "Food compositions purposefully designed, substantiated and marketed for specific, additional health benefits". He noted that, although some of the early excitement and investment in FF had declined, there is still a continuous stream of research and publicity about possible new FF ingredients. However, very few of these ever result in a commercially viable FF with substantiated claims, and a large gap exists between the 'promise' and reality of FF.

In many cases, FF R&D activities have been driven forward by over-optimism, from selective reading of literature, over-extrapolation of *in vitro* or biomarker evidence, and sometimes-dubious clinical trial data (e.g. Table 2 from Mela, 2007). He described a wide range of quality issues he had observed in FF research, from inappropriate research designs and materials to flawed analyses and interpretation. Whether intentional or not, these forces have often led to misleading results or communication, and a continued interest rather than a killing-off of ineffective concepts. He estimated that probably <1 in 300 FF ideas would ever result in a new product innovation with substantiated claims, and the cost of this entire process as 20-50+ MEuro. Moreover, substantiation of functional ingredient efficacy is not the only hurdle to commercial viability. Other criteria such as safety, sourcing, sensory, stability, cost, and a suitable food vehicle have to be met. Together, this may explain why so few FF products with claims based on 'new' functional ingredients (i.e. other than established nutrients) have ultimately appeared on the European market.

He concluded with examples of publications from his personal experience in industry, documenting several promising FF concepts that failed to be substantiated in well-designed human trials. There were also some examples of successes, but none that had resulted in a marketed FF product at that time.

In summary, Dr Mela reiterated that "superfoods" have no agreed definition or criteria. In judging these, it was important to consider the total composition of the food and its role in the diet. When used on-pack in commercial foods, "superfood" is a claim requiring substantiation. "Functional foods" also have no agreed definition. Claims of FF health benefits require explicit substantiation. New, truly 'functional' ingredients with authorised claims were generally rare, costly to bring to market and had a high R&D failure rate.

Panel discussion (audience questions) with Drs Young and Mela

- Educating consumers
  Several discussion points were raised around how and where consumers might be educated to better understand and make more informed choices about supplements and diet more generally. Dr Young advised that, for consumers as well as health professionals, the US National Institutes of Health Dietary Supplement Label Database (https://ods.od.nih.gov/Research/Dietary_Supplement_Label_Database.aspx) contains a wealth of readily-accessible information on supplements. She stressed that for nutrition education more generally, a key aspect was directing consumers to reliable information sources (rather than e.g. social influencers or sellers' own websites).

  Both speakers supported and encouraged ongoing efforts of professional organisations and universities to be pro-active source of nutrition communications, and to act as authoritative resources for media, social influencers and consumers. However, it was also acknowledged that these organisations would only be a small contributor to the totality of what consumers hear ("the noise") about nutrition. This may also be seen as part of a wider general issue of science education, and the ability of consumers to judge different information sources and seek out those with more recognised authority. Dr Young further added that this process is not just about helping consumers understand the science, but also would benefit from engagement to help scientists better understand and communicate with consumers.

  Professor Lovegrove commented that identifying trusted sources of nutrition information is more difficult while anyone can call themselves a "nutritionist". In the UK, the voluntary

register of the Association for Nutrition (https://www.associationfornutrition.org/) is a step forward, and part of ongoing efforts to make nutrition a chartered profession. This and other measures can help consumers and also the media to identify trustworthy authorities and distinguish their views from others who may be less qualified.

- "Natural" vs synthetic/processed foods
  A question was raised about the relevance of "natural" or whole foods vs synthetic ingredients as a basis for FF and supplements. Dr Mela recognised that there has been considerable recent debate and consumer uncertainty about (ultra-)processed foods, and it was almost inevitable that most FF and supplements would be industrial products. However, he suggested that the consumers focused on 'natural' products and those buying FF or supplements may be different groups. Furthermore, being "natural" or "intact" vs a manufactured food or synthetic ingredient does not by itself tell you what is better or worse. Dr Young added that terms like "natural" in marketing carry a halo effect, whereby people may assume a product is healthier.

- Concerns about industry-funding of research
  A question was raised as to how scientists can stay impartial when research support comes increasingly from industry, and how industry-driven research can be trusted. Dr Mela responded that he has seen poor quality research with academic as well as industry funding, but in the past decade the quality of industry research in nutrition, certainly from larger manufacturers, has often exceeded that of purely academic research. Ultimately one has to judge the quality of the science itself, not who funded it. Dr Stowell commented that companies generally had a strong interest in getting to the truth, and not investing further in routes which would fail later. Dr Mela also reiterated this with the mantra "fail early, fail cheap", i.e. that large companies with broad portfolios ultimately did not benefit from investments based on unsound science or misleading results.

  Professor Lovegrove commented that publication of all the research and data, including "negative" results, was crucial to addressing presumptions of bias in industrial collaborations. Professor McArdle, however, noted this was not always possible; that data from some industry-funded research may be kept proprietary and unpublished, unlike research which was publicly funded. A member of the audience expressed a further concern about industry-driven research, that work with potential public health relevance may not be pursued if it does not also lead to commercial opportunities.

Closing remarks

Dr Gibson closed the meeting by thanking the speakers, chairs and audience for their contributions to a successful event.

Acknowledgements and funding

The authors thank the staff of the Royal Society of Medicine for their important role in developing, promoting, organising and facilitating the event. Support for the meeting from the Sabri Ülker Foundation (www.sabriulkerfoundation.org/en) is gratefully acknowledged. Neither the authors nor any of the speakers received any form of remuneration for their participation in this event, other than accommodation if needed, and reimbursement of actual travel costs. Opinions expressed here are those of the individual speakers.

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Appendix: Event programme

"Dietary supplements, 'functional' and 'super' foods: Science, regulations and roles in the diet". Royal Society of Medicine, London, 29 November 2022

Welcome and introduction

- Dr Leigh Gibson, President, Food and Health Section, Royal Society of Medicine

Morning session (Chair: Dr Hayley Young)

An overview of the regulatory environment

- Mr Patrick Coppens, Director of Scientific and Regulatory Affairs, Food Supplements Europe

Risk assessment and risk-benefit assessment in food safety and nutrition

- Professor Hans Verhagen, Owner, Food Safety and Nutrition Consultancy

Assessing potential health and nutrition claims: What evidence is required?

- Professor Harry McArdle, Emeritus Professor, Rowett Research Institute, University of Aberdeen

Using authorised health and nutrition claims: Examples of use and mis-use in the market

- Mr Frans van der Sman, Consultant, Scoring Solutions

Afternoon session (Chair: Dr Tatiana Christides)

The potential role of food supplements in public health and restrictive diets

- Professor Julie Lovegrove, Director, Hugh Sinclair Chair in Human Nutrition, University of Reading

Guidance and experience on supplement use in clinical practice

- Professor Ian Young, Clinical Professor, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast

Who uses supplements and why? Consumer understanding, expectations, and behaviour

- Dr Hayley Young, Associate Professor, School of Psychology, Swansea University

"Functional" and "super" foods: Land of hopes and stories?

- Dr David Mela, Independent nutrition scientist

Closing remarks

- Dr Leigh Gibson