## Ensuring the Future of Functional Foods

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Introduction:

This review evaluates some of the latest research published over the last two years into functional food development with an emphasis on the development of baked goods such as bread, cakes, biscuits and crackers. The popularity of these products continues to grow on a global scale as consumers are looking for the convenience of nutritional snack products that fit their lifestyle. The drivers of consumer choice will be highlighted as defining characteristics into purchasing behaviour. Finally, the review will pose research questions that need to be addressed to maintain a buoyant future for the functional food industry.

A food can be regarded as functional if it is satisfactorily demonstrated to have a beneficial effect on one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either improved state of health and well-being and/or a reduction of disease risk (Batista et al., 2013, Paliwal et al., 2016). Diet is considered to be closely linked with a range of disease conditions and with significant age-related chronic disease states (Manach et al., 2017, Padayachee et al., 2017, Shlisky et al., 2017), therefore functional foods containing beneficial health related compounds have become a major focus for researchers and the food industry.

Consumers are increasingly seeking holistic solutions to help prevent chronic illness and optimise health (Khan et al., 2013). This had led to the emergence of a new market segment in functional food products that is growing by approximately 10% per year. It is estimated that by 2020 the global functional food market will be worth $192 billion US dollars (Euromonitor 2016). A recent review by Kaur & Singh (2017) indicated that a high level of education and high income greatly influence consumer uptake of these products, as well as an increased personal health consciousness. Price, taste, health claims, packaging and branding, as well as sensory attributes, also influence consumer behaviour and adoption practices (Kaur and Singh 2017). Furthermore, early adopters of these products tend to be younger health conscious consumers, that may be partly influenced by social
media channels and food ‘naturalness’ (Puhakka et al., 2018, Kraus et al., 2017, Bimbo et al., 2017, Román et al., 2017).

Fragmentation and complexity of consumer beliefs about food and health is a substantial defining trend within the functional food and nutraceutical market (Egan et al., 2017). It is partly driven by technology as consumers can now search for information regarding products on mobile devices and for information about diet and health, in addition this technology allows for small brands to reach consumers and drive sales without the need for multi-million pound marketing budgets. This trend is partly driven by conflicting information given by health experts which has led to a loss of trust in expert opinion, especially among adolescents (Rendahl et al., 2017). The single, most powerful trend in today’s marketplace is consumers’ desire for foods and ingredients that are ‘naturally functional’ (Hunter and Hegele 2017, Mirosa and Mangan-Walker 2018, Song and Im 2018). This growing trend underpins the success of almost all food developments. It is the key driver of most innovation in healthier food and beverages, from plant-based foods and beverages to the re-emergence of full-fat dairy, the rise of green juices, blueberries, almonds, seaweed/algae and snacking products (Puhakka et al., 2018, Tanna and Mishra 2018). A natural and intrinsic health benefit offers the most compelling message.

Within this field of functional food development it is worth noting the growth of published research studies over the past few years. Figure 1 shows the growth of published research since 2006 – to date, the ascendant number of publications is clearly shown indicating a consistent increase in scientific interest in development of these products, however within this landscape it is of particular interest that the growth of in vitro studies and defined clinical trials have not kept pace with the number of publications. Peer reviewed publications addressing functional food development have also grown by over 350% since 2006, indicating a consistent increase in scientific interest in development of these products.

Eight key market trends appear to be driving activity and growth in the functional food market:
(1) Marketplace convergence of range of categories; (2) Accelerated growth of functional foods and beverages; (3) Cobranding partnerships between ingredient suppliers and manufacturers; (4) Increased focus on science and claims validation; (5) Growing demand for sustainable and eco-friendly products; (6) Expansion of active nutrition products as consumers become more health conscious; (7) Emergence and popularity of innovative dosage and delivery forms; (8) Rise of the millennials and a new paradigm on health and wellness (Hilton 2017).

Rising awareness of health related benefits of good nutrition with the inclusion of functional foods has, in part, driven the rise in consumption of these products. Since the concept of functional food was first developed in the 1980s in Japan, where initial regulatory systems were devised (Food for Specified Health Uses; FOSHU), various countries have adopted different concepts of functional foods in terms of definition, scope and regulatory frameworks. However, no single universally accepted definition currently exists (Kaur and Singh 2017). A modified table of FOSHU criteria is presented in Table 1. Functional food can be further classified as natural products (for example fruit and vegetables); altered products (for example whole grains and fibre); fortified products (such as vitamin and mineral addition); enriched products (such as probiotics) or enhanced products (for example eggs with increased omega-3 fatty acids or salmon with increased beneficial fatty acids), (Kaur and Singh 2017). In 2015 Japan launched a food labelling system ‘Foods with Functional Claims’ (FFC) within this industry and agricultural producers independently evaluate scientific evidence towards health claims to promote informed use by consumers (Maeda-Yamamoto 2017).

Intervention strategies that may alleviate pathological conditions and control risk factors through dietary improvement and positive lifestyle changes have the potential to improve overall wellbeing. Plant sterols and stanols (Jones et al., 2018); monacolin K (Castelnuovo et al., 2018, Mazza et al., 2018a, Mazza et al., 2018b), red yeast rice (Cicero 2018) and beta glucans (Tamura et al., 2017, Stancu et al., 2017, Tessari and Lante 2017, Suchecka et al., 2017), have been shown to reduce plasma cholesterol. Modification of plasma LDL-cholesterol is causally associated with cardiovascular...
risk factors (Berryman et al., 2017, Gisterå and Hansson 2017, Poli et al., 2018). These compounds can inhibit the intestinal absorption of cholesterol from both food and bile in a dose-dependent manner (Poli et al., 2018), however, phytosterols also reduce absorption of carotenoids and fat-soluble vitamins. Beta-glucans can also positively influence glycaemic index levels and have a prebiotic effect by increasing the diversity of bacterial strains in the gut microbiota (Makki et al., 2018, Jayachandran et al., 2018). They are classed as a pre-pharmacological interventions based on their serum lipid lowering capabilities, positive effect on lowering the risk of diabetes and reducing cardiovascular risk factors (Kristek et al., Wang et al., 2017, Wolever et al., 2018).

These products are sometimes referred to as nutraceuticals and are classed as a pre-pharmacological interventions. The term nutraceutical, a syncretic neologism of the words nutrient and pharmaceutical (O’Connor 2017), was originally coined by Stephen DeFelice (1995), who defined nutraceuticals as “food or part of a food that provides medical or health benefits, including the prevention and/or treatment of a disease” (DeFelice 1995). Currently, nutraceuticals have no specific definition in regulatory terms. Further studies are required into the mechanisms of action of pharmaceutically active compounds contained in food that may have the potential to improve health and reduce the risk of pathological conditions. However, the claimed health benefits may not be properly substantiated by safety and efficacy information or in vitro and in vivo data, which can prompt false expectations of a product. Nutraceuticals exist in in the grey area between pharmaceuticals, food supplements and food (Santini et al., 2018).

Clinical trials to test the efficacy of functional food products in disease amelioration or for enhanced nutrition are limited by the considerable financial investment required. Furthermore, the criteria for interventional clinical trials of functional foods also provide significant challenges, not least in obtaining ethical approval for studies on participants with diagnosed disease states. Additionally, government regulatory bodies and health and safety agencies require stringent conditions to be met including, double-blinded; randomised; placebo-controlled, wash-out periods, cross-over studies and
complex inclusion and exclusion criteria (Brown et al., 2018). Some of the unique challenges presented to food companies when developing clinical trials are summarised in Table 2.

For consumers unfamiliar with the concept of functional foods, one product range that has in recent years become ubiquitous in the marketplace are prebiotics and probiotics, the most common category range is easy-drinking type yoghurts (Mishra et al., 2018). These products have a growing strong scientific basis of positive health effects on gut health directly through dietary modulation of the human gut microbiota (Sánchez et al., 2017). Many probiotics were originally isolated from the gastrointestinal tract, and they were defined by the Food and Agriculture Organization of the United Nations (FAO)/WHO as “live microorganisms which when administered in adequate amounts confer a health benefit on the host.” (FAO/WHO 2001).

Prebiotics:

The International Scientific Association for Probiotics and Prebiotics convened in 2016 to review the definition and scope of prebiotics. Consistent with the original example of prebiotics exploiting the latest scientific and clinical developments, the panel updated the definition of a prebiotic: “a substrate that is selectively utilized by host microorganisms conferring a health benefit.” This definition expands the concept of prebiotics to possibly include non-carbohydrate substances, applications to body sites other than the gastrointestinal tract and diverse categories other than food. The requirement for selective microbiota-mediated mechanisms was retained. Beneficial health effects must be documented for a substance to be considered a prebiotic (Gibson et al., 2017). The Gibson et al (2017) definition expands the concept of prebiotics to include non-carbohydrate compounds as potential substrates for beneficial bacterial strains. Beneficial health effects must be scientifically validated for a substrate to be considered a prebiotic. Ultimately, the goal of this Consensus Statement within the definition of prebiotics is to prompt appropriate use of the term 'prebiotic' by relevant stakeholders so that consistency and clarity can be achieved in
research reports, product marketing and regulatory oversight of the category (Gibson et al., 2017).

Prebiotics are recognized for their ability to manipulate host microbiota to the benefit of the host (Gibson et al., 2017). Currently fructans (Ahmad and Khalid 2018, Bajury et al., 2018, Joshi et al., 2018), inulin (Ahmadi et al., 2018, Fu et al., 2018, Heydari et al., 2018) and galactans (Cremon et al., 2018, Fehlbaum et al., 2018, Ndeh and Gilbert 2018), fit this definition of prebiotics. Prebiotic products have a strong science background from positive clinical trials but have yet to obtain regulator-approved health claims from the European Food Safety Authority (EFSA) in Europe.

**Probiotics**

These products are successfully marketed to older consumers who have either had a diagnosis of high cholesterol or who may be clinically prescribed pharmaceutical cholesterol lowering agents such as statins (Köhler et al., 2017, Yang et al., 2018, Scolaro et al., 2018, Poli et al., 2018). Plant stanol products are also attractive to consumers who want to maintain a healthy lifestyle regardless of a clinical diagnosis of potential cardiovascular risk factors. These products are not directly marketed to younger consumers who may consider them irrelevant to their lifestyle and age group.

Probiotics are the fastest growing group of dietary functional food supplements world-wide (Champagne et al., 2018). These products known as probiotic supplements have been extensively studied over recent years, indicative benefits have been reported such as their ability to neutralise toxins (Corbo et al., 2018); good sensory characteristics when microencapsulated (Mokhtari et al., 2017) and superior survival and transition through the gut (Campaniello et al., 2018). They have also been developed with a range of fortification approaches to further improve health benefits, such as the addition of linoleic acid (Abd El-Salam et al., 2011); green tea fortified with soy (Moumita et al., 2018); supplemented with Vitamin D as an aid to weight loss (Mohammadi-Sartang et al., 2018); added to fruit juices (Ephrem et al., 2018) and as an adjuvant or a prophylactic therapy in cancer treatment (Serna-Thome et al., 2018, Wardill et al., 2018).
Predicted sales of probiotic supplements are US$ 96 billion by 2020 (Statistica 2018). As well as yoghurt-type products, these probiotics can be found in cheese, fruit juices and cereal products (Kumar et al., 2015). These probiotic products are marketed to all consumer groups as an aid to improved digestive health. In order for these products to be successful in improving gut health, survival of the bacterial strains ingested must be shown to be able to survive transit through the gut where they can exert a beneficial effect. A recent study by Santarmaki et al., (2017), showed that *Lactobacillus planetarium* increased total IgG while decreased IgM and IgA serum levels. The strain of bacteria survived transit through the gastrointestinal tract for 24 hours, exhibited transient distinct adhesion to the intestinal mucosa and modulated the systemic immune response. Another study undertaken by Moumita et al., (2017), showed that lactic acid bacteria (LAB) in free and encapsulated forms exhibited tolerance towards stress conditions and encapsulation was found to protect the bacteria and enhance their survival. There was 72%–87% survivability of bacteria in symbiotic microcapsules after storage in a dry food matrix.

Various strategies have been developed to aid survival of these probiotics through the gut that mainly focus on the use of microencapsulation techniques using biopolymers that are formulated to resist the acidic environment of the stomach (Ramos et al., 2018, Eshrati et al., 2018). Consumers’ quest for ‘digestive wellness’, although this remains a complex concept as ‘wellness’ may have different meanings to individuals. Nevertheless, ‘digestive wellness’ or ‘digestive health’ remains a big driver of new opportunities for businesses large and small in product development. The rise of probiotic dairy, gluten-free and lactose-free dairy and plant milk is all driven by consumers looking to avoid digestive problems and has led to a disjointed market for these products as consumers do not fully understand if these products will actually be of benefit to them (Hill et al., 2014). Furthermore, the research on nutrition, health and disease risk reduction claims indicates a lack of consensus as to whether these claims have a positive or negative effect on consumer preferences and purchasing behaviour (Sarkar 2018, Steinhauser and Hamm 2018).
Postbiotics

A further emerging field within functional food development is the concept of postbiotics (Aguilar-Toalá et al., 2018). It is currently claimed that probiotics can modulate gut microbiota, improvement of the epithelial lining barrier function in the gut and modulation of the immune system leading to a positive effect in the microbiome (Azad et al., 2018, Ost and Round 2018, Nuñez et al., 2017, Schnupf et al., 2018) and in both sexes (Rizzetto et al., 2018). Postbiotics, also referred to as ‘parabiotics’ are claimed to be inactivated probiotics or ‘ghost probiotics’ and refer to non-viable bacterial cells, furthermore they can be comprised of whole-cell or cell-free extracts, purified cell wall components or culture supernatant administered in the same way as probiotics, these postbiotics have shown significant immunomodulatory effects (Aguilar-Toalá et al., 2018). It is also postulated that these postbiotics may hold safety advantages as risk of infection or enhanced inflammatory responses may be reduced in consumers with already compromised immune systems (Korpela 2018, Rodiño-Janeiro et al., 2018, Rout et al., 2018).

These postbiotics have been shown to possess different functional properties including systemic effects such as antioxidant, hypocholesterolemic, antihypertensive, antiobesogenic and hepatoprotective properties through modulation of the immune system (Aguilar-Toalá et al., 2018, Rodiño-Janeiro et al., 2018, Korpela 2018, de Almada et al., 2016, Pojić et al., 2018). These postbiotics could be an interesting alternative strategy for use in functional food products as they have a favourable safety profile as there is reduced opportunity for antibiotic resistance genes to be passed via horizontal transfer mechanisms that can occur in some probiotic strains (Imperial and Ibaña 2016, Taverniti and Guglielmetti 2011). Is it then possible that probiotic strains that do not survive intestinal transit because of the high acidic environment of the stomach, have the ability to become postbiotics and still exert a beneficial effect on the gastrointestinal tract perhaps by a completely
different biologically mechanism? It is evident that more research is needed into this area of postbiotics.

**Baked Goods as Functional Foods**

There is a considerable body of scientific evidence on the development of baked goods as a vehicle for development of functional food products. These products range from bread; biscuits; cakes; cookies; snack bars and dry crackers. The popularity of these products continues to grow on a global scale as consumers are looking for convenience of nutritional snack products that fit their lifestyle. The range of products entering the marketplace continues to show rapid expansion and is providing consumers with a range of ingredients and formulations that combines the benefit of fast-snacks with health and satiety. This rise in popularity for ‘on-the-go’ products has in part been dominated by changes in consumer habits, social environment and lifestyle choice (König *et al.,* 2017). The multipurpose function and convenience of snacks can match the consumer quest for time-efficiency if they omit traditional mealtimes while still eating nutrient dense products (Hess and Slavin 2017).

Baked goods are consumed globally and sales as well as the range of products, are increasing. The most common form of wheat used in the bakery industry is (*Triticum aestivum* L.) and was the world’s most abundant crop in 2014 with an estimated production of 730 million tons. Used as a major staple food for centuries across the globe for mostly bread making, bread provides a rich source of carbohydrates and protein supplying approximately 20% to total dietary protein per day (Arzani and Ashraf 2017). On average Europeans consume 50kg of bread per person per year or approximately 137g per day (Kourkouta *et al.,* 2017). However, market dynamics are changing with a growing demand for healthier baked goods and functional products combined with a growing trend in snacking and ‘food-to-go’ categories, forecast to increase by 5.8% per year globally (Martínez-Monzó *et al.,* 2013). The growing trend of artisan bakeries, coupled with high *per capita* consumption of bakery products is what drives the expansion of the baked goods market. The growing population in countries such as China and India indicate that these are becoming a major market for baked products and bakery ingredients.
Over the past few years there has been an increase in research into functionalised bakery products using a variety of approaches to improve the nutritional quality of these products. This is being achieved by encapsulation techniques for sensitive bioactive compounds or by substitution strategies to replace wheat flour with a range of fruit or vegetable by-products that are rich in nutrients and extra nutritional compounds that can contribute to overall health status (Gómez and Martinez 2017). Encapsulation techniques involve coating the compound of interest with a range of materials usually comprised of lipids, carbohydrates, biopolymers or proteins. Nanoencapsulation protocols involves the incorporation of natural bioactive substances, such as volatile additives; polyphenols; aromas; vitamins, enzymes, oils and antimicrobial compounds into nano-sized capsules to protect the cargo or mask flavours and aromas, that aim to deliver these compounds to target sites within the body. These technological advancements provide opportunities for higher stability and retention for targeted delivery and release efficiency (Akhavan et al., 2018). Reformulation of food products brings technical challenges in product formulation that have to be acceptable to consumers. The greatest influence on consumer acceptability is determined by sweetness, hardness, cohesiveness and moistness as the decisive factors (Morales et al., 2015). Concerns still remain over the fate and behaviour of nano-sized particles in the human body as limited published studies exist. Long-term studies need to be undertaken for evaluation of potential toxicology or bioaccumulation that theoretically could be detrimental in human systems (Temelli 2018, Recharla et al., 2017, Shishir et al., 2018, Wang et al., 2018).

Dietary fibre plays an important role in digestive health and regulation of intestinal transit time. Fibre extracted from waste valorisation of fruit and vegetables by-products have potential use in supplementation regimes in a range of functional food bakery products. Martins et al., (2017) found that wheat bread fortified with extracts of orange, elderberry and pomegranate extract increased the essential mineral content and bioaccessibility. However, the inclusion of pomegranate decreased
in mineral bioavailability. Functional bread and bakery products enhanced with bioactive compounds could help in fortification strategies of the elderly and help to enhance the absorption of nutrients (Amoah et al., 2018). Lesinski et al., (2015) found that soy isoflavones decrease markers of inflammation and could be a novel approach to address chronic nutrition related disease states.

Table 3 gives an overview of some of the latest fortification and supplementation strategies employed to enhance the functional properties of a range of baked goods. Some interesting examples include: Jarpa-Parra (2018) in a study on the use of lentil protein as an egg and milk replacer in cake and muffins. Whilst lentil protein is a good sustainable crop source, overall these products had a lower consumer acceptability and Aider et al., (2012) found that lentil was not successful in bread formulation. Lentil is a good source of dietary fibre, vitamins and minerals and a range of micronutrients, that have been demonstrated to have cholesterol and lipid lowering qualities (Jarpa-Parra et al., 2017). Notwithstanding the positive health benefits of lentil, there is some concern that lentil could cause IgE mediated allergic hypersensitivity and may not be optimally bioavailable (Jarpa-Parra 2018). A study by Plazzotta et al., (2018) incorporated lettuce waste dried into a flour for incorporation into bread. It has been estimated that up to 40% of lettuce biomass produced is wasted and is therefore a potentially valuable sustainable resource. When used as a partial replacement for wheat flour, the resulting product had an overall organoleptic acceptability with consumers. It was also found that air-drying lettuce waste promoted oxidation of phenolic compounds. Furthermore, lettuce contains high insoluble dietary fibre which as previously reported can have beneficial effects on gut health.

Recent research into the use of broccoli waste materials undertaken by Lafarga et al., (2018 In press) and Krupa-Kozak et al., (2018 In press), showed a distinct lack of consumer acceptance when used in a sponge cake, possibly due to the strong aftertaste. Although broccoli is high in compounds such as
glucosinolates which can have an anticarcinogenic effect, the product taste must be a defining
positive characteristic otherwise consumers will reject these innovative developments.

Recently, there has been renewed interested in edible insects as a valuable source of protein
(Churchward-Venne et al., 2017, van Huis 2017, Sinem Atakan and Wansink 2018). However,
Osimani et al., (2018) found low consumer acceptance and negative technical features when
incorporated into bread in a group that were used to eating insects. Furthermore, there were health
concerns that insect protein carries spore forming bacteria that is a potential safety issue. In further
studies on insect protein Sinem Atakan and Wansink (2018), identified IgE binding cross-reactivity
that was of concern. Schlüter et al., (2017), identified toxic substances, pathogens and heat-resistant
thiaminase that was responsible for ataxic syndrome. Additionally, antinutrients have been
identified in insect protein, including hydrocyanide, oxalate, phytate and tannins (Schlüter et al.,
2017). It is clear that further research should be undertaken into the safety aspects of incorporating
insect protein into food products and that strict regulatory processes should be implemented.

Fortification with microalgal materials

A rapidly growing sector within the functional foods market is in the use of microalgal protein that
has been incorporated into a wide range of food products. As a high-protein alternative, microalgae
have been identified as being able to partially replace animal derived protein in the diet and are a
reliable source of beneficial compounds by careful optimisation of culture conditions (Jeon et al.,
2014, Jung et al., 2016). Microalgae have been consumed as a traditional food source for
generations across Asia and Africa, in the USA consumption is generally limited to dietary
supplements and microalgal-derived nutraceutical products are generally recognised as safe (GRAS);
(Szabo et al., 2013). Furthermore, they have been shown to have low allergenic potential (Szabo et
al., 2013) and are known to be absorbed into the gastrointestinal system in the aqueous phase (Read
et al., 2015). Microalgae are known to contain a diverse range of biologically active compounds
including: essential amino acids; dietary fibre; fatty acids; minerals; phenolic compounds and
vitamins as well as α- and β-carotene (Machu et al., 2015, Rodrigues-Bernaldo de Quiros et al., 2010, Deli et al., 2014).

Microalgae may be a suitable alternative to animal derived products in various religious groups or specialised diets, as an example, the Hindu diet predominately follows a lacto-vegetarian diet and microalgae could therefore be a suitable protein addition or replacement. In addition to microalgae containing a high protein content, they are also high in antioxidants, phenolic compounds and vitamins (Dubey 2015, Watanabe et al., 2014, Machu et al., 2015); vitamins; essential amino acids; polyunsaturated fatty acids; minerals; carotenoids; enzymes; peptides and fibre (Matos et al., 2017).

Importantly, microalgae contain high levels of the carotenoid lutein (Chen et al., 2018).

It is reported that microalgae can contain 0.5 – 1.2% lutein content (Lin et al., 2015a). Lutein has been reported to ameliorate age-related macular degeneration (AMD), which is ranked as the 3rd most common cause of visual impairment and blindness globally (WHO 2015) and contribute to brain development and function (Erdman et al., 2015), is positively associated with temporal processing speed (Bovier et al., 2014) and protection of vulnerable neural tissue against oxidative stress (Stringham and Stringham 2015). Lutein is a xanthophyll and is synthesized by plants and microalgae in high quantities as fatty-acid esters and can protect the macula from photo-induced free radical induced blue light damage by protecting the photoreceptors in the eye against oxidative damage (Lin et al., 2015b, Nwachukwu et al., 2016). The selection of defined microalgal species with balanced nutritional profiles is a fundamental requirement for successful inclusion in novel functional food development (Batista et al., 2013). In addition to health benefits, microalgae containing high levels of valuable carotenoids which also exhibit antioxidative effects and could successfully be used in food processing to prevent oxidation especially of saturated, monosaturated and polyunsaturated fatty acids (Viegas et al., 2015).

Microalgal fats contain polyunsaturated fatty acids such as polyunsaturated fatty acids (PUFAs) with high market value (Udayan et al., 2017, Chen et al., 2018, Gateau et al., 2017), such as
eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), gamma linolenic acid (GLA) and arachidonic acid (AA), these PUFAs encompass both ω-3 and ω-6 fatty acids that are commonly associated with fish oil (Schlotterbeck et al., 2018, Schmid et al., 2018, Scrimgeour and Traynor 2017, Steinrücken et al., 2017). However, fish do not produce these fatty acids, they accumulate these oils through their diet of plankton and microalgae and should therefore be acceptable to vegan diets (Koller et al., 2014), furthermore, a commonly used microalgal species, Chlorella sp. do not produce toxins and are deemed safe for human consumption (Enzing et al., 2014). Interestingly, as an example of an enhanced food product, Lemahieu et al., (2017), published a study where microalgal feed supplementation was fed to chicken to enrich eggs with Omega-3 fatty acids.

There is considerable evidence for the health benefits of microalgal-derived food products, but there remain significant challenges in quantifying these benefits, as well as possible detrimental adverse effects. One concern is in quantifying which fractions of microalgal biomass are bioavailable to humans and which aspects influence how food constituents are released into the body, ranging from food preparation through genetic differentiation in the gut microbiome (Wells et al., 2017).

Recently, baked goods ranging from bread, biscuits, cookies, muffins and cake products have successfully incorporated microalgal proteins either as egg replacers or to boost protein and bioactive content (Batista et al., 2017, Graça et al., 2018, Hossain et al., 2017, Matos et al., 2017). A recent study by Hossain et al., (2017) incorporated Haematococcus pluvialis into cookies. This species of microalgae has a high concentration of astaxanthin implicated in cardiovascular health. The study also indicated that this species of microalgae also reduced the glycaemic response and had acceptable sensory characteristics. Conversely, Graça et al., (2018) used Chlorella vulgaris at an incorporation rate of 3%, although the technological properties such as gluten network and water retention were good, consumer preferences indicated a strong marine taste that scored negatively.
All microalgae present functional and technological properties and have recently shown encouraging antimicrobial properties (Graça et al., 2018). Species such as *Spirulina* and *Chlorella vulgaris* have been utilised for centuries, especially within Asian populations. However, incorporation of microalgal biomass into food products also has technological challenges, such as acceptable sensory profiles to address to enable future food products to become mainstream in the wider marketplace.

**Discussion**

It has been 20 years since the first functional food product with a health claim was launched; spreads supplemented with plant sterol esters that had been shown to lower serum cholesterol by up to 12% (Jones et al., 2018, Lestiani et al., 2018, Baumgartner et al., 2017). However, consumers want products that directly relate to them or their lifestyle that also may confer some health benefit. Within this scenario, consumers are often confused by health messages and the often overwhelming advice available through social media platforms. For many consumers the notion that they have unique nutritional needs has also driven the move towards personalised diets. However, as new information becomes available on nutrition and the benefits of new functional food products, they are more likely to become early adopters of new products if they think that these products are directly relevant to them and their lifestyle. The diversity of consumer beliefs about food and health are a substantial defining force. It is causing markets to fragment leading to a proliferation of new niche sectors and new brands to serve them, this can directly influence opportunity for product developers and entrepreneurially-minded companies (Thøgersen 2017, Ghvanidze et al., 2017, Her and Seo 2017, Buhrau and Ozturk 2018).

One group of consumers that are frequently overlooked and could arguably benefit significantly from functional food supplements are the elderly. Under-nutrition is a common feature in this group and in particular of those hospitalised (Mills et al., 2018). This group of patients can require complex intervention strategies to improve their nutritional status as it is estimated that approximately 44% of hospitalised elderly worldwide are nutritionally deficient (Mills et al., 2018), this can additionally
lead to increased recovery time and a potentially further decline in health status. One proposed stratagem to help increase nutritional status of the malnourished elderly is the provision of energy and protein dense meals. Fortification or supplementation with high calorie enriched snack products or protein enriched breads and biscuits may help alleviate poor appetite, as older people are also subject to a gradual decline in taste sensitivity and appetite due to physiological changes with age (Yamashita et al., 2018, McGree et al., 2017, Beelen et al., 2017, Vasse et al., 2018).

However, sensory-compromised situations, most often associated with taste and smell dysfunctionality are not confined to the elderly. Multiple aetiologies, including chemotherapy for cancer (Jeter et al., 2018, Murtaza et al., 2017), Alzheimer’s disease (Boesveldt et al., 2018, Sergi et al., 2017), sinonasal disease and anosmia (Whitcroft et al., 2017), can lead to poor appetite and potential malnutrition. Furthermore, cancer associated cachexia patients (Baracos et al., 2018, Crawford 2018, Werner et al., 2017), could significantly benefit from development of high-nutrient functional food products with soft texture characteristics as an aid to ease swallowing.

Some functional bioactive compounds have inherent problems with taste and bitterness; for example polyphenols. Inclusion of these compounds into food products could benefit from encapsulation protocols that have the potential to mask bitter attributes and aid palatability. Some recent examples include, Ho et al., (2019), who encapsulated catechin to mask the astringent taste and protect the antioxidant function for successful inclusion into a yoghurt product. Laokuldilok et al., (2016), encapsulated the pungent flavoured curcuminoid turmeric using β-cyclodextrin. Zhu (2017), used starch to encapsulate a range of sensitive bioactive compounds for targeted controlled release into the gastrointestinal tract. Encapsulation strategies have been successfully utilised to preserve stability, bioactivity and bioavailability (Mourtzinos and Goula 2019), to improve physical stability and as an aid to food quality (Foegeding et al., 2017, Ozkan et al., 2019). It is encouraging to note that research into encapsulation technologies continues to move forward as an aid in the development of novel strategies to preserve the bioactive function of many of these sensitive compounds.
Within the discourse of health promoting functional food development, there remains disagreement as to a precise definition of what ‘health’ actually implies. The World Health Organisation definition is currently the only one agreed upon by the member states, “A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” – WHO Constitution, (WHO 1948). However, the definition has been subject to criticism. Generally, the most important criticisms are levelled at ambiguity within the definition, idealism, limits of the definition, lack of comprehensiveness, lack of weighting to aspects of health and lack of a precise definition of the normal condition and disease (Yazdi Feyzabadi et al., 2018). The concept of ‘health’ and ‘healthy’ remain intangible as these concepts are not just an absence of disease. The social context in which we live and ageing are crucial determinants in health and resource distribution across the world and plays a large part in inequalities (Donkin et al., 2018).

There is currently a great research focus on the human microbiome and its determination towards health, however, many questions remain unanswered. A growing body of knowledge and understanding suggests that the connection between diet, gut microbiota and human health greatly influence overall health status. Diverse physiological functions of the host, ranging from metabolic and immune regulation to nervous system and endocrine development are possibly mediated by structural components of the microbiota or through the products of microbial metabolism, which are in turn modulated by dietary macronutrients and micronutrients (Li et al., 2017). Consequently, development of functional food products that aim to modulate the gut microbiota may be inherently flawed because of individual variation in the human population – in this case ‘one size does not necessarily fit all’.

Modification in the composition and functional characteristics of the gut microbiome have been implicated in a diverse range of conditions and disease states. Recent research shows that older people have a different microbiome composition than that of younger adults, indicating changes with biological age and this can be independent of health status (O'Toole and Jeffery 2018).
understanding of the human gut microbiome continues to evolve, but practical applications of this emerging field of knowledge remain scarce. Research is currently required to translate microbiome investigation into targeted practical outcomes that benefit the human host (Schmidt et al., 2018).

However, the interaction between host and the gut microbiota is highly dynamic and complex (Lamichhane et al., 2018) and can be significantly influenced by overall health status, diet, genetic factors, age, response of the immune system, inflammatory status, drug interaction and composition of the diet. These factors are modulators of the microbiome, therefore dietary intervention strategies aim to alter the diversity of organisms in the gut (Sharma et al., 2018). Perhaps, the real answer lies in personalised medicine and diet recommendations, however this type of strategy is beyond the reach of most consumers due in part to the high economic cost of implementation (Forster et al., 2015, Rankin et al., 2017, Poinhos et al., 2017, de Roos and Brennan 2017).

Functional foods are not currently legally defined within European food law, but are generally taken to imply that these products provide additional benefits beyond nutrient intake and have positive health benefits. In Europe statements on health benefits are regulated by the Nutrition and Health Claim Regulation (NHCR), this regulation requires that proposed health benefits or claims of food items are scientifically validated (EC 2006), furthermore a recent Roadmap for Evaluation Criteria has also been published by the EU (NHCR 2017). The NHCR is designed to protect consumers from misleading claims made regarding these products (Lenssen et al., 2018) and that any health claim refers to the relationship between food and health. For claim substantiation, a dossier of scientific evidence must be evaluated by EFSA, however there remain stringent rules and very few claims are validated.

The validation process involves three criteria:

1: The bioactive substance is sufficiently characterised.

2: The proposed claim should comprise a beneficial physiological effect.

3: A cause and effect relationship between the bioactive substance and the beneficial physiological effect should be established (de Boer et al., 2016).
A recent review of the EFSA health claim assessment procedure suggests that the food industry in general is sceptical on both EFSA and NHCR regulations that ultimately have a negative effect on food innovation, due in part to a lack of transparency on the evaluation process regarding potential health claims (Lenssen et al., 2018). Within a proposed health claim, evidence is required on bioaccessibility and bioavailability of the substance within the claim and most often this evidence comes from complex clinical trials, often with their own unique set of challenges. EFSA regulations have led to uncertainties for new product development within the category of functional foods. These uncertainties increase the financial risk for the food industry and can negatively impact on the future of functional food innovation and development.

**Conclusions**

Formulation of functional food products can impact on the organoleptic characteristics of the final product, however, it is essential to ensure that consumer acceptance is maintained. For example, the majority of supplementations of baked goods, such as bread based on the use of single functional ingredients have demonstrated a range of negative effects. Despite these observations, it may be possible to avoid these through the selection of specific combinations of functional ingredients. Currently there are no published reports of functional food developments using a blended range of beneficial bioactive compounds. Would it then be possible to utilise positive attributes in a blended formulation that could mask some of the detrimental effects of these compounds? It is tempting to speculate that a combined formulation would provide the required functional outcomes for the product but avoid the organoleptic defects and maintain consumer acceptance. This is an area that would benefit from further investigation.

In many cases, demonstration of beneficial health effects once the functional ingredients have been processed into an end-product and then consumed still lacks strong clinical evidence, with the result that regulators in EU and USA have frequently not supported manufacturers’ health claims. The diversity of individual microbiomes may have resulted in a confounding effect and potentially
masked the benefits gained by some individuals within the test group that have consumed the functional foods (Vatanen et al., 2018, Costea et al., 2017, Lloyd-Price et al., 2017).

Our diet influences the bacterial species composition of our gut microbiota. Determined by diet composition which influences the supply of substrates for microbial growth as this impacts on gut transit within the gut environment. Subsequently, the gut microbiota are influenced by diet and dietary change. A deeper understanding of metabolic capabilities and host-interactions of gut microbiota will aid the ability to improve human health through the combination of microbiome and dietary interventions (Flint et al., 2017), leading to conclusive evidence of gut health benefits.

The use of conventional processing methods that retain the functionality of bioactive ingredients in complex food matrices continues to be a challenge for the food industry. If, for example these compounds are masked or bound by processing methods and are not bioavailable, then the product fails in its overall objective. The demonstration of physiological effects after ingestion of these products is also often lacking in the published literature, however this is an essential pre-requisite for health claim approval. Furthermore, development of novel functional foods must demonstrate characteristics that match consumer expectations to ensure the future of these products. Any claim made by a product must be verifiable, otherwise fraudulent claims could become more commonplace. Development of new functional foods is of little or no commercial value without consumer acceptance.

Research into the development of functional foods has increased over the last decade and this has been reflected by a rise in published output of over 280%. The majority of the research has been on the production and evaluation of new food bioactive compounds, whilst relatively few have addressed the bioavailability of the active ingredients or their clinical efficacy. This has contributed to the inability of manufacturers of functional food products to make health claims in markets such as the European Union, yet despite this, sales of functional products show strong growth.
goods such as bread, biscuits and cake are a popular category for innovation due to their widespread
consumption and a need to retain consumer engagement through the introduction of new products.
Diverse reformulation strategies for the functionalisation of baked goods have been reported, with
agri-food by-products frequently exploited as a source of bioactive materials. These have had a wide
range of effects on the organoleptic properties of the finished products and thus consumer
acceptance. Algal biomass, a by-product of oil production, has attracted attention recently due to its
potential as an egg replacement, as a means of increasing the overall protein content and to raise
the levels of carotenoids such as lutein. Availability and consumption of such functional foods
suggests a strategy to reduce the incidence of chronic health disorders or provide benefits for
specific population groups such as the elderly. Whilst this is a message that has resonated with
consumers and has driven market growth, a growing understanding of the role of the microbiome in
human health has indicated that the efficacy of functional foods is unlikely to be uniform within the
population. Nevertheless, the increase in popularity of products containing prebiotics and probiotics
and their purported effect on gut health continues to rise. Further growth in the functional foods
market, whilst avoiding future public scepticism, is likely to require greater evidence of the
bioavailability of active ingredients, clinical effect and support for health claims by regulators. In
addition, the use of selected functional ingredient blends might prove useful as a means of
counteracting negative impacts on product organolepsis due to re-formulation, thus maintaining
consumer acceptance.

It is clear that some modification of health claim verification and regulatory approval processes will
be required to enable further development of the sector. However, there must be a scientifically
verifiable and demonstrable benefit to consumers in order for these products to be successful in the
marketplace and ensure a future for the functional food industry.
Conflict of Interest Statement: The authors declare there is no conflict of interest.
References:


behaviour, technological properties and sensory quality of gluten-free mini sponge cake. *International Journal of Food Science & Technology, 0.*


NHCR (2017). Evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods EFSA.


Dear Editor


This review covers the latest research in the field and discusses the influence of market drivers and consumer acceptance of new products.

Baked goods such as bread, biscuits and cake are highlighted as a popular category for innovation due to their widespread consumption and a need to retain consumer engagement through the introduction of new products.

The role of the human microbiome is discussed as a confounding factor which can influence the efficacy of functional food products.

Recommendations are made for further research, such as blends of bioactive ingredients to avoid defects in organolepsis.

Kind regards

Dr. Catherine S. Birch and Prof. Graham A. Bonwick
Figure 1:

The bibliometric data was obtained using the Scopus® database from 2006 – 2018 (to date), the index search terms were ‘functional food’ AND ‘in vitro’ AND ‘clinical studies’; exclusion criteria were ‘theses’, ‘book chapters’ and ‘conference proceedings’.
Classification criteria for Foods for Specified Health Uses (FOSHU)

Classification criteria for foods for specified health uses

1: Improvement in dietary habit and health maintenance from consumption of product
2: Available and reviewed scientific evidence to support the product’s health claim
3: Established clinical and nutritional information of functional ingredients
4: The product and functional ingredients are safe for human consumption
5: The functional ingredients are well defined in terms of:
   a) Physical, chemical and biological characteristics
   b) Methods of qualitative and quantitative analytical determination are recognised
6: No significant changes in nutrient characteristics with food processing or extended shelf-life
7: The food is intended to be consumed daily for maximum health benefit
8: The product or its functional ingredient is not considered a pharmaceutical

Table 1: Classification criteria for Foods with Specified Health Uses (FOSHU); Japan (Adapted from Maeda-Yamamoto 2017).
### Challenges for Functional Food Clinical Trials

<table>
<thead>
<tr>
<th>Challenge:</th>
<th>Solution:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Difficulty in obtaining industrial funding</td>
<td>Collaboration with University Research Centres could lead to funding proposals</td>
</tr>
<tr>
<td>2: Technical support may be lacking</td>
<td>Use of University expertise</td>
</tr>
<tr>
<td>3: Placebo identification challenges</td>
<td>Detailed development of alternative products without active ingredients</td>
</tr>
<tr>
<td>4: Difficulty in delivering fresh products to participants</td>
<td>Home delivery service</td>
</tr>
<tr>
<td>5: Compliancy by participants</td>
<td>Trust – Develop a range of products to maintain interest</td>
</tr>
<tr>
<td>6: Identification of appropriate biomarkers</td>
<td>Plasma biomarkers must be unique to functional food active ingredient</td>
</tr>
<tr>
<td>7: Accidental intake of bioactive ingredient by placebo group</td>
<td>Identify sensitive biomarker in plasma</td>
</tr>
<tr>
<td>8: Statistical analysis</td>
<td>Careful planning of study design in early stages</td>
</tr>
<tr>
<td>9: Response of general public</td>
<td>Publication of study results in learned journals to increase trust in results</td>
</tr>
<tr>
<td>10: Response of medical community</td>
<td>Well-designed studies lend credibility</td>
</tr>
</tbody>
</table>

Table 2: Challenges for Functional Food Clinical Trials (Adapted from Brown et al (2018)).
Table 3: Table: Impact of Functional Ingredients in Baked Goods

<table>
<thead>
<tr>
<th>Functional Ingredient</th>
<th>Product</th>
<th>Functional Characteristic</th>
<th>Organoleptic Properties</th>
<th>Physical Properties</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lentil Protein</td>
<td>Multiple products</td>
<td>↓Cholesterol</td>
<td>↑Chewiness</td>
<td>No effect on product volume</td>
<td>Jarpa-Parra (2018)</td>
</tr>
<tr>
<td>(Lens culinaris)</td>
<td></td>
<td>↓Lip</td>
<td>↑Hardiness</td>
<td>No effect on dough formation</td>
<td>Aider et al. (2012)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑Increased hydrolysis of polyphenols</td>
<td>↓Unacceptable in bread</td>
<td>↓Significant lower baking loss</td>
<td></td>
</tr>
<tr>
<td>Pomegranate seed powder</td>
<td>Bread</td>
<td>↑Phenolics increased from 46% to 181%</td>
<td>↑Springiness</td>
<td>↑Significant red colour change</td>
<td>Bustamante et al. (2017)</td>
</tr>
<tr>
<td>(Punica granatum)</td>
<td></td>
<td>↑Antioxidant level increased</td>
<td>Hardness</td>
<td>above 7.5% inclusion</td>
<td>Bourekoua et al. (2018)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↓Mineral bioavailability</td>
<td>Chewiness</td>
<td></td>
<td>Martins et al. (2017)</td>
</tr>
<tr>
<td>Polyphenols (Encapsulated)</td>
<td>Multiple products</td>
<td>↑Phenolic profile</td>
<td>↓Bitter taste</td>
<td>↑Maintains structure and</td>
<td>Ye et al. (2018)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑Antioxidant capacity</td>
<td></td>
<td>functional integrity</td>
<td></td>
</tr>
<tr>
<td>Fish oils (Omega 3-6-9)</td>
<td>Bread</td>
<td>↑Controlled release</td>
<td>↓Fish smell and taste</td>
<td>↑Maintains structure and</td>
<td>Ye et al. (2018)</td>
</tr>
<tr>
<td>(Encapsulated)</td>
<td></td>
<td>↑Cardioprotective activity</td>
<td></td>
<td>functional integrity</td>
<td></td>
</tr>
<tr>
<td>Chia oil (Salvia hispanica)</td>
<td>Bread</td>
<td>↑Fatty acid profile +13-16%</td>
<td>No difference on firmness or</td>
<td>No discernible difference on</td>
<td>González et al. (2018)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑Linolenic acid</td>
<td>chewiness</td>
<td>specific volume</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>↓Hydroperoxide radicals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Green tea polyphenols</td>
<td>Bread</td>
<td>↑Antioxidant capacity</td>
<td>No data</td>
<td>↑Crumb firmness</td>
<td>Pasrija et al. (2015)</td>
</tr>
<tr>
<td>(Camellia sinensis)</td>
<td></td>
<td></td>
<td></td>
<td>↑Retained volume</td>
<td></td>
</tr>
<tr>
<td>Sorghum flour</td>
<td>Bread</td>
<td>↓Weight loss</td>
<td>↓Food texture</td>
<td>↓Starch interaction</td>
<td>Girard and Awika (2018)</td>
</tr>
<tr>
<td>(Sorghum bicolor)</td>
<td></td>
<td>↓Fat accumulation</td>
<td>Sandy/gritty texture</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>↓Oxidative stress</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>↓Inflammation</td>
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<tr>
<td></td>
<td></td>
<td>↑Satiety</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>↑Glucose metabolism</td>
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<td></td>
<td></td>
<td>↑Lip metabolism</td>
<td></td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Product</th>
<th>Changes</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macadamia flour (Macadamieae)</td>
<td>Bread</td>
<td>↑ Protein</td>
<td>Enhanced texture, ↑ Flavour, ↑ Solubility, ↑ Emulsification, ↑ Moisture retention, ↑ Freshness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑ Fibre</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑ Vitamins &amp; minerals</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑ Magnesium</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑ Tocopherols</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>↓ Lysine</td>
<td></td>
</tr>
<tr>
<td>Lactic acid bacteria (LAB)</td>
<td>Sourdough</td>
<td>↓ Glycaemic index, ↑ Acid taste, ↑ Saltiness, ↑ Taste intensity, ↓ Sweetness</td>
<td>↑ Starch hydrolysis, ↑ Elasticity, ↑ Dryness, ↑ Structure density</td>
</tr>
<tr>
<td>Red potato (Oxalis tuberosa) (Gluten free)</td>
<td>Bread</td>
<td>↑ Protein, ↑ Fibre, ↑ Antioxidants, ↑ Phenolics</td>
<td>↑ Consumer acceptability, ↑ Taste, ↑ Leavening, ↑ Structure stability, ↑ Starch</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑ Antioxidant status</td>
<td></td>
</tr>
<tr>
<td>Bee pollen</td>
<td>Bread</td>
<td>↑ Antioxidants, ↑ Flavour</td>
<td>↑ Sweetness, ↑ Leavening, ↑ Texture, ↑ Colour, ↑ Freshness</td>
</tr>
<tr>
<td>Amaranth (Amaranthoideae) (Gluten free)</td>
<td>Cookies</td>
<td>↑ Protein, ↑ Fibre, ↑ Antithrombotic, ↑ Antihypertensive</td>
<td>↑ Organoleptic qualities, ↓ Uniform colour</td>
</tr>
<tr>
<td>Lettuce (Lactuca sativa)</td>
<td>Bread</td>
<td>↑ Polyphenols, ↑ Antioxidants, ↑ Fibre</td>
<td>Acceptable consumer preference, ↑ Increased herbaceous flavour, ↑ Soursness, ↓ Leavening, ↑ Moisture, ↑ Firmness, ↓ Aerated dough, ↓ Elasticity, ↓ Maillard reaction</td>
</tr>
<tr>
<td>Papaya (Carica papaya) Dietary fibre</td>
<td>Dietary fibre</td>
<td>↑ Fibre, ↑ Antioxidant capacity, ↑ Phenolics, ↑ Regulation of intestinal microflora, ↓ Diabetes, ↓ Cardiovascular disease</td>
<td>↑ Satiety, Used as a polymer modifier in food, ↑ Swelling, ↑ Water retention</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑ Phenolics</td>
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<tr>
<td></td>
<td></td>
<td>↑ Regulation of intestinal microflora</td>
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<td></td>
<td></td>
<td>↓ Diabetes</td>
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<tr>
<td></td>
<td></td>
<td>↓ Cardiovascular disease</td>
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<td>Tananuwong and Jitngarmkusol (2011)</td>
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<td>Pontonio et al., (2017)</td>
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<td>Vera et al., (2018)</td>
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<td>Conte et al., (2018)</td>
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<td>Sabbione et al., (2018 In press)</td>
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<td>Plazzotta et al., (2018)</td>
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<td>Nieto-Calvache et al., (2018 In press)</td>
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<tr>
<td>Aquafaba Chickpeas (Cicer arietinum)</td>
<td>Sponge cake</td>
<td></td>
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<tr>
<td>Broccoli (Brassica oleracea var.</td>
<td>Baked crackers</td>
<td></td>
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<tr>
<td>italica)</td>
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<tr>
<td>Broccoli leaf powder (Brassica</td>
<td>Sponge cake (Gluten free)</td>
<td></td>
<td></td>
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<tr>
<td>oleracea var. italica)</td>
<td></td>
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<tr>
<td>Whey protein</td>
<td>Banana cake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apple pomace (Malus domestica)</td>
<td>Biscuits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barley (Hordeum vulgare)</td>
<td>Bread</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soy bean (Black and yellow)</td>
<td>Crackers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corn bran (Zea mays)</td>
<td>Cakes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inulin</td>
<td>Bread</td>
<td>↑Fibre</td>
<td>↓LDL Cholesterol</td>
</tr>
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</tr>
<tr>
<td>Cricket powder</td>
<td>Bread</td>
<td>↑Fatty acid profile</td>
<td>↑Protein</td>
</tr>
<tr>
<td><em>Acheta domesticus</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grape skin pomace</td>
<td>Muffins</td>
<td>↑Soluble fibre</td>
<td>↑Polyphenolic profile</td>
</tr>
<tr>
<td><em>Vitis vinifera</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sea grapes</td>
<td>Biscuit</td>
<td>↑Fibre</td>
<td>↑Protein</td>
</tr>
<tr>
<td><em>Caulerpa racemosa</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>Cookies</td>
<td>↑Astonxanthin</td>
<td>↑Phenolic profile</td>
</tr>
<tr>
<td><em>Haematococcus pluvialis</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Chlorella vulgaris</em> 3%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>Cookies</td>
<td>↑Phenolic compounds</td>
<td>↑Carotenoids</td>
</tr>
<tr>
<td><em>Arthospira platensis</em>; <em>Spirulina &amp; Chlorella vulgaris</em></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Table 3: Functional, organoleptic and physical properties of bakery products with incorporation of functional ingredients. Key: ↑ Increase in function; ↓ Decrease in function.
Figure 1:
The bibliometric data was obtained using the Scopus® database from 2006 – 2018 (to date), the index search terms were ‘functional food’ AND ‘in vitro’ AND ‘clinical studies’; exclusion criteria were ‘theses’, ‘book chapters’ and ‘conference proceedings’.

Table 1: Classification criteria for Foods with Specified Health Uses (FOSHU); Japan (Adapted from Maeda-Yamamoto 2017).

Table 2: Challenges for Functional Food Clinical Trials (Adapted from Brown et al (2018)).

Table 3: Functional, organoleptic and physical properties of bakery products with incorporation of functional ingredients. Key: ↑Increase in function: ↓Decrease in function.